

CUTERA INC
Form 10-K
March 16, 2007
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

For fiscal year ended December 31, 2006

Commission file number: 000-50644

Cutera, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

3240 Bayshore Blvd.

Brisbane, California 94005

(415) 657-5500

77-0492262
(I.R.S. Employer
Identification Number)

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

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

Title of Each Class
Common Stock, \$0.001 par value per share

Name of Each Exchange on Which Registered
The NASDAQ Stock Market, LLC

Edgar Filing: CUTERA INC - Form 10-K

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

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

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

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

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

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

Large accelerated filer Accelerated filer Non-accelerated filer

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

The aggregate market value of the registrant's common stock, held by non-affiliates of the registrant as of June 30, 2006 (which is the last business day of registrant's most recently completed second fiscal quarter) based upon the closing price of such stock on the NASDAQ Global Market on that date, was \$244 million. For purposes of this disclosure, shares of common stock held by entities and individuals who own 5% or more of the outstanding common stock and shares of common stock held by each officer and director have been excluded in that such persons may be deemed to be affiliates as that term is defined under the Rules and Regulations of the Securities Exchange Act of 1934. This determination of affiliate status is not necessarily conclusive.

The number of shares of Registrant's common stock issued and outstanding as of February 28, 2007 was 13,528,119.

DOCUMENTS INCORPORATED BY REFERENCE

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

Table of Contents**TABLE OF CONTENTS**

	Page
PART I	
Item 1. <u>Business</u>	3
Item 1A. <u>Risk Factors</u>	18
Item 1B. <u>Unresolved Staff Comments</u>	29
Item 2. <u>Properties</u>	29
Item 3. <u>Legal Proceedings</u>	29
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	29
PART II	
Item 5. <u>Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	30
Item 6. <u>Selected Financial Data</u>	31
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	32
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	44
Item 8. <u>Financial Statements and Supplementary Data</u>	45
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	75
Item 9A. <u>Controls and Procedures</u>	75
Item 9B. <u>Other Information</u>	76
PART III	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	77
Item 11. <u>Executive Compensation</u>	77
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	77
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	77
Item 14. <u>Principal Accounting Fees and Services</u>	77
PART IV	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	78

Table of Contents

PART I

ITEM 1. BUSINESS

We are a global medical device company specializing in the design, development, manufacture, marketing and servicing of laser and other light-based aesthetics systems for practitioners worldwide. We offer easy-to-use products based on three platforms CoolGlide®, Xeo® and Solera® which enable dermatologists, plastic surgeons, gynecologists, primary care physicians and other qualified practitioners to perform safe, effective and non-invasive aesthetic procedures for their customers.

CoolGlide- Our first product platform, CoolGlide, was launched in March 2000. This product offers hair removal, treatment of a range of vascular lesions, including leg and facial veins, and laser genesis a non-ablative procedure to promote healthy looking skin, reduce pore size and improve skin texture.

Xeo- In 2003, we introduced the Xeo platform of products, which combine pulsed light and laser applications in a single platform. The Xeo is a fully upgradeable platform on which a customer can use every application that we offer, in order to perform such procedures as hair removal, skin rejuvenation, vascular and pigmented lesion therapies and wrinkle treatment.

Solera- In 2004, we introduced our Solera platform a compact tabletop system designed to support a single technology platform.

i **Solera Titan-** The first technology available on the Solera platform was the Titan®, an infrared heat lamp used for deep dermal heating to treat wrinkles. In 2006, we introduced two new handpieces Titan V and Titan XL that improve the efficiency of the Titan procedures. Titan V allows practitioners to effectively treat delicate areas such as the skin around the eyes and nose, and the Titan XL designed for treating large body areas, such as arms, abdomens and legs.

i **Solera Opus-** In 2005, we introduced a product called Solera Opus that offers applications for hair removal, skin rejuvenation and treatment of facial vascular conditions.

In addition, in 2006, we also introduced a product called LimeLight a three-in-one hand piece for skin rejuvenation, pigmented lesions and facial vascular lesions. LimeLight can be used with our Xeo or Solera platforms.

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.

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.

Table of Contents

The Market for Non-Surgical Aesthetic Procedures

The market for non-surgical aesthetic procedures has grown significantly over the past several years. The American Society of Plastic Surgeons estimates that in 2005 there were 8.4 million minimally-invasive aesthetic procedures performed, a 13% increase over 2004 and a 53% increase over 2000. We believe there are several factors contributing to the growth of these aesthetic procedures, including:

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

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

Changing Practitioner Economics. Managed care and government payer reimbursement restrictions in the United States, and similar payment related constraints outside the United States, are motivating practitioners to establish or expand their elective aesthetic practices with procedures that are paid for directly by patients. As a result, in addition to the traditional users such as dermatologists and plastic surgeons, other practitioners, such as gynecologists, primary care physicians and other practitioners, or non-core customers, are performing these procedures.

Non-Surgical Aesthetic Procedures for Improving the Skin's Appearance and Their Limitations

Many alternative therapies are available for improving 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 results. 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 light-based hair removal. Electrolysis is usually painful, time-consuming and expensive for large areas, but is the most common method for removing light-colored hair. During electrolysis, an electrologist inserts a needle directly into a hair follicle and activates an electric current in the needle. Since electrolysis only treats one hair follicle at a time, the treatment of an area as small as an upper lip may require numerous visits and up to ten hours of treatment. In addition, electrolysis can cause blemishes and infection related to needle use.

Leg and Facial Veins- The current aesthetic treatment methods for leg and facial veins include sclerotherapy and light-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 590,000 sclerotherapy procedures in 2005.

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 these treatments.

Table of Contents

Some skin rejuvenation treatments, such as chemical peels and microdermabrasions, can have undesirable side effects. Chemical peels use acidic or caustic solutions to peel away the epidermis, and microdermabrasion generally utilizes sand crystals to resurface the skin. These techniques can lead to post-procedure stinging, redness, irritation and scabbing. In addition, more serious complications, such as changes in skin color, can result from deeper chemical peels. Patients that undergo these deep chemical peels are also advised to avoid exposure to the sun for several months following the procedure. The American Society of Plastic Surgeons estimates that in 2005 its members administered 3.8 million injections of Botox and over 870,000 injections of collagen and other soft-tissue fillers, and performed 1.0 million chemical peels and over 800,000 microdermabrasion procedures.

Tissue Tightening and the Treatment of Wrinkles- Non-surgical techniques for treating wrinkles include radiofrequency and light-based technologies. In radio-frequency tissue tightening 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 surgical facelift. Drawbacks to this approach may include surface irregularities that can resolve over time, and the risk of burning the treatment area.

Laser and Other Light-Based Aesthetic Treatments

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

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

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

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

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

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

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

Our Products

Our unique CoolGlide, Xeo and Solera platforms provide the long-lasting benefits of laser and other light-based aesthetic treatments. Our technology allows for a combination of a wide 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,

Table of Contents

treatment of unsightly veins, skin rejuvenation, treatment of pigmented lesions and tissue tightening. Because practitioners can use our systems for multiple indications, the cost of a unit may be spread across a potentially greater number of patients and procedures, and therefore may be more rapidly recovered.

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

Upgradeable Platform. We design our products to allow our customers to cost-effectively upgrade to our multi-application systems, 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 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. Our ClearView handpiece allows practitioners to view an area as it is being treated, reducing the possibility of unintended damage to the skin and increasing the speed of application. The Titan V handpiece has a treatment tip that extends beyond the handpiece housing to give an unobstructed view of the skin's surface, thus making it easier to treat delicate areas such as the skin surrounding the eye and nose areas. In addition to increased visibility, the Titan XL handpiece has a larger spot size than the original Titan, for treating large body areas, such as arms, abdomens and legs. The clinical navigation user interface on the Xeo platform provides recommended clinical treatment parameter ranges based on patient criteria entered.

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

Strategy

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

Continuing to Develop New Products. We have introduced at least one new product every year since 2000. In 2006, we introduced two new Titan handpieces—Titan V and Titan XL—added the LimeLight pulsed light handpiece for treating veins and pigmented lesions, and introduced the Navigation feature for the Xeo platform. We are continuing to develop our existing technology platforms and are developing other platforms with the intent of expanding applications for our customers.

Increasing Sales of Existing Products in the United States. We believe that the U.S. market for aesthetic systems is growing rapidly. As a result, in 2006 we expanded our U.S. direct sales force,

Table of Contents

excluding management and customer relations, to 46 employees. We plan on continuing to hire additional sales representatives to take advantage of our growing U.S. market opportunity.

Expanding our International Presence. We believe that the international market continues to be a significant growth opportunity for us. As such, we are focused on increasing our market penetration overseas and building global brand-recognition. In 2006, we increased our direct international sales force to 25 employees, from 18 employees as of December 31, 2005. In addition to direct sales employees, in 2006 we expanded our distributor territories to over 30 countries. We plan on continuing to hire additional international direct sales employees, distributors and support staff to increase sales and strengthen customer relationships in the international markets.

Broadening our Customer Base. We believe we have an opportunity for significant growth targeting non-traditional aesthetic practitioners. Dermatologists and plastic surgeons had generally been regarded as the traditional customers for laser and other light-based aesthetic equipment. However, in the United States, in 2006 and 2005, approximately 78% and 72%, respectively, of the number of our orders were received from non-traditional aesthetic practitioners, which include gynecologists, primary care physicians, physicians offering aesthetic treatments in a spa environment, and other qualified practitioners.

Leveraging our Installed Base with Sales of Upgrades. Each time we have introduced a major new product, we have designed it to allow existing customers to upgrade their previously purchased systems to offer additional capabilities. We believe that providing upgrades to our existing installed base of customers continues to represent a significant opportunity for recurring revenue. We also believe that our upgrade program aligns our interest in generating revenue with our customers' interest in improving the return on their investment by expanding the range of applications they can perform.

Generating Revenue from Services and Disposables. Our Titan product includes a disposable component, which provides us with a source of recurring revenue from our existing customers. Our extended service contracts are also a source of recurring revenue. We will continue to focus our research and development and our sales and marketing efforts on opportunities that can leverage our relationships with our existing customers for additional revenue opportunities.

Table of Contents**Products**

Our CoolGlide, Xeo and Solera platforms allow for the delivery of multiple laser and other light-based aesthetic applications from a single system. With our Xeo and Solera platforms, practitioners can purchase customized systems with a variety of our multi-technology applications. The following table lists our products and each checked box represents the incremental applications that were added to the respective platforms in the years noted.

Applications: Technology:			Hair Removal		Vascular		Skin Rejuvenation		Skin Tightening Infrared
			Laser	Flashlamp	Laser	Flashlamp	Laser	Flashlamp	
Platforms	Products	Year Introduced							
CoolGlide	CV	2000	X						
	Excel	2001			X				
	Vantage	2002					X		
Xeo	OPS 600	2003	X		X		X	X	
	LP560	2004						X	
	Titan S	2004							X
	Prowave	2005		X					
	Accutip	2005				X			
	Titan V & XL	2006							X
	LimeLight	2006				X		X	
Solera	Titan S	2004							X
	Prowave	2005		X					
	OPS 600	2005						X	
	LP560	2005						X	
	Accutip	2005				X			
	Titan V & XL	2006							X
	LimeLight	2006				X		X	

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

Control Console

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

Handpieces

ClearView Handpiece- Our ClearView handpiece delivers laser energy to the treatment area for hair removal, leg and facial vein treatment, and skin rejuvenation procedures. The ClearView handpiece consists of an energy-

Table of Contents

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 or 10 millimeter spot size, for our other models.

Pulsed Light Handpieces- The OPS600, LP560, ProWave 770, AcuTip 500 and LimeLight handpieces are designed to produce a pulse of light over a wavelength spectrum to treat pigmented lesions, such as age and sun spots, hair removal and superficial facial vessels. The handpieces each consist of a custom flashlamp, proprietary wavelength filter, closed-loop power control and embedded temperature monitor, and weigh approximately 13 ounces. The filter in the OPS600 and AcuTip 500 eliminates long and short wavelengths, transmitting only the therapeutic range required for safe and effective treatment. The filter in the LP560 and ProWave 770 eliminates short wavelengths, allowing longer wavelengths to be transmitted to the treatment area. In addition, the wavelength spectrum of the ProWave 770 and the LimeLight can be shifted based on the setting of the control console. Our power control includes a monitoring system to ensure that the desired energy level is delivered. The handpieces protect the epidermis by regulating the temperature of the handpiece window through the embedded temperature monitor. These handpieces are available on the Xeo and Solera Opus platforms.

Titan Handpieces- The Titan handpieces are designed to produce a sustained pulse of light over a wavelength spectrum tailored to provide heating in the dermis to treat wrinkles (although it is cleared in the United States by the U.S. Food and Drug Administration, or FDA, only for deep dermal heating). The handpiece consists of a custom light source, proprietary wavelength filter, closed-loop power control, sapphire cooling window and embedded temperature monitor, and weighs approximately three pounds. The temperature of the epidermis is controlled by using a sapphire window to provide cooling before, during and after the delivery of energy to the treatment site. We offer three different Titan handpieces Titan S, Titan V and Titan XL.

Titan S: the standard Titan handpiece

Titan V: has a treatment tip that extends beyond the handpiece housing to provide enhanced visibility of the skin's surface to effectively treat delicate areas such as the skin around the eyes and nose

Titan XL: like the Titan V, extends beyond the housing for improved visibility. It also has a larger treatment spot size to more quickly treat larger body areas such as the arms and legs.

The Titan handpieces can be used on the Xeo and Solera platforms. The Titan handpiece requires a periodic refilling process, which includes the replacement of the optical source, after a set number of pulses have been used.

Cutera Applications and Procedures

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

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

Table of Contents

handpiece, with its pulsed light technology, allow our customers to treat all skin types quickly and effectively. Using the interface, the practitioner selects the appropriate mode and fluence to achieve the desired result.

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

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

The vein treatment procedure is performed in a substantially similar manner to the hair removal procedure. In addition to pre-cooling the area to be treated using the ClearView handpiece, the handpiece is also used to cool the treatment area after the practitioner applies the laser pulse. With the AcuTip 500, the pulse of light is delivered while the treatment area is being cooled with the sapphire tip. The delivered energy damages the vein and, over time, it is absorbed by the body. Patients receive on average between one and six treatments, with six weeks or longer between treatments.

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

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

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

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

Tissue Tightening- Our Titan technology allows our customers to use deep dermal heating to tighten lax skin. The practitioner delivers a spectrum of light to the skin through our Titan handpiece. This handpiece includes our

Table of Contents

proprietary light source and wavelength filter which tailors the delivered spectrum of light to provide heating at the desired depth in the skin.

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

Our CE Mark allows us to promote the Titan in the European Union, Australia and certain other countries outside the United States for the treatment of wrinkles through skin tightening. However, in the United States we have a 510(k) clearance for only deep dermal heating. We continue to work with physicians and other experts in the medical aesthetic market to gather additional data on the clinical effectiveness of Titan.

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

In the United States, we market and sell our products primarily through a direct sales force of 46 employees as of December 31, 2006. In addition, we have a distribution relationship with PSS World Medical Shared Services, Inc., or PSS, a wholly-owned subsidiary of PSS World Medical, that operates medical supply distribution service centers with over 700 sales representatives serving physician offices throughout the United States. For the years ended December 31, 2006, 2005 and 2004, revenue from PSS accounted for 15%, 16% and 12%, respectively, of our total revenue.

International sales are generally made through a direct sales force of 25 employees as of December 31, 2006, as well as independent sales representatives and distributors in over 30 countries worldwide. We have direct sales offices located in Australia, Canada, France, Germany, Japan, Spain, Switzerland and the United Kingdom. Our international revenue represented 31%, 28% and 34% of total revenue for the years ended December 31, 2006, 2005 and 2004, respectively.

We also sell certain items like Titan handpiece refills and marketing brochures via the web.

Although specific customer requirements can vary depending on applications, customers generally demand quality performance, ease of use, and high productivity in relation to the cost of ownership. We have responded to these customer demands by introducing new products focused on these requirements in the markets we serve. Specifically, we believe that we differentiate our products from those of our competitors, by introducing new products and applications that are innovative, address the specific aesthetic procedures in demand, and are upgradeable on our customers' existing systems. In addition, we provide attractive upgrade pricing to new product families, as and when they are introduced and are responsive to our customers' financing preferences. To increase market penetration, in addition to marketing to our historic customer base of plastic surgeons and dermatologists, we remain focused on selling to the non-core aesthetic practices consisting of gynecologists, primary care physicians, physicians offering aesthetic treatments in a spa environment and other qualified practitioners.

Table of Contents

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

Competition

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

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

Research and Development

Our research and development group develops new products to address unmet or underserved market needs. The major focus of this group is to leverage our existing technology platforms for new aesthetic applications. As of December 31, 2006, our research and development activities were conducted by a staff of 19 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 2006, 2005 and 2004, were \$6.5 million, \$5.4 million and \$4.5 million, respectively.

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. As of December 31, 2006, we had a 34-person global service department. Internationally, we provide direct service support through our Australia, France, Germany, Japan, and Switzerland offices, and also through the network of distributors in over 30 countries and third-party service providers. We provide initial warranties on our products to cover parts and service and offer extended warranty packages that vary by the type of product and the level of service desired. Our base warranty on system sales covers parts and service for a standard period of one year. From time to time, we also have promotions whereby we include a two year warranty with the sale of our products. Customers are notified before their initial

Table of Contents

warranty expires and are able to choose from two different extended service plans covering preventative maintenance and replacement parts and labor. One plan allows the customer to pay only for time and materials at a reduced rate and a second provides yearly preventative maintenance for a fixed fee. In the event one of our customers declines an additional warranty, we will continue to service our products and charge customers for time and materials. We have invested substantial financial and management resources to develop an international infrastructure to meet the needs of our customers worldwide.

Manufacturing

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

We purchase certain components and subassemblies from a limited number of suppliers. We have flexibility with our suppliers to adjust the number of components and subassemblies as well as the delivery schedules. The forecasts we use are based on historical demands and sales projections. Lead times for components and subassemblies may vary significantly depending on the size of the order, time required to fabricate and test the components or subassemblies, specific supplier requirements and current market demand for the components and subassemblies. We reduce the potential for disruption of supply by maintaining sufficient inventories 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. Our single manufacturing facility located in Brisbane, CA, was inspected by the FDA in 2004 and 2005. There were no significant findings as a result of these audits and our responses have been accepted by the FDA. We are scheduled to have another inspection in March 2007. 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 business. In the event that one of our suppliers fails to maintain compliance with our quality requirements, we may have to qualify a new supplier and could experience manufacturing delays as a result. We have opted to maintain quality assurance and quality management certifications to enable us to market our products in the United States, 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. Our manufacturing facility is ISO 9001 and ISO 13485 certified.

Patents and Proprietary Technology

We rely on a combination of patent, copyright, trademark and trade secret laws, non-disclosure, confidentiality and invention assignment agreements to protect our intellectual property rights. As of December 31, 2006, we had seven issued U.S. patents and 21 pending U.S. patent applications. Cutera, CoolGlide, Xeo, Titan, Solera Opus, Prowave 770 and AcuTip are only some of our trademarks. We have trademark rights in these and others trademarks in the United States and have registrations issued and pending in the United States and other countries for these and others of our trademarks. We intend to file for additional patents and trademarks to continue to strengthen our intellectual property rights.

Table of Contents

In conjunction with the settlement of our patent litigation with Palomar and Massachusetts General Hospital, or MGH, in June 2006, Palomar the exclusive licensee of the patents owned by MGH granted us an irrevocable sublicense to the patents for removing hair using lasers or pulsed-light technology. The patents are set to expire in February 2015. The royalty rate for hair-removal-only systems is 7.5% of net revenue and for multi-application systems containing hair-removal functionality it is either 3.75% or 5.25% of net revenue, depending on whether there is one or more hair removal technologies included in the system, respectively. Our revenue from systems that do not include hair-removal capabilities (such as our Titan) and revenue from service contracts are not subject to royalties.

Our 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.

Government Regulation

Our products are medical devices subject to extensive and rigorous regulation by the U.S. Food and Drug Administration, as well as other regulatory bodies. FDA regulations govern the following activities that we perform and will continue to perform to ensure that medical products distributed domestically or exported internationally are safe and effective for their intended uses:

product design and development;

product testing;

product manufacturing;

product safety;

product labeling;

product storage;

recordkeeping;

pre-market clearance or approval;

advertising and promotion;

production; and

product sales and distribution.

FDA s Pre-market Clearance and Approval Requirements

Edgar Filing: CUTERA INC - Form 10-K

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

Table of Contents

distribution before May 28, 1976 for which the FDA has not yet called for the submission of Pre-Market Approval, or PMA. applications, 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 deep dermal heating for the temporary relief of minor muscle and joint pain and for the temporary increase in local circulation where applied. In October 2004, we received FDA clearance to market our Titan tabletop console for use with the Titan handpiece. In January 2005, we received FDA clearance to market our Solera tabletop console for use with our pulsed-light handpieces. In March 2005, we received FDA clearance to market our pulsed light handpieces for hair removal and vascular treatments. In May 2005, the FDA determined that our 510(k) application with respect to marketing our Titan product in the United States for wrinkle reduction was not substantially equivalent to predicate devices for the treatment of wrinkles. We continue to evaluate opportunities for future submissions to the FDA to expand our marketing claims.

Pre-Market Approval (PMA) Pathway

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

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

Product Modifications

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

Clinical Trials

When FDA approval of a class I, class II or class III device requires human clinical trials, and if the device presents a significant risk, as defined by the FDA, to human health, the device sponsor is required to file an Investigational Device Exemption, or IDE, application with the FDA and obtain IDE approval prior to commencing the human clinical trial. If the device is considered a non-significant risk, IDE submission to the

Table of Contents

FDA is not required. Instead, only approval from the Institutional Review Board, or IRB, overseeing the clinical trial is required. Human clinical studies are generally required in connection with approval of class III devices and may be required for class I and II devices. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specified number of patients. Clinical trials for a significant risk device may begin once the application is reviewed and cleared by the FDA and the appropriate institutional review boards at the clinical trial sites. Future clinical trials of our products may require that we submit and obtain clearance of an IDE from the FDA prior to commencing clinical trials. The FDA, and the IRB at each institution at which a clinical trial is being performed, may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable health risk.

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

Pervasive and Continuing Regulation

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

quality system regulations, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;

labeling regulations and FDA prohibitions against the promotion of products for un-cleared, unapproved or off-label uses;

medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur; and

post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Health Services, or CDHS, to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our subcontractors. In the past, our prior facility has been inspected, and observations were noted. There were no findings that involved a material violation of regulatory requirements. Our responses to these observations have been accepted by the FDA and CDHS, and we believe that we are in substantial compliance with the QSR. Our current manufacturing facility has been inspected by the FDA but not by the CDHS. The FDA noted observations, but there were no findings that involved a material violation of regulatory requirements. Our responses to those observations have been accepted by the FDA.

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

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

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

repair, replacement, recall or seizure of our products;

Table of Contents

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.

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 twenty-five countries encompassing most of the major countries in Europe. Three member states of the European Free Trade Association have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. Other countries, such as Switzerland, have entered into Mutual Recognition Agreements and allow the marketing of medical devices that meet European Union requirements. The European Union has adopted numerous directives and European Standardization Committees have promulgated voluntary standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear CE conformity marking, indicating that the device conforms with the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the member states of the European Union, the member states of the European Free Trade Association and countries which have entered into a Mutual Recognition Agreement. The method of assessing conformity varies depending on the type and class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a Notified Body, an independent and neutral institution appointed by a country to conduct the conformity assessment. This third-party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's device. An assessment by a Notified Body in one member state of the European Union, the European Free Trade Association or one country which has entered into a Mutual Recognition Agreement is required in order for a manufacturer to commercially distribute the product throughout these countries. ISO 9001 and ISO 13845 certification are voluntary harmonized standards. Compliance establishes the presumption of conformity with the essential requirements for a CE Marking. In February 2000, our facility was awarded the ISO 9001 and EN 46001 certification. In March 2003, we received our ISO 9001 updated certification (ISO 9001:2000) as well as our certification for ISO 13485:1996 which replaced our EN 46001 certification. In March 2004, we received our ISO 13485:2003 certification, which is the most current ISO certification for medical device companies.

Employees

As of December 31, 2006, we had 221 employees, of which 99 were in sales and marketing, 45 in manufacturing operations, 34 in technical service, 19 in research and development and 24 in general and administrative. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel. None of our employees is represented by a labor union, and we believe our employee relations are good.

Table of Contents

Available Information

We are subject to the reporting requirements under the Securities Exchange Act of 1934. Consequently, we are required to file reports and information with the Securities and Exchange Commission, or SEC, including reports on the following forms: annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. These reports and other information concerning the company may be accessed through the SEC's website at <http://www.sec.gov> and our website at <http://www.cutera.com>. Such filings are placed on our website as soon as reasonably possible after they are filed with the SEC.

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

ITEM 1A. RISK FACTORS

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, Cynosure, Elen (in Italy), Iridex, Palomar, Syneron and Thermage, as well as private companies such as Alma, Aesthera, Lumenis, Reliant Technologies, Sciton and several other smaller companies. Competition with these companies could result in price-cutting, reduced profit margins and loss of market share, any of which would harm our business, financial condition and results of operations. We also face competition from medical products, such as Botox, an injectable compound used to reduce wrinkles, and collagen injections. Other alternatives to the use of our products include sclerotherapy, a procedure involving the injection of a solution into the vein to collapse it, electrolysis, a procedure involving the application of electric current to eliminate hair follicles, and chemical peels. We may also face competition from manufacturers of pharmaceutical and other products that have not yet been developed. Our ability to compete effectively depends upon our ability to distinguish our company and our products from our competitors and their products, and includes such factors as:

intellectual property protection;

product performance;

product pricing;

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.

Edgar Filing: CUTERA INC - Form 10-K

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,

Table of Contents

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 energy-based devices for the aesthetic market is characterized by rapid innovation, and we must continuously develop new products or our revenue may decline.

While we attempt to protect our products through patents and other intellectual property, there are few barriers to entry that would prevent new entrants or existing competitors from developing products that compete directly with ours. For example, while our CoolGlide product was the first long-pulse Nd:YAG, or long wavelength, laser system cleared by the FDA for permanent hair reduction on all skin types, competitors have subsequently introduced systems that utilize Nd:YAG lasers, and received FDA clearances to market these products as treating all skin types. We expect that any competitive advantage we may enjoy from other current and future innovations, such as combining multiple handpieces in a single system to perform a variety of applications, may diminish over time, as companies successfully respond to our, or create their own, innovations. Consequently, we believe that we will have to continuously innovate and improve our products and technology to compete successfully. If we are unable to innovate successfully, our products could become obsolete and our revenue will decline as our customers purchase our competitors' products.

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

We have created products to apply our technology to hair removal, treatment of veins, skin rejuvenation, treatment of pigmented lesions and treatment of wrinkles. Currently, these applications represent the majority of laser and other energy-based aesthetic procedures. To be successful in the future, we must develop new and innovative aesthetic applications, identify new markets for our existing technology, and develop new technology from various platforms. 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 a broad customer base;

identify new markets and alternative applications for our technology;

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

satisfy and maintain all regulatory requirements for commercialization.

Every year since 2000, we have introduced at least one new product and a corresponding upgrade to our existing products. Historically, these introductions have been a significant component of our financial performance. Our business strategy is based, in part, on our expectation that we will continue to make annual product introductions that we can sell to new customers and to existing customers as upgrades. For the year ending December 31, 2006, we invested \$6.5 million or 6% of net revenue, in our research and development department. Even with a significant investment in research and development, we may be unable, however, to continue to develop new products and technologies annually, or at all, which could adversely affect our projected growth rate.

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

Edgar Filing: CUTERA INC - Form 10-K

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

the cost of procedures performed using our products;

Table of Contents

the cost, safety and effectiveness of alternative treatments, including treatments which are not based upon laser- or other energy-based technologies and treatments which use pharmaceutical products;

the success of our sales and marketing efforts; and

consumer confidence, which may be impacted by economic and political conditions.

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

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

We have a distribution agreement with PSS World Medical Shared Services, Inc., or PSS, a wholly-owned subsidiary of PSS World Medical. PSS sales representatives work in coordination with our sales force to locate new potential customers for our products throughout the United States. For the year ended December 31, 2006 approximately 15% of our revenue came from PSS.

If PSS does not perform adequately under the arrangement, or terminates our relationship, it may have a material adverse effect on our business, financial condition, results of operations or future cash flows.

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

We provide guidance to the investing community regarding our anticipated future operating performance, both for the coming quarter and fiscal year. Our business typically has a short sales cycle, we do not have significant backlog of orders at the start of a quarter, and our ability to sell our products successfully is subject to many uncertainties, as discussed herein. In light of those factors, it is difficult for us to estimate with accuracy our future results. In the past, our actual performance had turned out to be significantly different from our prior guidance. For example, at the beginning of 2006, we indicated that we expected our 2006 revenue to increase by 25%, compared with 2005. Actual 2006 growth, compared with 2005, was higher, at 33%. As we stated at the time, such expectations are subject to numerous risks and uncertainties which could make actual results differ materially, either higher or lower. On January 31, 2007, we guided that our 2007 revenue is expected to increase by 25%, compared with 2006. If our actual results do not meet our public guidance, or our results or guidance as to the future were to be below the expectations of third party financial analysts, our stock price could decline significantly.

The price of our common stock may fluctuate substantially.

The public market price of our common stock has in the past fluctuated substantially and may do so in the future. The market price for our common stock will be affected by a number of factors, including:

quarterly variations in our, or our competitors, results of operations;

changes in earnings estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' earnings estimates;

the announcement of new products or service enhancements by us or our competitors;

regulatory developments or delays concerning our, or our competitors', products;

the initiation of litigation by us or one of our competitors; and

general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors. Actual or perceived instability in our stock price could reduce demand from potential buyers of our stock, thereby causing our stock price to decline.

Table of Contents

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

We settled our patent litigation with Palomar in June 2006- see Item 3 Legal Proceedings. As with that case, our competitors or other patent holders may assert that our present or future planned 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. For example, we have been, and may hereafter become, involved in litigation to protect the trademark rights associated with our company name or the names of our products. Infringement and other intellectual property claims, with or without merit, can be expensive and time-consuming to litigate, and could divert management's attention from our core business. We do not know whether necessary licenses would be available to us on satisfactory terms, or whether we could redesign our products or processes to avoid infringement. If we lose this kind of litigation, a court could require us to pay substantial damages, and prohibit us from using technologies essential to our products, any of which would have a material adverse effect on our business, results of operations and financial condition.

Intellectual property rights may not provide adequate protection for some or all of our products, which may permit third parties to compete against us more effectively.

We rely on patent, copyright, trade secret and trademark laws and confidentiality agreements to protect our technology and products. At December 31, 2006, we had seven issued U.S. patents. 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.

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

Our Titan product, introduced in 2004, is a material component of our growth strategy. We currently have FDA clearance to market Titan in the United States for deep dermal heating. The FDA has denied our initial 510(k) application to market Titan for wrinkle reduction on the basis that Titan is not substantially equivalent to predicate devices for the treatment of wrinkles. We cannot promote or advertise our Titan product in the United

Table of Contents

States for any indications other than deep dermal heating until we receive additional FDA clearances, but there are no assurances as to when, or whether, we will ever obtain such clearances. In the event that we do not obtain additional FDA clearances, our ability to market Titan in the United States and revenue derived therefrom, including revenue from both Titan unit sales and handpiece refills, may be adversely affected.

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

Our products are medical devices that are subject to extensive regulation in the United States by the FDA for manufacturing, labeling, sale, promotion, distribution and shipping. Before a new medical device, or a new use of or labeling claim for an existing product, can be marketed in the United States, it must first receive either 510(k) clearance or pre-marketing approval from the FDA, unless an exemption applies. Either process can be expensive and lengthy. In the event that we do not obtain FDA clearances or approvals for our products, our ability to market and sell them in the United States and revenue derived therefrom may be adversely affected. For example, we filed a regulatory submission with the FDA in December 2006 for a new 2790 nm wave-length based laser technology for skin rejuvenation. However, unless and until the FDA issues a clearance or pre-marketing approval for that product, we will not be able to market or sell it in the United States.

Medical devices may be marketed only for the indications for which they are approved or cleared and if we are found to be marketing our products for off-label, or non-approved, uses we might be subject to FDA enforcement action or have other resulting liability. We have obtained 510(k) clearance for the indications for which we market our products. However, our clearances can be revoked if safety or effectiveness problems develop. We also are subject to Medical Device Reporting regulations, which require us to report to the FDA if our products cause or contribute to a death or serious injury, or malfunction in a way that would likely cause or contribute to a death or serious injury. Our products are also subject to state regulations, which are, in many instances, in flux. Changes in state regulations may impede sales. For example, federal regulations allow our products to be sold to, or on the order of, licensed practitioners, as determined on a state-by-state basis. As a result, in some states, non-physicians may legally purchase our products. However, a state could change its regulations at any time, thereby disallowing sales to particular types of end users. We cannot predict the impact or effect of future legislation or regulations at the federal or state levels.

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

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

repair, replacement, recall or seizure of our products;

operating restrictions or partial suspension or total shutdown of production;

refusing our requests for 510(k) clearance or pre-market approval of new products, new intended uses, or modifications to existing products;

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

criminal prosecution.

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

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

We are currently required to demonstrate and maintain compliance with the FDA's Quality System Regulation, or QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design,

Table of Contents

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 informed of a planned inspection in late March 2007 and could be subject to additional future inspections. Our failure to take satisfactory corrective action in response to an adverse QSR inspection or our failure to comply with applicable laser performance standards could result in enforcement actions, including a public warning letter, a shutdown of our manufacturing operations, a recall of our products, civil or criminal penalties, or other sanctions, such as those described in the preceding paragraph, which would cause our sales and business to suffer.

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

Any modifications to an FDA-cleared device that would significantly affect its safety or effectiveness or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a pre-market approval. We may not be able to obtain additional 510(k) clearance or pre-market approvals for new products or for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future clearance would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and future profitability. We have made modifications to our devices in the past and may make additional modifications in the future that we believe do not or will not require additional clearance or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices, which could harm our operating results and require us to redesign our products.

We may be unable to obtain or maintain international regulatory qualifications or approvals for our current or future products and indications, which could harm our business.

Sales of our products outside the United States are subject to foreign regulatory requirements that vary widely from country to country. In addition, exports of medical devices from the United States are regulated by the FDA. Complying with international regulatory requirements can be an expensive and time-consuming process and approval is not certain. The time required to obtain clearance or approvals, if required by other countries, may be longer than that required for FDA clearance or approvals, and requirements for such clearances or approvals may significantly differ from FDA requirements. We may be unable to obtain or maintain regulatory qualifications, clearances or approvals in other countries. We may also incur significant costs in attempting to obtain and in maintaining foreign regulatory approvals or qualifications. If we experience delays in receiving necessary qualifications, clearances or approvals to market our products outside the United States, or if we fail to receive those qualifications, clearances or approvals, we may be unable to market our products or enhancements in international markets effectively, or at all, which could have a material adverse effect on our business and growth strategy.

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

For the year ended December 31, 2006, approximately 31% of our revenue was derived from international customers, which are a material component of our growth strategy. We depend on third-party distributors and a relatively new direct sales operation to sell our products internationally, and if these distributors or direct sales personnel under-perform, we may be unable to increase or maintain our level of international revenue. We will need to expand the territories in which we sell our products and attract additional international distributors to grow our business. Distributors may not accept our business or commit the necessary resources to market and sell our products to the level of our expectations. If current or future distributors do not perform adequately, or we are

Table of Contents

unable to engage distributors in particular geographic areas, we may not realize projected international revenue growth. Additionally, we expect to expand our direct sales force in Europe and Asia. If we are unable to hire, retain and obtain satisfactory performance from such additional personnel, our revenue from international operations may be adversely affected.

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

difficulties in staffing and managing our foreign operations;

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

reduced protection for intellectual property rights in some countries;

export restrictions, trade regulations and foreign tax laws;

fluctuating foreign currency exchange rates;

foreign certification and regulatory requirements;

lengthy payment cycles and difficulty in collecting accounts receivable;

customs clearance and shipping delays;

political and economic instability;

lack of awareness of our brand in international markets; and

preference for locally-produced products.

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

The expense and potential unavailability of insurance coverage for our customers could adversely affect our ability to sell our products, and therefore 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 energy-based products due to the cost of, or inability to, procure insurance coverage. The unavailability of insurance coverage for our customers could adversely affect our ability to sell our products, and therefore our financial condition.

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

Federal regulations allow us to sell our products to or on the order of licensed practitioners. The definition of licensed practitioners varies from state to state. As a result, our products may be purchased or operated by physicians with varying levels of training, and in many states by non-physicians, including nurse practitioners, chiropractors and technicians. Outside the United States, many jurisdictions do not require specific qualifications or training for purchasers or operators of our products. We do not supervise the procedures performed with our products, nor do we require that direct medical supervision occur. We, and our distributors, generally offer but do not require purchasers or operators of our products to attend training sessions. In addition, we sometimes sell our systems to companies that rent our systems to third parties and that provide a technician to perform the procedure. The lack of training and the purchase and use of our products by non-physicians may result in product misuse and adverse treatment outcomes, which could harm our reputation and expose us to costly product liability litigation.

Table of Contents

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. In addition, 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 insurance coverage, or we have product liability claims in excess of our insurance coverage, claims would be paid out of cash reserves, thereby harming our financial condition, operating results and profitability.

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

Table of Contents

components to specification, or if the suppliers, or we, use defective materials or workmanship in the manufacturing process, the reliability and performance of our products will be compromised.

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

loss of customer orders and delay in order fulfillment;

damage to our brand reputation;

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

inability to attract new customers;

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

legal action.

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

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 twelve 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 inventories, which would increase our expenses. If we underestimate our component and material requirements, we may have inadequate inventories, 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.

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

Most of our revenue in the United States is derived from sales to customers outside of the core dermatologist and plastic surgeon specialties, such as family practitioners, primary care physicians, gynecologists and medi-spas. Continuing to achieve further penetration into this new market is a material assumption of our growth strategy. Demand for our products in the non-core market could be weakened by several factors including poor financial performance of businesses introducing aesthetic procedures to their practice or medi-spas, reduced patient demand for alternative treatments and services being provided by non-core practitioners and an increase in malpractice law suits against non-core practitioners. If we do not achieve anticipated demand for our products in the non-core market, our expected revenue growth may not be achieved.

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. We do not have a succession plan in place for each of our officers and key employees. 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.

Table of Contents

Our ability to retain our skilled labor force and our success in attracting and hiring new skilled employees will be a critical factor in determining whether we will be successful in the future. We may not be able to meet our future hiring needs or retain existing personnel. We will face particularly significant challenges and risks in hiring, training, managing and retaining engineering and sales and marketing employees. Failure to attract and retain personnel, particularly technical and sales and marketing personnel, would materially harm our ability to compete effectively and grow our business.

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

Beginning with the annual report for our fiscal year ended on December 31, 2005, Section 404 of the Sarbanes-Oxley Act of 2002 required us to include a report by our management on our internal control over financial reporting. Such report contained an assessment by management of the effectiveness of our internal control over financial reporting as of the end of our fiscal year and a statement as to whether or not such internal control is effective. Also included in our Annual Report on Form 10-K was an opinion by our Independent Registered Public Accounting Firm on management's assessment of such internal control.

Our efforts to comply with Section 404 have resulted in, and are likely to continue to result in, significant costs, and take up a significant amount of management's time and operational resources. Though we did not identify any material weaknesses in our internal control over financial reporting during the years ended December 31, 2006 and 2005, if we are unable to assert that our internal control over financial reporting is effective as in our 2007 and future years, our stock price may decline and it could have an adverse effect on our business.

Stock-based compensation expense adjustments could adversely affect our reported financial results, which could cause the price of our stock to decline.

As of January 1, 2006, we adopted SFAS 123(R), which requires us to measure and record stock-based compensation expense using a fair value method, which can adversely affect our results of operations by increasing our cost by the amount of such stock-based compensation charges. Determining the appropriate fair value model and calculating the fair value of stock-based payment awards require the input of highly subjective assumptions, which involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our stock-based compensation expense could be materially different in the future. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those shares expected to vest. If our actual forfeiture rate is materially different from our estimate, the stock-based compensation expense could be significantly different from what we have recorded in the current period. Actual stock-based compensation expense significantly higher than our expectations would materially decrease our net income and adversely affect our reported financial results, which could cause the price of our stock to decline.

Our effective income tax rate may vary significantly.

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

The quarterly royalty payments under our patent sublicense with Palomar are subject to an annual audit. Any material adjustments from this audit could result in a material adverse effect on our business and our stock price.

We pay royalties to Palomar after each fiscal quarter for applicable product sales made in that quarter. These royalty amounts are subject to an annual review by an independent public accountant hired by Palomar. The

Table of Contents

independent public accountant's interpretation of the applicable royalty rate for any new products, or combination of products, and the net revenue for which to calculate the royalty, could be different from ours. In the event that the independent public accountant's assessment of the accuracy of our estimated royalty payments to Palomar is materially different from our calculations, we could owe a higher amount to Palomar than we accrued for, and would then have to report it as an additional expense in our financial statements for the applicable period. This could result in a material adverse effect on our business and stock price.

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 investment will only occur if our stock price appreciates.

Table of Contents

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Our corporate headquarters and U.S. operations are located in a 66,000 square foot facility in Brisbane, California. We lease these premises under a non-cancelable operating lease which expires in 2014. In addition, we have leased office facilities of approximately 3,700 square feet, 2,690 square feet, and 1,240 square feet, in Japan, Switzerland, and France, respectively. The lease in Switzerland expires in July 2008, the lease in Japan expires in May 2008, and the lease in France expires in December 2009. We believe that these facilities are adequate for our current and future needs for at least the next twelve months.

ITEM 3. LEGAL PROCEEDINGS

As of December 31, 2006, we are not a party to any material pending litigation.

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

Not Applicable.

Table of Contents**PART II****ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES*****Stock Exchange Listing***

Our common stock trades on The NASDAQ Global Market under the symbol CUTR. At February 28, 2007, the closing sale price of our common stock was \$34.95 per share.

Common Stockholders

We had 13 stockholders of record as of February 28, 2007, one of whom was CEDE & CO, a large clearing house that holds shares in its name for banks, brokers and institutions, in order to expedite the sale and transfer of stock. Since many stockholders' shares are listed under their brokerage firm's name, we believe the actual number of stockholders is over 8,500.

Stock Prices

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

	Common Stock			
	2006		2005	
	High	Low	High	Low
4th Quarter	\$ 29.93	\$ 25.32	\$ 43.50	\$ 22.08
3rd Quarter	26.59	18.86	25.94	16.06
2nd Quarter	27.94	16.49	19.56	14.37
1st Quarter	31.24	24.99	19.71	12.47

Dividend Policy

We have never paid a cash dividend and have no present intention to pay cash dividends in the foreseeable future. We intend to retain any future earnings for use in our business.

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

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

Securities Authorized for Issuance Under Equity Compensation Plans

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

Edgar Filing: CUTERA INC - Form 10-K

Total stockholders equity	109,732	97,177	68,456	7,875	3,106
---------------------------	---------	--------	--------	-------	-------

Table of Contents

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

The following discussion should be read in conjunction with the attached financial statements and notes thereto, and with our audited financial statements and notes thereto for the fiscal year ended December 31, 2006. 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 forecasted operating expenses. These forward-looking statements involve risks and uncertainties. The cautionary statements set forth below and those contained in Item 1A Risk Factors commencing on page 18, identify important factors that could cause actual results to differ materially from those predicted in any such forward-looking statements. The reader is cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Annual Report on Form 10-K. We undertake no obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Form 10-K.

Introduction

The MD&A is organized as follows:

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

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

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

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

Liquidity and capital resources. This section provides an analysis of our liquidity and cash flows, as well as a discussion of our commitments that existed as of December 31, 2006.

Executive Summary

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

Our corporate headquarters and U.S. operations are located in Brisbane, California, where we conduct our manufacturing, warehousing, research, regulatory, sales, marketing and administrative activities. In the United States, we market and sell our products primarily through a direct sales force of 46 employees as of December 31, 2006 and through a distribution relationship with PSS World Medical Shared Services, Inc., a wholly owned subsidiary of PSS World Medical, which has over 700 sales representatives serving physician offices throughout the United States. In addition, we also sell certain items like Titan handpiece refills and marketing brochures via the web.

International sales are generally made through a direct sales force, independent sales representatives and distributors in over 30 countries worldwide. Outside the United States, we have a direct sales presence in Australia, Canada, France, Germany, Japan, Spain, Switzerland and the United Kingdom.

Table of Contents

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

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

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

Continuing introduction of new aesthetic products and applications.

Marketing to physicians outside the core dermatologist and plastic surgeon specialties.

Generating service and Titan handpiece refill revenue from our growing installed base of customers.

During 2006, our business continued to experience significant growth. In 2006, compared to 2005, our U.S. revenue grew 28% and our international revenue grew 46%. In contrast, in 2005, compared to 2004, our U.S. revenue grew by 57%, while our international revenue grew by 19%. The weaker U.S. revenue growth from 2005 to 2006, as compared to 2004 to 2005, was primarily attributable to the slow ramp-up of revenue from newly hired sales representatives. The stronger international revenue growth from 2005 to 2006, compared to 2004 to 2005, was primarily attributable to significant revenue growth coming from Canada, Japan, and Switzerland. The growth in revenue from Switzerland was attributable to the setting up of our European hub office in Zurich in July 2005, from where we coordinate our European marketing and service activities. We believe that, amongst other factors, if and when we obtain FDA marketing clearance for our YSGG-based laser technology, our revenue will be positively impacted.

For 2006, our gross margin declined to 70%, compared to 74% in 2005. This decrease was primarily attributable to the royalty expense recorded with effect from April 1, 2006 due to the settlement of our litigation with Palomar, which was 3% of net revenue in 2006, and to higher stock-based compensation expense due to the adoption of the fair value recognition provisions of SFAS 123(R) with effect from January 1, 2006. Given our royalty expense and stock-based compensation expense will continue in 2007, we expect our gross margin for 2007 to be similar to 2006.

General and administrative expenses for 2006, compared with 2005, increased by \$6.4 million, or 73%, to \$15.2 million and were 15% of net revenue. In 2007, we expect our G&A expenses to decrease and be in the range of approximately 10% - 12% of revenue. This expected decrease is primarily attributable to the following expenses which were included in G&A in 2006 but not expected to be incurred in 2007: \$3.3 million of legal expenses related to the patent litigation matter and an estimated charge of \$505,000 relating to a liability for sales taxes in jurisdictions that we had believed we did not have a taxable presence.

Factors that May Impact Future Performance

Our industry is impacted by numerous competitive, regulatory and other significant factors. Our industry is highly competitive and our success depends on our ability to compete successfully. Additionally, the growth of our business relies on our ability to continue to develop new products and innovative technologies, obtain

Table of Contents

regulatory clearances for our products, protect the proprietary technology of our products and our manufacturing processes, manufacture our products cost effectively, and successfully market and distribute our products in a profitable manner. If we fail to compete effectively, fail to continue to develop new products and technologies, fail to obtain regulatory clearances, fail to protect our intellectual property, fail to produce our products cost effectively, or fail to market and distribute our products in a profitable manner, our business could suffer. A detailed discussion of these and other factors that could impact our future performance are provided in Part I, Item 1A Risk Factors section.

Critical Accounting Policies and Estimates

The preparation of our financial statements and related disclosures in conformity with generally accepted accounting principles in the United States, or GAAP, requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses. These estimates and assumptions are based on historical experience and on various other factors that we believe are reasonable under the circumstances. We periodically review our accounting policies and estimates and make adjustments when facts and circumstances dictate. In addition to the accounting policies that are more fully described in the Notes to the Consolidated Financial Statements included in this Annual Report on Form 10-K, we consider the critical accounting policies described below to be affected by critical accounting estimates. Our critical accounting policies that are affected by accounting estimates include, stock-based compensation expense, revenue recognition, valuation of allowance for doubtful accounts, valuation of inventories, valuation of warranty obligations and valuation of income taxes on earnings. 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 these estimates.

Stock-based Compensation Expense

Effective January 1, 2006, we adopted Statement of Financial Accounting Standards, or SFAS No. 123(R), *Share-Based Payment (revised 2004)*, using the modified prospective transition method, which requires the measurement and recognition of compensation expense for all share-based payment awards made to our employees and directors, including stock options, employee stock purchases related to the Employee Stock Purchase Plan and restricted stock unit awards. Our consolidated financial statements as of and for the year ended December 31, 2006 reflect the impact of SFAS 123(R). In accordance with the modified prospective transition method, our consolidated financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R). Share-based compensation expense recognized is based on the value of the portion of share-based payment awards that is ultimately expected to vest. Share-based compensation expense recognized in our Consolidated Statements of Operations for the year ended December 31, 2006 included compensation expense for share-based payment awards granted prior to, but not yet vested as of, December 31, 2005 based on the fair value estimated in accordance with the pro forma provisions of SFAS 123 and compensation expense for the share-based payment awards granted subsequent to December 31, 2005 based on the fair value estimated in accordance with the provisions of SFAS 123(R). In conjunction with the adoption of SFAS 123(R), we estimated the fair value of each stock option on the date of grant using the Black-Scholes option valuation model and elected to attribute the value of share-based compensation to expense using the straight-line method, which was previously used for our pro forma information required under SFAS No. 123 *Accounting for Stock-Based Compensation*, or SFAS 123. The Black-Scholes option valuation model requires the input of subjective assumptions including expected stock price volatility, expected term of stock option and risk-free interest rate. Due in part to the limited amount of historical data available to us, particularly with respect to stock-price volatility, employee exercise patterns and forfeitures, actual results could differ from our assumptions.

Prior to the adoption of SFAS 123(R), we accounted for stock-based employee compensation arrangements in accordance with the provisions of Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, and its interpretations and complied with the disclosure provisions of SFAS 123 as

Table of Contents

amended by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure an amendment of FASB Statement No. 123*. Under APB Opinion No. 25, compensation expense is based on the difference, if any, on the date of the grant between the fair market value of our stock and the exercise price. Employee stock-based compensation is amortized on a straight-line basis over the vesting period of the underlying options.

Revenue Recognition

We recognize distributor and non-distributor revenue in accordance with the SEC's Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition*. SAB No. 104 requires that four basic criteria must be met before revenue can be recognized:

persuasive evidence of an arrangement exists;

delivery has occurred or services have been rendered;

the fee is fixed and determinable; and

collectibility is reasonably assured.

Determination of whether persuasive evidence of an arrangement exists and whether delivery has occurred or services have been rendered, are based on management's judgments regarding the fixed nature of the fee charged for services rendered and products delivered, and the collectibility of those fees. In instances where final acceptance of the product is specified by the customer or collectibility has not been reasonably assured, revenue is deferred until all acceptance criteria have been met. Revenue under service contracts is recognized on a straight-line basis over the period of the applicable service contract. Service revenue, not under a service contract, is recognized as the services are provided. Total deferred revenue for service contracts was \$6.7 million and \$3.1 million as of December 31, 2006 and December 31, 2005, 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 \$9.6 million as of December 31, 2006, compared with \$6.5 million as of December 31, 2005. The allowance for doubtful accounts as of December 31, 2006, was \$34,000, compared with \$177,000 as of December 31, 2005. 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.

Inventories

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 and updated quarterly or as necessary, to reflect changes in raw material costs, labor to manufacture the product and overhead rates. Our inventories balance was \$5.2 million as of December 31, 2006 and 2005. Our inventories allowances as of December 31, 2006 were \$851,000, compared with \$992,000 as of December 31, 2005. 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 inventories. We balance the need to maintain strategic inventory levels with the risk of

Table of Contents

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 Obligations

We provide a standard one-year warranty coverage on our systems and from time to time have promotional offers when we offer a twenty-four month warranty. Warranty coverage provided is for labor and parts necessary to repair the systems during the warranty period. We provide for the estimated future costs of warranty obligations in cost of revenue when the related revenue is recognized. The accrued warranty costs represent our best estimate at the time of sale, and as reviewed and updated quarterly, of the total costs that we expect to incur in repairing or replacing product parts that fail while still under warranty. Accrued warranty costs include costs of material, technical support labor and associated overhead. The amount of accrued estimated warranty costs obligation for established products is primarily based on historical experience as to product failures adjusted for current information on repair costs. For new products, estimates will include historical experience of similar products, as well as reasonable allowance for start-up expenses. Actual warranty costs could differ from the estimated amounts. On a quarterly basis, we review the accrued balances of our warranty obligations and update the historical warranty cost trends. The accrued balance for product warranties was \$3.1 million and \$2.0 million as of December 31, 2006 and 2005, respectively. For more information on warranty reserves, see Note 3 to the Notes to Consolidated Financial Statements. If we were required to accrue additional warranty cost in the future due to actual product failure rates, material usage, service delivery costs or overhead costs differing from our estimates, revisions to the estimated warranty liability would be required, which would negatively impact our operating results.

Provision for Income Taxes

We are subject to taxes on earnings in both the United States and numerous foreign jurisdictions. As a global taxpayer, significant judgments and estimates are required in evaluating our tax positions and determining our provision for taxes on earnings. The calculation of our tax liabilities involves addressing uncertainties in the application of complex tax regulations. We maintain reserves for potential tax contingencies arising in the jurisdictions in which we do business. Such reserves are based on our assessment of the likelihood of an unfavorable outcome and the potential loss from such contingencies, and may be adjusted from time to time in light of changing facts and circumstances. These reserves are maintained until such time as the matter is settled or the statutory period for adjustment has passed. Adjustments could be required in the future if we determine that our reserves for tax contingencies are inadequate. The provision for taxes on earnings includes the effect of changes to these reserves that are considered appropriate. In addition, the carrying value of our net deferred tax assets assumes that we will be able to generate sufficient future taxable earnings in certain tax jurisdictions to utilize these deferred tax assets.

Earnings derived from our international regions are generally taxed at different rates than in the United States. Our effective rate is impacted by existing tax laws in both the United States and in the respective countries in which our international subsidiaries are located. A change in the mix of total earnings from our United States operations and the respective international regions among particular tax jurisdictions could change our effective income tax rate. Also, our current effective tax rate does not assume U.S. taxes on undistributed profits of foreign subsidiaries. These earnings could become subject to incremental foreign withholding or U.S. federal and state taxes, should they either be deemed or actually remitted to the United States.

Recent Accounting Pronouncements

In February 2007, the FASB issued Statement of Financial Accounting Standard No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159). SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. Unrealized gains and losses on items

Table of Contents

for which the fair value option has been elected are reported in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007. We are currently evaluating the impact of implementing SFAS 159 on our consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*. This standard defines fair value, establishes a framework for measuring fair value in accounting principles generally accepted in the United States, and expands disclosure about fair value measurements. This pronouncement applies under other accounting standards that require or permit fair value measurements. Accordingly, this statement does not require any new fair value measurement. This statement is effective for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. We will be required to adopt SFAS No. 157 in the first quarter of fiscal year 2008. We are currently assessing the impact that SFAS 157 may have on our consolidated financial position, results of operations or cash flows.

In September 2006, the SEC issued SAB No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, or SAB 108, to address diversity in practice in quantifying financial statement misstatements. SAB 108 requires the quantification of misstatements based on their impact on both the balance sheet and the income statement to determine materiality. The guidance provides for a one-time cumulative effect adjustment to correct for misstatements that were not deemed material under a company's prior approach but are material under the SAB 108 approach. SAB No. 108 has not had any impact on our annual financial statements for the year ended December 31, 2006.

In July 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109*, or SFAS 109. This interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109. The Interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Interpretation also provides guidance on derecognition, classification, interest and penalties, accounting for interim periods, disclosure, and transition. This interpretation is effective for us in the first quarter ending on March 31, 2007. Based on a preliminary evaluation of the impact of adopting this Interpretation, we believe that it will not have a material effect on our financial position or results of operations in 2007.

Table of Contents**Results of Operations**

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

	Year ended December 31,		
	2006	2005	2004
Operating Ratios:			
Net revenue	100%	100%	100%
Cost of revenue	30%	26%	28%
Gross profit	70%	74%	72%
Operating expenses:			
Sales and marketing	33%	33%	37%
Research and development	6%	7%	8%
General and administrative	15%	12%	17%
Litigation settlement	19%	%	%
Total operating expenses	73%	52%	62%
Income (loss) from operations	(3)%	22%	10%
Interest and other income, net	4%	3%	1%
Income before income taxes	1%	25%	11%
Provision (benefit) for income taxes	(1)%	7%	4%
Net income	2%	18%	7%

Total Revenue

(Dollars in thousands)	Year ended December 31,				
	2006	% Change	2005	% Change	2004
Revenue mix by geography:					
United States	\$ 69,895	28%	\$ 54,506	57%	\$ 34,826
Asia, excluding Japan	8,384	0%	8,378	69%	4,958
Japan	7,397	53%	4,842	(35)%	7,460
Europe	7,239	66%	4,351	98%	2,199
Rest of the world	7,777	120%	3,543	11%	3,198
Total international revenue	30,797	46%	21,114	19%	17,815
Consolidated total revenue	\$ 100,692	33%	\$ 75,620	44%	\$ 52,641
United States as a percentage of total revenue	69%		72%		66%
International as a percentage of total revenue	31%		28%		34%
Revenue mix by product category:					
Products	\$ 84,695	34%	\$ 63,349	45%	\$ 43,540
Product upgrades	6,006	(9)%	6,630	0%	6,615

Edgar Filing: CUTERA INC - Form 10-K

Service	5,890	52%	3,881	61%	2,414
Titan handpiece refills	4,101	133%	1,760	N/A	72
Consolidated total	\$ 100,692	33%	\$ 75,620	44%	\$ 52,641

The total revenue increase in 2006 and 2005, compared with the respective prior years, was primarily attributable to product revenue growth, especially from our multi-application Xeo and Solera platforms, both of which

Table of Contents

include the Titan product. In addition, the overall revenue growth was attributable to the expansion of our direct sales force and the penetration of customer bases outside the core specialties of dermatologists and plastic surgeons. Service revenue continued to increase as a result of an increase in our installed base of customers purchasing extended service contracts. Growth in Titan handpiece refills reflected increased adoption of the Titan product by new and existing customers as well as an increased consumer demand for Titan procedures. Upgrade revenue declined in 2006 and was flat in 2005, due primarily to an increase in the number of customers choosing to purchase a new system from our Solera platform, instead of upgrading their existing systems. We believe that, amongst other factors, if and when we obtain FDA marketing clearance for our YSGG-based laser technology, our revenue will be positively impacted.

International revenue growth in 2006 was primarily attributable to growth from Canada, Japan and Switzerland. The growth in revenue from Switzerland was attributable to the setting up of our European hub office there in July 2005. In 2005, compared to 2004, the slower international growth was primarily attributable to reduced sales to a national chain of clinics in Japan, who purchased systems for all their members beginning in early 2004 and ending in the first quarter of 2005.

Gross Margin

(Dollars in thousands)	Year Ended December 31,				
	2006	% Change	2005	% Change	2004
Gross margin	\$ 70,833	27%	\$ 55,828	47%	\$ 37,952
<i>As a percentage of total revenue</i>	<i>70%</i>		<i>74%</i>		<i>72%</i>

Our cost of revenue consists primarily of material, labor, employee stock-based compensation, royalty expense, warranty, and manufacturing overhead expenses. The decrease in gross margin in 2006, compared to 2005, was primarily attributable to the following two expense items which were recorded in 2006 but not in 2005: \$3.3 million, or 3% of net revenue, of royalty expense recorded with effect from April 1, 2006 as a result of the Palomar patent licensing agreement—see Note 10 of Notes to Consolidated Financial Statements for further details and accounting of the settlement agreement—and \$551,000, or 1% of revenue, of higher stock-based compensation expense due to the adoption of the fair value recognition provisions of SFAS 123(R) with effect from January 1, 2006. Given our royalty expense and stock-based compensation expenses will continue in 2007, we expect our gross margin for 2007 to be similar to our gross margin in 2006.

The improvement in gross margin in 2005 over 2004 was primarily attributable to a favorable product mix towards our multi-application Xeo and Solera platform products, the growth of which was fueled by our launch of the Titan product, as well as reduced warranty and service costs associated with improved product reliability.

Sales and Marketing

(Dollars in thousands)	Year Ended December 31,				
	2006	% Change	2005	% Change	2004
Sales and marketing	\$ 32,890	31%	\$ 25,021	29%	\$ 19,326
<i>As a percentage of total revenue</i>	<i>33%</i>		<i>33%</i>		<i>37%</i>

Sales and marketing expenses consist primarily of personnel cost, stock-based compensation expense and expenses associated with customer-attended workshops, trade shows and advertising. Even though our sales and marketing expenses increased in 2006, compared with 2005, by \$1.3 million due to the higher stock-based compensation expenses associated with the adoption of FAS 123(R) in 2006, our sales and marketing expenses as a percentage of total revenue remained flat at 33%. This, as well as the decrease in sales and marketing expenses as a percentage of revenue in 2005, compared to 37% in 2004, was a result of the improved operating leverage due to the higher revenue growth and improved productivity. Compared with 2006, due to our planned increase in headcount, we expect our sales and marketing expenses to increase in 2007.

Table of Contents

Of the \$7.9 million increase in sales and marketing expenses in 2006, compared with 2005, \$4.7 million was attributable to personnel expenses associated primarily with increased headcount, \$1.3 million of stock-based compensation expenses and \$1.6 million of advertising and promotional expenses. The \$5.7 million increase in sales and marketing expenses in 2005, compared to 2004, was primarily attributable to \$4.7 million of personnel expenses associated primarily with the increased headcount.

Research and Development (R&D)

(Dollars in thousands)	Year Ended December 31,				
	2006	% Change	2005	% Change	2004
Research and development	\$ 6,473	21%	\$ 5,353	18%	\$ 4,549
<i>As a percentage of total revenue</i>	<i>6%</i>		<i>7%</i>		<i>8%</i>

Research and development expenses consist primarily of personnel cost, stock-based compensation expenses and clinical, regulatory and material costs. R&D expenses as a percentage of total revenue decreased in 2006 and 2005, compared to the respective prior years, due to the improved operating leverage resulting from higher revenue growth, compared to the expense growth. Compared with 2006, due to a planned increase in R&D activities and headcount, we expect our R&D expenses to increase in 2007.

Of the \$1.1 million increase in R&D expenses in 2006 over 2005, \$565,000 was attributable to personnel related expenses associated primarily to increased headcount, and \$492,000 was attributable to stock-based compensation expenses associated with the adoption of FAS 123(R) in 2006. The \$804,000 increase in R&D expense in 2005, over 2004, was primarily attributable to \$888,000 of personnel expense associated primarily with increased headcount, partially offset by a \$125,000 decrease in stock-based compensation expenses.

General and Administrative (G&A)

(Dollars in thousands)	Year Ended December 31,				
	2006	% Change	2005	% Change	2004
General and administrative	\$ 15,192	73%	\$ 8,782	(2)%	\$ 8,924
<i>As a percentage of total revenue</i>	<i>15%</i>		<i>12%</i>		<i>17%</i>

General and administrative expenses consist primarily of personnel costs, stock-based compensation expenses, legal fees, accounting fees and other general and administrative expenses. The increase in G&A expenses in 2006, compared with 2005, was primarily attributable to \$2.6 million of legal expenses associated primarily with the then-active Palomar litigation matter, \$759,000 of stock-based compensation expenses associated with the adoption of FAS 123(R) in 2006, \$673,000 of personnel expenses, due in part to increased headcount, \$602,000 of audit and tax consulting fees related primarily to the audit of our internal control over financial reporting, and an estimated charge of \$505,000 recorded in 2006 relating to a liability for sales taxes in jurisdictions that we previously believed we did not have a taxable presence. In 2007, we expect our G&A expenses to decrease and be in the range of approximately 10% - 12% of revenue due primarily to the expected reduction in legal expenses.

In 2005, compared to 2004, G&A expenses decreased by \$142,000 and were 12% of total revenue, compared with 17% in 2004. This decrease was attributable primarily to lower legal expenses of \$1.4 million partly due to the timing of our litigation with Palomar and expenses incurred in 2004 but not in 2005, including costs of \$291,000 associated with moving our facilities from Burlingame, California to Brisbane, California and a litigation settlement of \$175,000. This was offset by \$1.7 million of higher personnel expenses due in part to higher headcount, higher stock-based compensation expenses of \$219,000, and a net increase of \$340,000 in audit fees, tax and audit consulting fees due primarily to the implementation and audit of our internal control over financial reporting in 2005.

Table of Contents**Litigation Settlement**

On June 2, 2006, we settled all patent litigation brought against us by Palomar and MGH. Under the terms of the settlement agreement, we owed Palomar \$20.2 million relating to royalties on sales of infringing systems, accrued interest and reimbursement of Palomar's legal costs, through March 31, 2006. Of the \$20.2 million, we recorded \$18.9 million as a litigation settlement expense and \$1.2 million as the intangible asset representing the value of the ongoing sublicense agreement obtained as part of the settlement agreement. See Note 10 of Notes to Consolidated Financial Statements, for further details and accounting of the settlement agreement.

Interest and Other Income, Net

(Dollars in thousands)	Year Ended December 31,				
	2006	% Change	2005	% Change	2004
<i>Interest and other income, net</i>	\$ 3,596	77%	\$ 2,034	222%	\$ 632

The increase in interest and other income, net, in 2006 and 2005, compared to the respective prior years, was primarily attributable to improved tax-exempt interest yields on investments in government bonds from 2004 to 2006 and an increased amount invested. Our cash, cash equivalents and marketable investment balances was at \$108.1 million, \$92.0 million and \$66.3 million as of December 31, 2006, 2005 and 2004, respectively.

Benefit (Provision) for Income Taxes

(Dollars in thousands)	Fiscal Years				
	2006	Change	2005	Change	2004
Income before income taxes	\$ 939	\$ (17,767)	\$ 18,706	\$ 12,921	\$ 5,785
Provision (benefit) for income taxes	(1,184)	(6,089)	4,905	2,880	2,025
<i>Effective tax rate</i>	<i>(126)%</i>	<i>(152)%</i>	<i>26%</i>	<i>(9)%</i>	<i>35%</i>

Our effective tax rate reflects applicable United States federal and state tax rates and the tax impact of foreign operations, offset by research and development tax credits, tax exempt interest income and deductions for disqualifying incentive stock option exercises. The change in the effective tax rate for 2006, compared with 2005, was primarily due to the reduction of income as a result of the litigation settlement expense, the tax exempt interest income, the R&D tax credits, and the decrease in benefits from disqualifying dispositions of incentive stock options. In 2006, given the litigation settlement expense resulted in a significantly lower level of income before income taxes, the impact of deductible permanent items R&D tax credits, tax-exempt interest income and deductions for disqualifying incentive stock option exercises resulted in a substantially more pronounced impact on our effective income tax rate, as they represented a larger percentage of our income before income taxes.

The reduction in our effective income tax rate in 2005, compared with 2004, was primarily attributable to the increase in the benefits from disqualified incentive stock option exercises, higher benefit from research and development credits resulting from increased research and development expenses and higher tax-exempt interest income.

Net Income and Net Income Per Diluted Share

(Dollars in thousands, except per share data)	Fiscal Years				
	2006	% Change	2005	% Change	2004
Net income	\$ 2,123	(85)%	\$ 13,801	267%	\$ 3,760
Net income per diluted share	\$ 0.15	(85)%	\$ 1.00	223%	\$ 0.31

Table of Contents

The decrease in net income and the net income per diluted share in 2006, compared with 2005, was primarily attributable to:

\$11.7 million, or \$0.82 per diluted share, relating to the patent litigation settlement expense of \$18.9 million, net of the marginal tax impact of \$7.2 million;

\$2.0 million, or \$0.14 per diluted share, relating to the \$3.1 million of increased stock-based compensation expenses recorded in 2006 due to the adoption of FAS 123(R), net of the marginal income tax benefit of \$1.1 million;

\$2.3 million, or \$0.16 per diluted share, as a result of \$3.3 million of royalty expenses for the Palomar patent sublicense, net of the \$1.0 million tax benefit; and

\$1.8 million, or \$0.13 per diluted share, due to the \$2.6 million increase in legal expenses associated primarily with the Palomar patent litigation matter, net of \$817,000 of tax benefit.

These decreases were offset by a \$6.2 million net after tax, or \$0.40 per diluted share, increase in net income due primarily to:

33% growth in revenue;

the leveraging of our operating expenses, due to revenue growing faster than our manufacturing and operating expenses; and

a decrease in our effective income tax rate.

The increase in net income and income per diluted share in 2005, compared with 2004, was primarily attributable to the 44% increase in total revenue, an improvement in gross margins to 74% in 2005, compared with 72% in 2004, the leveraging of our operating expenses due to revenue growing faster than our manufacturing and operating expenses and a decrease in our effective income tax rate to 26%, from the 35% in 2004.

Liquidity and Capital Resources

Liquidity is the measurement of our ability to meet potential cash requirements, fund the planned expansion of our operations and acquire businesses. Our sources of cash include operations, stock option exercises and employee stock purchases and interest income. We actively manage our cash usage and investment of liquid cash to ensure the maintenance of sufficient funds to meet our daily needs.

Cash, Cash Equivalents and Marketable Investments

The following table summarizes our cash, cash equivalents and marketable securities:

(Dollars in thousands)	As of December 31,		
	2006	2005	Increase
Cash, cash equivalents and marketable securities:			
Cash and cash equivalents	\$ 11,800	\$ 5,260	\$ 6,540
Marketable investments	96,285	86,736	9,549
Total	\$ 108,085	\$ 91,996	\$ 16,089

Edgar Filing: CUTERA INC - Form 10-K

The net increase in cash and cash equivalents and marketable investments of \$16.1 million in 2006, was primarily a result of \$12.5 million generated by operations after \$20.2 million cash used to pay Palomar in settlement of our patent litigation and \$4.4 million of cash provided by the issuance of common stock related to stock option exercises and employee stock purchases. As of December 31, 2006, we had cash, cash equivalents and marketable investments of \$108.1 million, which we believe are sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months.

Table of Contents**Cash Flows**

(Dollars in thousands)	Year ended December 31,		
	2006	2005	2004
Net cash flow provided by (used in):			
Operating activities	\$ 12,466	\$ 20,388	\$ 9,244
Investing activities	(11,355)	(28,342)	(59,813)
Financing activities	5,429	6,144	47,349
Net increase (decrease) in cash and cash equivalents	\$ 6,540	\$ (1,810)	\$ (3,220)

Net Cash Provided by Operating Activities

We generated net cash from operating activities of \$12.5 million in 2006, compared to \$20.4 million and \$9.2 million, in 2005 and 2004, respectively. The \$7.9 million decrease in net cash from operating activities in 2006, compared to 2005, was driven by a decrease in net income of \$11.7 million due primarily to the patent litigation settlement in June 2006 and higher stock-based compensation expenses as a result of the adoption of FAS 123(R) in 2006 a \$6.1 million decrease in non-cash items (primarily \$5.6 million of lower tax benefit from stock option exercises that could be utilized due to the lower income before taxes, and \$2.0 million of higher deferred tax assets recorded), offset partially by \$9.8 million of cash generated by a net change in operating assets and liabilities.

The \$11.1 million increase in cash from operating activities in 2005, compared to 2004, was driven by an increase in net income of \$10.0 million, an increase in non-cash items by \$6.6 million (primarily due to tax benefits from the employee sales of stock options and ESPP stock), offset partially by \$5.5 million of cash used by a net increase in operating assets and liabilities.

Net Cash Used in Investing Activities

We used \$11.4 million of cash in investing activities in 2006. Of this amount, \$9.5 million was used to invest in marketable securities, \$1.2 million was used to purchase an ongoing patent sublicense from Palomar and \$642,000 was used to purchase capital equipment for R&D and manufacturing departments. In 2006, compared to 2005, we experienced a \$17.0 decrease in our investing activities, due primarily to the decrease in investment balances as a result of the Palomar litigation settlement payment in June 2006.

In 2005, we used \$28.3 million for investing activities. Of this amount, \$27.6 million was used to purchase additional marketable investments from the cash generated by operations, the exercises of stock options and employee stock purchases. In addition, \$539,000 was primarily used to purchase research and development and manufacturing equipment; and \$165,000 was used to purchase intangibles associated with the set up of a new office in Zurich, Switzerland. In comparing 2005 to 2004, there was a \$31.5 million decrease in cash used for investing activities, given in 2004 we raised \$46.3 million of cash through the initial public offering of our common stock.

Net Cash Provided by Financing Activities

Net cash provided by financing activities in 2006, 2005 and 2004, was \$5.4 million, \$6.1 million and \$47.3 million, respectively. This was primarily attributable to the proceeds from the issuance of stock through our stock option and employee stock purchase plans, and in 2004, to \$46.3 million raised from the sale of common stock through our initial public offering.

Table of Contents***Contractual Cash Obligations***

The following summarizes our contractual obligations as of December 31, 2006 for minimum lease payments related to facility leases.

Contractual Obligations	Total	Payments Due by Period (\$ 000 s)			
		Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Operating leases	\$ 8,394	\$ 1,023	\$ 1,945	\$ 2,456	\$ 2,970
<i>Off-Balance Sheet Arrangements</i>					

We do not participate in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance, variable interest or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As of December 31, 2006, we were not involved in any unconsolidated transactions.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to interest rate risk relates primarily to our investment portfolio. Fixed rate securities may have their fair market value adversely impacted due to fluctuations in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectation due to changes in interest rates or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates. The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in debt instruments of the U.S. Government and its agencies, municipal bonds and high-quality corporate issuers, and, by policy, restrict our exposure to any single corporate issuer by imposing concentration limits. To minimize the exposure due to adverse shifts in interest rates, we maintain investments at a weighted average maturity (interest reset date for auction-rate securities and variable rate demand notes) of generally less than eighteen months. For maturities of our marketable investments, see Note 2 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, 2006 would have potentially declined by \$519,000.

We have international subsidiaries and operations and are, therefore, subject to foreign currency rate exposure. To date, our exposure to exchange rate volatility has not been significant. We cannot assure that there will not be a material impact in the future. Although the majority of our sales and purchases are denominated in U.S. dollars, future fluctuations in the value of the U.S. dollar may affect the price competitiveness of our products. We do not believe, however, that we currently have significant direct foreign currency exchange rate risk and have not hedged exposures denominated in foreign currencies.

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

Table of Contents

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA
CUTERA, INC. AND SUBSIDIARY COMPANIES**

ANNUAL REPORT ON FORM 10-K

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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

	Page
<u>Report of Independent Registered Public Accounting Firm</u>	46
<u>Consolidated Balance Sheets</u>	48
<u>Consolidated Statements of Operations</u>	49
<u>Consolidated Statements of Stockholders' Equity</u>	50
<u>Consolidated Statements of Cash Flows</u>	51
<u>Notes to Consolidated Financial Statements</u>	52

The following Consolidated Financial Statement Schedule of the Registrant and its subsidiaries for the years ended December 31, 2006, 2005 and 2004 is filed as a part of this Report as required to be included in Item 15(a) and should be read in conjunction with the Consolidated Financial Statements of the Registrant and its subsidiaries:

Schedule		Page
II	<u>Valuation and Qualifying Accounts</u>	74

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

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Cutera, Inc.:

We have completed integrated audits of Cutera, Inc.'s (the Company) 2006 and 2005 consolidated financial statements and of its internal control over financial reporting as of December 31, 2006, and an audit of its 2004 consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

Consolidated financial statements and financial statement schedule

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

As discussed in Note 1 to the consolidated financial statements, the Company changed the manner in which it accounts for share-based compensation for the year ended December 31, 2006.

Internal control over financial reporting

Also, in our opinion, management's assessment, included in management's report on internal control over financial reporting appearing under Item 9A, that the Company maintained effective internal control over financial reporting as of December 31, 2006 based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on criteria established in *Internal Control - Integrated Framework* issued by the COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management's assessment and on the effectiveness of the Company's internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

Table of Contents

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

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

/s/ PRICEWATERHOUSECOOPERS LLP

San Jose, California

March 15, 2007

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

	December 31,	
	2006	2005
Assets		
Current assets:		
Cash and cash equivalents	\$ 11,800	\$ 5,260
Marketable investments	96,285	86,736
Accounts receivable, net of allowance for doubtful accounts in 2006 and 2005 of \$34 and \$177, respectively	9,601	6,478
Inventories	5,220	5,245
Deferred tax asset	5,792	3,027
Other current assets	2,702	3,728
Total current assets	131,400	110,474
Property and equipment, net	1,029	1,015
Intangibles, net	1,446	469
Total assets	\$ 133,875	\$ 111,958
Liabilities and Stockholders' Equity		
Liabilities:		
Accounts payable	\$ 2,212	\$ 1,352
Accrued liabilities	13,675	9,131
Deferred revenue	3,514	1,673
Total current liabilities	19,401	12,156
Deferred rent	1,424	1,096
Deferred revenue, net of current portion	3,258	1,469
Deferred tax liability	60	60
Total liabilities	24,143	14,781
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Redeemable convertible preferred stock, \$0.001 par value		
Authorized: 5,000,000 shares; none issued and outstanding		
Common stock, \$0.001 par value:		
Authorized: 50,000,000 shares in both 2006 and 2005;		
Issued and outstanding: 12,939,389 and 12,213,474 shares in 2006 and 2005, respectively	13	12
Additional paid-in capital	86,242	77,705
Deferred stock-based compensation	(331)	(2,171)
Retained earnings	23,866	21,743
Accumulated other comprehensive loss	(58)	(112)
Total stockholders' equity	109,732	97,177
Total liabilities and stockholders' equity	\$ 133,875	\$ 111,958

Edgar Filing: CUTERA INC - Form 10-K

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

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

	Year Ended December 31,		
	2006	2005	2004
Net revenue	\$ 100,692	\$ 75,620	\$ 52,641
Cost of revenue	29,859	19,792	14,689
Gross profit	70,833	55,828	37,952
Operating expenses:			
Sales and marketing	32,890	25,021	19,326
Research and development	6,473	5,353	4,549
General and administrative	15,192	8,782	8,924
Litigation settlement	18,935		
Total operating expenses	73,490	39,156	32,799
Income (loss) from operations	(2,657)	16,672	5,153
Interest and other income, net	3,596	2,034	632
Income before income taxes	939	18,706	5,785
Provision (benefit) for income taxes	(1,184)	4,905	2,025
Net income	\$ 2,123	\$ 13,801	\$ 3,760
Net income available to common stockholders used in basic earnings per share	\$ 2,123	\$ 13,801	\$ 3,284
Net income per share:			
Basic	\$ 0.17	\$ 1.20	\$ 0.38
Diluted	\$ 0.15	\$ 1.00	\$ 0.31
Weighted-average number of shares used in per share calculations:			
Basic	12,558	11,535	8,573
Diluted	14,278	13,864	12,222

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

Table of Contents**CUTERA, INC.****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY****(in thousands, except share amounts)**

	Common Stock			Deferred	Retained	Other	Total
	Shares	Amount	Additional Paid-in Capital	Stock-Based Compensation	Earnings	Comprehensive Loss	Stockholders Equity
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
Issuance of common stock for employee purchase plan	58,323		575				575
Exercise of stock options	1,197,949	1	5,568				5,569
Deferred stock-based compensation			(323)	323			
Issuance of restricted stock units			1,448	(1,448)			
Non-employee stock compensation			262	(262)			
Amortization of stock-based compensation				1,442			1,442
Tax benefit related to employee stock options			7,437				7,437
Components of other comprehensive income:							
Net income					13,801		13,801
Other comprehensive loss						(103)	(103)
Comprehensive income							13,698
Balance at December 31, 2005	12,213,474	12	77,705	(2,171)	21,743	(112)	97,177
Issuance of common stock for employee purchase plan	40,651		881				881
Exercise of stock options	673,940	1	3,515				3,516
Issuance of common stock in settlement of restricted stock units, net of shares withheld for employee taxes.	11,324		(112)				(112)
Share-based compensation expense			3,973	569			4,542
Change in deferred stock-based compensation, net of terminations			(1,271)	1,271			
Tax benefit from exercises of stock-based payment awards			1,551				1,551
Components of other comprehensive income:							

Edgar Filing: CUTERA INC - Form 10-K

Net income						2,123			2,123
Other comprehensive income							54		54
Comprehensive income									2,177
Balance at December 31, 2006	12,939,389	\$ 13	\$ 86,242	\$ (331)	\$ 23,866	\$ (58)	\$ 109,732		

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

Table of Contents**CUTERA, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS**

(in thousands)

	Year Ended December 31,		
	2006	2005	2004
Cash flows from operating activities:			
Net income	\$ 2,123	\$ 13,801	\$ 3,760
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	869	689	524
Change in allowance for doubtful accounts	(143)	(310)	293
Provision for excess and obsolete inventories	90	905	300
Change in deferred tax asset/liability	(2,765)	(735)	(476)
Stock-based compensation	4,542	1,442	1,435
Tax benefit from employee stock options	1,808	7,437	674
Excess tax benefit related to stock-based compensation expense	(1,032)		
Loss on disposal of assets			47
Changes in assets and liabilities:			
Accounts receivable	(2,980)	475	661
Inventory	(65)	(3,146)	(1,065)
Other current assets	1,026	(2,850)	1
Accounts payable	860	157	(720)
Accrued liabilities	4,175	937	2,485
Deferred rent	328	448	648
Deferred revenue	3,630	1,138	677
 Net cash provided by operating activities	 12,466	 20,388	 9,244
Cash flows from investing activities:			
Acquisition of property and equipment	(642)	(539)	(854)
Purchase of intangibles	(1,218)	(165)	
Proceeds from sales of marketable investments	23,522	18,324	9,133
Proceeds from maturities of marketable investments	99,439	49,948	14,310
Purchase of marketable investments, net	(132,456)	(95,910)	(82,652)
Change in restricted cash			250
 Net cash used in investing activities	 (11,355)	 (28,342)	 (59,813)
Cash flows from financing activities:			
Proceeds from exercise of stock options and employee stock purchase plan	4,397	6,144	1,037
Excess tax benefit related to stock-based compensation expense	1,032		
Proceeds from issuance of common stock, net			46,312
 Net cash provided by financing activities	 5,429	 6,144	 47,349
 Net increase (decrease) in cash and cash equivalents	 6,540	 (1,810)	 (3,220)
Cash and cash equivalents at beginning of year	5,260	7,070	10,290
 Cash and cash equivalents at end of year	 \$ 11,800	 \$ 5,260	 \$ 7,070
Supplemental and non-cash disclosure of cash flow information:			
Conversion of preferred stock to common stock	\$	\$	\$ 7,372

Edgar Filing: CUTERA INC - Form 10-K

Change in deferred stock-based compensation, net of terminations	\$ (1,271)	\$ 1,387	\$ (227)
Cash paid (received) for income taxes	\$ (1,990)	\$ 1,837	\$ 2,526

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

Table of Contents

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Operations and Principles of Consolidation.

Cutera Inc. (Cutera or the Company) is a global provider of laser and other light-based aesthetic systems for practitioners worldwide. The Company, designs, develops, manufactures, and markets the CoolGlide, Xeo and Solera product platforms for use by dermatologists, plastic surgeons, gynecologists, primary care physicians, and other qualified practitioners to offer safe, effective and non-invasive aesthetic treatments to their customers.

Headquartered in Brisbane, California, the Company has wholly-owned subsidiaries in Australia, Canada, France, Germany, Japan, Spain, Switzerland and United Kingdom. The purpose of these subsidiaries is to market, sell and service the Company's products outside of the United States. The Consolidated Financial Statements include the accounts of the Company and its subsidiaries. All inter-company transactions and balances have been eliminated.

Management Estimates.

The preparation of the Consolidated Financial Statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the Consolidated Financial Statements and the reported amounts of revenue and expenses during the reporting periods. 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. The Company's marketable investments are classified 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. All investments are held for use in current operations and are classified in current assets. All realized gains and losses and unrealized losses and declines in fair value that are other than temporary are recorded in earnings in the period of occurrence. The specific identification method is used to determine the realized gains and losses on investments.

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. The fair value of marketable investments is based on quoted market prices.

Table of Contents

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 two major banks in the United States. In addition, the Company has operating cash balances in each of the international locations that it operates in. Deposits in these banks may exceed the amount of insurance provided on such deposits, if any. Management believes that these financial institutions are 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 revenue 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. Concentrations of accounts receivable balances are presented in Note 2 and segment, geographic and major customer information is presented in Note 9.

The Company invests in debt instruments of the U.S. Government and its agencies, municipal bonds and high-quality corporate issuers, and, by policy, restricts its exposure to any single corporate issuer by imposing concentration limits. To minimize the exposure due to adverse shifts in interest rates, the Company maintains 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 additional 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.

Inventories.

Inventories are 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 inventories. 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 or in the respective operating expense line based on which function and purpose it is being used for. Proceeds from the sale of demonstration units are recorded as revenue and all costs incurred to refurbish the systems prior to sale are charged to cost of revenue.

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 three years. Amortization of leasehold improvements is computed using

Table of Contents

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

the straight-line method over the shorter of the remaining lease term or the estimated useful life of the related assets. 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 operating expenses. Maintenance and repairs are charged to operations as incurred.

Intangible Assets.

Purchased technology sublicense and other intangible assets are presented at cost, net of accumulated amortization. The technology licenses are being amortized on a straight-line basis over their expected useful life of 9-10 years and the other intangibles are being amortized over their expected useful life of two years.

Impairment of Long-lived Assets.

In accordance with the provisions of Statement of Financial Accounting Standards Board, or SFAS, No. 144, *Accounting for the Impairment or Disposal of Long-lived Assets*, the Company reviews long-lived assets, including property and equipment, and intangible assets, 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, 2006, there have been no such impairments.

Warranty Obligations.

The Company provides a standard one-year warranty coverage on its systems and from time to time has promotional offers when it offers a twenty-four month warranty. Warranty coverage provided is for labor and parts necessary to repair the systems during the warranty period. The Company accounts for the estimated warranty cost as a charge to costs of revenue, when revenue is recognized. The estimated warranty cost is based on historical product performance. Utilizing actual service records, the Company calculates the average service hours and parts expense per system and applies the actual labor and overhead rates to determine the estimated warranty charge. The Company updates these estimated charges every quarter.

Revenue Recognition.

Product revenue, including upgrade revenue, and revenue from Titan handpiece refills, is recognized when title and risk of ownership has been transferred, provided that persuasive evidence of an arrangement exists, the price is fixed or 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. Revenue under service contracts is recognized on a straight-line basis over the period of the applicable service contract. Service revenue, from customers whose systems are not under a service contract, is recognized as the services are provided. Service revenue for the years ended December 31, 2006, 2005 and 2004, were \$5,890,000, \$3,881,000, and \$2,414,000 respectively.

Shipping and Handling Costs.

Shipping and handling costs are included as a component of cost of revenue.

Table of Contents

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Research and Development Expenditures.

Costs related to research, design, development and testing of products are charged to research and development expense as incurred. Expenses incurred primarily relate to employees, facilities, material, third party contractors and clinical and regulatory fees.

Advertising Costs.

Advertising costs are included as part of sales and marketing expense and are expensed as incurred. Advertising expense for the years ended December 31, 2006, 2005 and 2004, were \$1,546,000, \$1,201,000 and \$1,314,000, respectively.

Stock-based Compensation.

Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment (revised 2004)*, or SFAS 123(R), using the modified prospective transition method, which requires the measurement and recognition of compensation expense for all share-based payment awards made to the Company's employees and directors, including stock options, employee stock purchases related to the Employee Stock Purchase Plan and restricted stock units. The Company's consolidated financial statements for the year ended December 31, 2006 reflects the impact of SFAS 123(R). In accordance with the modified prospective transition method, the Company's consolidated financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R). Share-based compensation expense recognized is based on the value of the portion of share-based payment awards that is ultimately expected to vest. Share-based compensation expense recognized in the Company's Consolidated Statements of Operations during the year ended December 31, 2006 included compensation expense for share-based payment awards granted prior to, but not yet vested as of, December 31, 2005 based on the fair value estimated in accordance with the pro forma provisions of SFAS No. 123 *Accounting for Stock-Based Compensation*, or SFAS 123, and compensation expense for the share-based payment awards granted subsequent to December 31, 2005 based on the fair value estimated in accordance with the provisions of SFAS 123(R). In conjunction with the adoption of SFAS 123(R), the Company estimated the fair value of each stock option on the date of grant using the Black-Scholes option valuation model and elected to attribute the value of share-based compensation to expense using the straight-line method, which was previously used for its pro forma information required under SFAS 123.

Prior to the adoption of SFAS 123(R) the Company recognized stock-based compensation expense in accordance with Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*. In March 2005, the SEC issued Staff Accounting Bulletin No 107, *Share-Based Payment*, or SAB 107, regarding the SEC's interpretation of SFAS 123(R) and the valuation of stock-based payments for public companies. The Company has applied the provisions of SAB 107 in its adoption of SFAS 123(R). See Note 5 for a further discussion on stock-based compensation.

Income Taxes.

The Company accounts for income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes*, which requires that deferred tax assets and liabilities be recognized using enacted tax rates for the effect of temporary differences between the book and tax bases of recorded assets and liabilities. SFAS No. 109 also requires that deferred tax assets be reduced by a valuation allowance if it is more likely than not that a portion of the deferred tax asset will not be realized. The Company has determined that its future taxable income will be sufficient to recover all of the deferred tax assets. However, should there be a change in their ability to recover the deferred tax assets, the Company could be required to record a valuation allowance against its deferred tax assets. This would result in an increase to the Company's tax provision in the period in which they determined that the recovery was not probable.

Table of Contents**CUTERA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In addition, the calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax regulations. The Company recognizes liabilities for anticipated tax audit issues in the U.S. and other tax jurisdictions based on the Company's estimate of whether additional tax payments are probable. If the Company ultimately determines that payment of these amounts is not probable, the Company will reverse the liability and recognize a tax benefit during the period in which the Company makes the determination. The Company will record an additional charge in the Company's provision for taxes in the period in which the Company determines that the recorded tax liability is less than the Company expects the ultimate assessment to be.

Comprehensive Income.

Comprehensive income generally represents all changes in stockholders' equity except those resulting from investments or contributions by stockholders. The Company's unrealized loss on marketable investments represents the only component of other comprehensive income that is excluded from net income.

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 operating 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 for each of the three years ended December 31, 2006. 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, 2006.

Recent Accounting Pronouncements.

In February 2007, the FASB issued Statement of Financial Accounting Standard No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159). SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact of implementing SFAS 159 on its Consolidated Financial Statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, or SFAS No. 157. This standard defines fair value, establishes a framework for measuring fair value in accounting principles generally accepted in the United States of America, and expands disclosure about fair value measurements. This pronouncement applies under other accounting standards that require or permit fair value measurements. Accordingly, this statement does not require any new fair value measurement. This statement is effective for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company will be required to adopt SFAS 157 in the quarter ended March 31, 2008. The Company is currently assessing the impact that SFAS 157 may have on its consolidated financial position, results of operations and cash flows.

In September 2006, the SEC issued SAB No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, or SAB 108, to address diversity in practice in quantifying financial statement misstatements. SAB 108 requires the quantification of misstatements based on their impact on both the balance sheet and the income statement to determine materiality. The guidance provides for a one-time cumulative effect adjustment to correct for misstatements that were not deemed material under a company's prior approach but are material under the SAB 108 approach. SAB 108 has not had any impact on the Company's annual financial statements for the year ended December 31, 2006.

Table of Contents**CUTERA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In July 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* an interpretation of FASB Statement No. 109, or SFAS 109. This interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109. The Interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Interpretation also provides guidance on derecognition, classification, interest and penalties, accounting for interim periods, disclosure, and transition. This interpretation is effective for the Company's first quarter ending on March 31, 2007. Based on a preliminary evaluation of the impact of adopting this Interpretation, we believe that it will not have a material effect on our financial position or results of operations in 2007.

NOTE 2 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.

December 31, 2006 (in thousands)	Amortized Cost	Gross Unrealized Gains	Unrealized Losses	Fair Market Value
Checking and money market funds	\$ 11,800	\$	\$	\$ 11,800
Auction rate securities and municipal bonds	96,343		(58)	96,285
	\$ 108,143	\$	\$ (58)	\$ 108,085

Reported as:

Cash and cash equivalents	\$ 11,800	\$	\$	\$ 11,800
Marketable investments	96,343		(58)	96,285
	\$ 108,143	\$	\$ (58)	\$ 108,085

December 31, 2005 (in thousands)	Amortized Cost	Gross Unrealized Gains	Unrealized Losses	Fair Market Value
Checking and money market funds	\$ 5,260	\$	\$	\$ 5,260
Variable rate demand notes	12,403			12,403
Auction rate securities and municipal bonds	74,445		(112)	74,333
	\$ 92,108	\$	\$ (112)	\$ 91,996

Reported as:

Cash and cash equivalents	\$ 5,260	\$	\$	\$ 5,260
Marketable investments	86,848		(112)	86,736
	\$ 92,108	\$	\$ (112)	\$ 91,996

Table of Contents**CUTERA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The contractual maturities of cash, cash equivalents and marketable-investments as of December 31, 2006, are as follows (in thousands):

December 31, 2006	Amount
Due in less than one year	\$ 51,343
Due in 1 to 3 years	26,476
Due in 3 to 5 years	
Due in 5 to 10 years	
Due in greater than 10 years (primarily auction rate securities that can be readily liquidated)	30,266
 Total	 \$ 108,085

Accounts Receivable:

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses existing in accounts receivable and is based on historical write-off experience and any specific customer issues that have been identified. Account balances are charged off against the allowance when it is probable the receivable will not be recovered. As of December 31, 2006 and 2005, one customer accounted for 28% and 27% of the Company's total accounts receivable balance, respectively.

Inventories:

Inventories consist of the following (in thousands):

	December 31,	
	2006	2005
Raw materials	\$ 2,816	\$ 3,071
Finished goods	2,404	2,174
	\$ 5,220	\$ 5,245

Other Current Assets:

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

	December 31,	
	2006	2005
Tax receivable	\$ 1,739	\$ 3,017
Prepaid expenses	698	530
Deposits	265	181
	\$ 2,702	\$ 3,728

Table of Contents**CUTERA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Property and Equipment, net:**

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

	December 31,	
	2006	2005
Leasehold improvements	\$ 140	\$ 100
Office equipment and furniture	1,926	1,563
Machinery and equipment	1,663	1,423
	3,729	3,086
Less: Accumulated depreciation and amortization	(2,700)	(2,071)
	\$ 1,029	\$ 1,015

Depreciation and amortization expense related to property and equipment was \$628,000, \$594,000 and \$470,000 for the years ended December 31, 2006, 2005 and 2004, respectively.

Intangible Assets:

Intangible assets principally comprised of a technology sublicense acquired in 2002, a patent sublicense acquired from Palomar in 2006; and other intangible assets acquired in 2005. The components of intangible assets at December 31, 2006 and 2005 were as follows:

	Gross Carrying Amount	Accumulated Amortization Amount	Net Amount
December 31, 2006 (in thousands)			
Patent sublicense	\$ 1,218	\$ 104	\$ 1,114
Technology sublicense	538	247	291
Other intangibles	165	124	41
Total	\$ 1,921	\$ 475	\$ 1,446
December 31, 2005 (in thousands)			
Technology sublicense	\$ 538	\$ 193	\$ 345
Other intangibles	165	41	124
Total	\$ 703	\$ 234	\$ 469

For the year ended December 31, 2006, 2005 and 2004, amortization expense for intangible assets was \$241,000, \$95,000 and \$54,000, respectively.

Table of Contents**CUTERA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Based on intangible assets recorded at December 31, 2006, and assuming no subsequent additions to, or impairment of the underlying assets, the remaining estimated annual amortization expense is expected to be as follows (in thousands):

Year ending December 31,	
2007	\$ 233
2008	192
2009	192
2010	192
2011	192
2012 and thereafter	445
Total	\$ 1,446

Accrued Liabilities:

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2006	2005
Payroll and related expenses	\$ 5,101	\$ 4,694
Warranty	3,055	2,043
Royalty	1,304	
Professional fees	202	344
Income tax payable	785	
Sales and marketing accruals	698	322
Sales tax	1,107	485
Customer deposits	781	581
Other	642	662
	\$ 13,675	\$ 9,131

NOTE 3 WARRANTY AND SERVICE CONTRACTS:

The Company has a direct field service organization in the United States. Internationally, the Company provides direct service support through its wholly-owned subsidiaries in Australia, France, Germany, Japan and Switzerland as well as through a network of distributors and third-party service providers in several other countries where it does not have a direct presence. The Company generally provides a warranty with its products, depending on the type of product. After the warranty period, maintenance and support are offered on a service contract basis or on a time and materials basis. The Company currently provides for the estimated cost to repair or replace products under warranty at the time of sale.

Table of Contents**CUTERA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Warranty Accrual (in thousands):**

	Year Ended December 31,	
	2006	2005
Balance at beginning of year	\$ 2,043	\$ 1,850
Add: Accruals for warranties issued during the year	5,552	2,785
Less: Settlements made during the year	(4,540)	(2,592)
Balance at end of year	\$ 3,055	\$ 2,043

Deferred Service Contract Revenue (in thousands):

	Year Ended December 31,	
	2006	2005
Balance at beginning of year	\$ 3,117	\$ 1,906
Add: Payments received	7,455	4,925
Less: Revenue recognized	(3,920)	(3,714)
Balance at end of year	\$ 6,652	\$ 3,117

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

Costs incurred under service contracts during the years ended December 31, 2006, 2005 and 2004 amounted to \$1,642,000, \$1,130,000, and \$702,000, respectively, and are recognized as incurred.

NOTE 4 COMMITMENTS AND CONTINGENCIES:**Facility Leases.**

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 3,700 square feet, 2,690 square feet and 1,240 square feet, in Japan, Switzerland and France, respectively. The leases in Japan, Switzerland and France expire in May 2008, July 2008 and December 2009, respectively. In September 2005, the Company terminated its Germany facility lease and incurred a termination charge of \$31,000.

On January 11, 2005, the Company entered into a three year agreement to sublease a portion of its Brisbane, California, facility to an unaffiliated third-party. In February 2006, the Sub lessee gave notice to terminate the sublease effective September 14, 2006.

Table of Contents**CUTERA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

As of December 31, 2006, the Company was committed to minimum lease payments for facilities and other leased assets under long-term non-cancelable operating leases is as follows (in thousands):

Year Ending December 31,	
2007	\$ 1,023
2008	925
2009	1,020
2010	1,149
2011	1,307
2012 and thereafter	2,970
Future minimum rental payments	\$ 8,394

For the years ended December 31, 2006, 2005 and 2004, gross rent expense was \$1.3 million, \$1.3 million and \$1.2 million, respectively.

NOTE 5 STOCKHOLDERS EQUITY, STOCK PLANS AND STOCK-BASED COMPENSATION EXPENSE:**Stock Option Plans.**

As of December 31, 2006, the Company had the following stock-based employee compensation plans.

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, or 2004 ESPP, eligible employees are permitted to purchase common stock at a discount through payroll deductions. Prior to November 1, 2006, the Company had a rolling one-year offering period, each with two six-month purchase periods. Beginning with the offering period that started on November 1, 2006, all future offering periods will run for approximately six months, each with one purchase period. Shares of common stock eligible for purchase are increased on the first day of each fiscal year 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. The Company added 244,269 reserved shares to the 2004 ESPP on January 1, 2006. 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 Company issued 40,651 and 58,323 shares of common stock under the 2004 ESPP in fiscal years 2006 and 2005, respectively. At December 31, 2006, 529,204 shares remained available for future issuance.

2004 Equity Incentive Plan and 1998 Stock Plan.

In 1998, the Company adopted the 1998 Stock Plan, or 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 un-issued under the 1998 Plan and shares returned to the 1998 Plan as the result of termination of options or the repurchase of shares.

Table of Contents

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2006, the Company added 610,674 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 either five, seven or ten years.

During the year ended December 31, 2005, under the 2004 Equity Incentive Plan, the Company's Board of Directors approved the grant of 71,500 shares of restricted stock to selected members of the Company's management. These restricted stock units generally vest in four equal, annual installments on the anniversaries of the date of grant. The Company recorded \$1,448,000 of deferred stock-based compensation for these restricted stock grants as a component of stockholders' equity and is amortizing that amount over the service period of four years. The value of the restricted stock awards was based on the closing market price of the Company's common stock on the date of award. Amortization expense for these awards for the year ended December 31, 2006 was \$326,000.

Table of Contents**CUTERA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Option Activity.**

Activity under the 1998 Plan and 2004 Equity Incentive Plan is summarized as follows:

	Shares Available for Grant	Number of Shares	Options Outstanding		Aggregate Intrinsic Value (in \$ millions)*
			Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	
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		
Additional shares reserved	547,860				
Options granted	(682,625)	682,625	\$ 18.03		
Restricted stock units granted	(71,500)				
Options exercised		(1,197,949)	\$ 4.65		
Options cancelled	188,495	(188,495)	\$ 8.74		
Balances, December 31, 2005	1,479,622	3,244,609	\$ 6.91		
Additional shares reserved	610,674				
Options granted	(603,943)	603,943	\$ 24.37		
Options exercised		(673,940)	\$ 5.22		
Options cancelled or forfeited	189,081	(189,081)	\$ 17.46		
Restricted stock units forfeited	7,312		\$ 16.87		
Balances, December 31, 2006	1,682,746	2,985,531	\$ 10.16	5.69	\$ 50.3
Exercisable as of December 31, 2006		1,864,435	\$ 4.30	4.52	\$ 42.3

* Based on the closing stock price of \$27.00 for the Company's common stock on December 29, 2006, the last day of trading for the 2006 fiscal year. The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (the aggregate difference between the Company's closing stock price on the last trading day of the fiscal year 2006 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 31, 2006. This amount changes based on the fair market value of the Company's common stock. Total intrinsic value of options exercised in the twelve months ended December 31, 2006 was \$13.5 million. Total fair value of vested and expensed stock options, restricted stock units and ESPP shares for the twelve months ended December 31, 2006 was \$3.0 million, net of tax. The Company issues new shares upon the exercise of options, restricted stock units and ESPP shares.

Table of Contents**CUTERA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The options outstanding and exercisable at December 31, 2006 were in the following exercise price ranges:

Range of Exercise Prices	Options Outstanding		Options Exercisable	
	Number Outstanding	Weighted-Average Remaining Contractual Life (in years)	Number Outstanding	Weighted-Average Exercise Price
\$ 0.10 \$ 0.10	890,000	2.70	890,000	\$ 0.10
\$ 0.50 \$ 3.00	212,565	4.02	212,565	1.48
\$ 4.25 \$ 4.25	338,400	6.09	302,257	4.25
\$ 5.50 \$13.30	323,726	7.06	179,647	9.52
\$13.80 \$16.25	311,822	7.41	160,074	14.00
\$17.99 \$20.25	311,280	8.45	107,643	19.14
\$20.59 \$21.84	52,000	9.36		
\$23.75 \$23.75	348,738	6.44		
\$25.73 \$26.32	147,000	8.75	12,249	25.78
\$27.36 \$27.36	50,000	8.30		
\$ 0.10 \$27.36	2,985,531	5.69	1,864,435	\$ 4.30

As of December 31, 2005, there were 1,977,301 outstanding options that were exercisable at a weighted average exercise price of \$2.18.

Impact of Adoption of SFAS 123(R).

The Company elected to adopt the modified prospective application method as provided by SFAS No. 123(R). Accordingly, in 2006, the Company recorded stock-based compensation cost totaling the amount that would have been recognized had the fair value method been applied since the effective date of SFAS No. 123, valued under SFAS No. 123 for the pre-January 1, 2006 grants and under SFAS No. 123(R) for the 2006 grants.

In November 2005, the Financial Accounting Standards Board (FASB) issued FASB Staff Position (FSP) No. FAS 123(R)-3, Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards (FSP 123R-3). The Company has elected not to adopt the alternative transition method provided in the FSP 123R-3 for calculating the tax effects of stock-based compensation pursuant to SFAS No. 123(R). The Company followed paragraph 81 of SFAS No. 123(R) to calculate the initial pool of excess tax benefits and to determine the subsequent impact on the APIC pool and Consolidated Statements of Cash Flows of the tax effects of employee stock-based compensation awards that are outstanding upon adoption of SFAS No. 123(R).

Table of Contents**CUTERA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The effect of adopting SFAS No. 123(R) in the year ended December 31, 2006 was as follows:

	Year Ended
	December 31,
	2006
(in thousands, except per share data)	
Stock-based compensation expense by award type:	
Employee stock options granted at their intrinsic value	\$ (3,316)
Employee stock options granted below their deemed intrinsic fair value prior to the Company's initial public offering (1)	(569)
Employee stock purchase plan	(331)
Restricted stock units	(326)
Total stock-based compensation	(4,542)
Tax effect on stock-based compensation at the Company's marginal tax rate	1,568
Effect on net income	\$ (2,974)
Effect on net income per share:	
Basic	\$ (0.24)
Diluted	\$ (0.21)
Change in deferred stock-based compensation	
Due to reversal of unamortized deferred stock-based compensation upon adoption	\$ (1,237)
Due to reversal of unamortized deferred stock-based compensation for terminations of employee stock options granted below their deemed intrinsic fair value prior to the Company's initial public offering (1)	(34)
	\$ (1,271)
Effect on cash flows:	
Cash flows from operations	\$ (1,032)
Cash flows from financing activities	\$ 1,032

(1) This amount would also have been recorded under the provisions of APB 25, prior to the adoption of FAS 123(R). As of January 1, 2006, the Company had an unrecorded deferred stock-based compensation balance related to stock options of \$7.1 million before estimated forfeitures. In the Company's pro forma disclosures prior to the adoption of SFAS 123(R), the Company accounted for forfeitures when they actually occurred. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised if necessary in subsequent periods if actual forfeitures differ from those estimates. Under SFAS 123(R), the Company estimated that \$160,000 of the unrecorded deferred stock-based compensation amount as of January 1, 2006 will not be recognized due to forfeitures.

During the twelve months ended December 31, 2006, the Company granted stock options for 603,943 shares of common stock with an estimated weighted-average fair values of \$ 14.16 and a total grant-date fair value of \$8.5 million. Of the grant-date fair value of options granted in the twelve months ended December 31, 2006, the Company estimates that the amount of unrecorded deferred stock-based compensation that is not expected to vest due to forfeiture is \$278,000. As of December 31, 2006, the unrecognized compensation cost, net of expected forfeitures,

Edgar Filing: CUTERA INC - Form 10-K

related to non-vested stock options was \$8.5 million, which will be recognized using the straight-line attribution method over an estimated weighted-average amortization period of 1.3 years.

Table of Contents**CUTERA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

As of January 1, 2006, the Company had an unrecorded deferred stock-based compensation balance related to restricted stock unit awards of \$1.2 million before estimated forfeitures. Under SFAS 123(R), the Company estimated that \$343,000 of the unrecorded deferred stock-based compensation amount as of January 1, 2006 will not be recognized due to forfeitures. As of December 31, 2006, the unrecognized compensation cost related to restricted stock unit awards was \$673,000, after estimated forfeitures, which will be recognized over an estimated weighted average amortization period of 2.4 years.

As of December 31, 2006, the unrecognized compensation cost related to ESPP shares was \$102,000, which will be recognized using the straight-line attribution method over 0.3 years. The weighted-average estimated fair values of each stock issuance under the ESPP for the years ended December 31, 2006 was \$8.97 per share.

Valuation Assumptions.

The Company estimates the fair value of employee stock options and stock issued under the ESPP using the Black-Scholes option-pricing model, consistent with the provisions of SFAS 123(R), SAB 107 and the Company's prior period pro forma disclosures of net income, including stock-based compensation (determined under a fair value method as prescribed by SFAS 123). The fair value of each option grant and each stock issuance under the ESPP was estimated on the date of grant using the Black-Scholes model with the following weighted-average assumptions:

	Year Ended December 31, 2006
Risk-free interest rate for stock options	4.90%
Risk-free interest rate for ESPP	4.38%
Expected life for stock options (in years)	5.05
Expected life for ESPP option (in years)	0.75
Expected stock price volatility for stock options	64%
Expected stock price volatility for ESPP	58%
Dividend yield	

Option-pricing models require the input of various subjective assumptions, including the following:

Expected Volatility: The expected stock price volatility is based on a combination of the Company's historical volatility combined with the weighted average of the volatility of other similar companies in the same industry. With effect from April 2006, the expected stock price volatility was based on a combination of the Company's historical volatility combined with the implied volatility of the Company's quoted stock options. The Company believes these methods of computing volatility are more reflective and a better indicator of the expected future volatility, than using an average of a comparable market index or of a comparable company in the same industry.

Expected Term: The expected term of ten year contractual term options granted in 2006, was based on the Company's historical exercise behavior for these options. For five and seven year contractual term options, that the Company started granting from April 2006, the expected term was derived from the short-cut method described in SEC's SAB 107.

Risk-Free Interest Rate: The risk-free rate for the expected term of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

Expected Dividend: The Company has not paid and does not anticipate paying any dividends in the near future.

Table of Contents**CUTERA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Estimated Pre-vesting Forfeitures: When estimating forfeitures, the Company considers voluntary termination behavior based on actual historical information.

Non-employees Option Grants.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force, or 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. The compensation expense for non-employee option grants is recognized over the expected service period on a straight-line basis and was \$0, \$262,000 and \$0, for the year ended December 31, 2006, 2005 and 2004, respectively

The following table summarizes information concerning outstanding and exercisable options as of December 31, 2006.

Periods Prior to the Adoption of SFAS 123(R).

Prior to January 1, 2006, the Company accounted for stock-based compensation under the recognition and measurement provisions of APB 25. Accordingly, the Company generally recognized compensation expense only when it granted options with a discounted exercise price. Any resulting compensation expense was recognized ratably over the associated service period, which was generally the option vesting term of four years. Effective January 1, 2006, the Company adopted SFAS 123(R), using the modified prospective application transition method, which requires the presentation of pro-forma information for periods prior to the adoption of SFAS 123(R) regarding the net income and net income per share as if the Company had accounted for its stock options under the fair value method of SFAS 123. For the purpose of this pro-forma disclosure, the estimated value of the stock awards is recognized on a straight line basis over the vesting periods of the awards. If compensation had been determined based upon the fair value at the grant date for employee compensation arrangements, consistent with the methodology prescribed in SFAS 123, the Company's pro-forma net income and pro-forma net income per share under SFAS 123 would have been as shown in the table below (in thousands, except per share data):

	Year Ended December 31,	
	2005	2004
Net income, as reported	\$ 13,801	\$ 3,760
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects	857	1,184
Less: Total stock-based employee compensation determined under fair-valued based method for all awards, net of related tax effects	(2,126)	(1,823)
Pro forma net income	\$ 12,532	\$ 3,121
Net income per share:		
Basic: as reported	\$ 1.20	\$ 0.38
Basic: pro forma	\$ 1.09	\$ 0.32
Diluted: as reported	\$ 1.00	\$ 0.31
Diluted: pro forma	\$ 0.91	\$ 0.26

Table of Contents**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 that date. The fair value of each option grant and each stock issuance under the ESPP was estimated on the date of grant using the Black-Scholes model with the following weighted-average assumptions:

	Year Ended December 31,	
	2005	2004
Risk-free interest rate for stock options	3.88%	3.12%
Risk-free interest rate for ESPP	3.48%	1.14%
Expected life for stock options (in years)	3.81	3.63
Expected life for ESPP option (in years)	0.75	0.57
Expected stock price volatility for stock options	67%	69%
Expected stock price volatility for ESPP	51%	55%
Dividend yield		

NOTE 6 INCOME TAXES:

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

	December 31,		
	2006	2005	2004
Current:			
Federal	\$ 1,024	\$ 4,393	\$ 2,123
State	176	433	309
Foreign	382	231	69
	1,582	5,057	2,501
Deferred:			
Federal	(2,457)	(103)	(410)
State	(309)	(81)	(34)
Foreign		32	(32)
	(2,766)	(152)	(476)
Provision (benefit) for income taxes	\$ (1,184)	\$ 4,905	\$ 2,025

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

	December 31,	
	2006	2005
Credits	\$ 1,216	\$ 606
Accrued warranty	1,204	808
Other accruals and reserves	1,912	1,529

Edgar Filing: CUTERA INC - Form 10-K

Stock-based compensation	1,460	84
Deferred tax asset	5,792	3,027
Depreciation and amortization	(60)	(60)
Net deferred tax asset	\$ 5,732	\$ 2,967

Table of Contents**CUTERA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

	Year Ended December 31,		
	2006	2005	2004
Tax at federal statutory rate	35.00%	35.00%	34.00%
State, net of federal benefit	4.98	4.48	4.07
Meals and entertainment	11.80	0.45	0.89
Benefit for research and development credit	(109.81)	(7.89)	(3.71)
Stock-based compensation	19.89	(3.17)	1.67
Tax-exempt interest	(112.08)	(3.26)	(3.37)
Other	24.07	0.61	1.45
Provision (benefit) for income taxes	(126.15)%	26.22%	35.00%

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

Undistributed earnings of the Company's foreign subsidiaries of approximately \$1.1 million at December 31, 2006, are considered to be indefinitely reinvested and, accordingly, no provision for federal and state income taxes has 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.

As of December 31, 2006, the Company had cumulative net operating loss carry-forwards for federal and state income tax reporting purposes of approximately \$5.0 million and \$11.2 million, respectively. The federal net operating loss carry-forwards expire through the year 2026 and the state net operating loss carry-forwards expire at various dates through the year 2026. Such net operating losses consist of excess tax benefits from employee stock option exercises and have not been recorded in the Company's deferred tax assets in accordance with FAS 123(R). The Company will record \$2.4 million as a credit to additional paid in capital as and when such excess tax benefits are ultimately realized.

As of December 31, 2006, the Company had cumulative carry-forwards for research and development credits for federal and state income tax purposes of approximately \$770,000 and \$1.2 million, respectively. These federal research and development tax credits expire through the year 2024. The state research and development credits can be carried forward indefinitely, except for \$284,000, which will expire at various dates through the year 2020. Furthermore, the Company has federal alternative minimum tax credits of approximately \$116,000 that can be carried forward indefinitely. Certain tax credit carryovers are attributable to excess tax benefits from employee stock option exercises and have not been recorded in the Company's deferred tax assets in accordance with FAS 123(R). The Company will record \$450,000 as a credit to additional paid in capital as and when such excess tax benefits are ultimately realized.

NOTE 7 NET INCOME PER SHARE:

Basic net income per share is calculated by dividing net income available to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted earnings per share is calculated by using the weighted-average number of common shares outstanding during the period increased to include the number of additional shares of common stock that would have been outstanding if the dilutive potential shares of common stock had been issued. The dilutive effect of outstanding options, ESPP shares and restricted stock units is reflected in diluted earnings per share by application of the treasury stock method, which

Table of Contents**CUTERA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

includes consideration of stock-based compensation required by SFAS No. 123(R) and SFAS No. 128, *Earnings Per Share*.

The following table sets forth the computation of basic and diluted earnings per share (in thousands, except per share amounts):

	Year Ended December 31,		
	2006	2005	2004
Numerator:			
Net income	\$ 2,123	\$ 13,801	\$ 3,760
Less: Amount allocated to participating preferred stockholders:			(476)
Net income available to common stockholders Basic	\$ 2,123	\$ 13,801	\$ 3,284
Net income available to common stockholders Diluted	\$ 2,123	\$ 13,801	\$ 3,760
Denominator:			
Weighted-average number of common shares outstanding used in computing basic net income per share	12,558	11,535	8,573
Dilutive potential common shares used in computing diluted net income per share	1,720	2,329	3,649
Total weighted-average number of shares used in computing diluted net income per share	14,278	13,864	12,222

Anti-dilutive Securities

The following number of outstanding options and ESPP shares, 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 anti-dilutive effect (in thousands):

	Year Ended December 31,		
	2006	2005	2004
Common stock options and ESPP shares	621	7	566

NOTE 8 DEFINED CONTRIBUTION PLAN:

In the United States, the Company has an employee savings plan that qualifies as a deferred salary arrangement under Section 401(k) of the Internal Revenue Code. Eligible employees may make voluntary contributions to the Plan up to 100% of their annual compensation, subject to statutory annual limitations. Since April 1999, the Company has made discretionary matching contributions of 50% to 75% of all employees contributions in each Plan year. During the years ended December 31, 2006, 2005 and 2004 the Company made discretionary contributions of \$557,000, \$420,000 and \$227,000, respectively, under the Plan.

For some of the Company's foreign subsidiaries, the Company has a defined contribution plan for their employees. Consistent with the requirements of local laws, the Company deposits funds for these plans with insurance companies, third-party trustees, or into government-managed accounts and have been fully funded or accrued as of December 31, 2006. The Company's contributions for its foreign employees were not material in each of the years ended December 31, 2006, 2005 and 2004.

Table of Contents**CUTERA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****NOTE 9 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 where product is delivered.

For the years ended December 31, 2006, 2005 and 2004, the Company had one customer that represented 15%, 16% and 12%, respectively, of net revenue.

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

	2006	2005	2004
Revenue mix by geography:			
United States	\$ 69,895	\$ 54,506	\$ 34,826
Asia, excluding Japan	8,384	8,378	4,958
Japan	7,397	4,842	7,460
Europe	7,239	4,351	2,199
Rest of the world	7,777	3,543	3,198
Consolidated total	\$ 100,692	\$ 75,620	\$ 52,641
Revenue mix by product category:			
Products	\$ 84,695	\$ 63,349	\$ 43,540
Product upgrades	6,006	6,630	6,615
Service	5,890	3,881	2,414
Titan handpiece refills	4,101	1,760	72
Consolidated total	\$ 100,692	\$ 75,620	\$ 52,641

NOTE 10 LITIGATION SETTLEMENT:

On June 2, 2006, patent litigation between the Company and Palomar Medical Technologies and Massachusetts General Hospital was settled with Palomar granting the Company an irrevocable sublicense to the subject patents. Under the terms of the settlement agreements, the Company agreed to pay Palomar \$20,153,000 representing the royalties due on sales of the infringing systems, plus accrued interest and reimbursement of Palomar's legal costs through March 31, 2006. Of the \$20,153,000 settlement amount, \$18,935,000 relating to past royalties, interest and legal settlement costs, was recorded as a litigation settlement expense, and \$1,218,000, representing the value of the on-going sublicense agreement, was capitalized as an intangible asset. The intangible asset is being amortized on a straight line basis over the useful economic life of the patents, which expire in February 2015.

Under the terms of the sublicense granted by Palomar, the royalty rate for sales of hair-removal-only systems is equal to 7.5% of net revenue. For multi-application systems containing hair-removal functionality, the royalty rate is either 3.75% or 5.25%, depending on whether there is one or two hair-removal technologies included in the system, respectively. The Company's revenue from systems that do not include hair-removal capabilities and revenue from service contracts is not subject to royalties. The royalty cost incurred from April 1, 2006 has been

Edgar Filing: CUTERA INC - Form 10-K

recorded as a component of cost of revenue. These royalty obligations will continue for applicable sales made through February 2015 which is the expiration date for the subject patents.

Table of Contents**SUPPLEMENTARY FINANCIAL DATA (UNAUDITED)**

(In thousands, except per share amounts)

Quarter ended:	Dec 31, 2006	Sept 30, 2006	June 30, 2006	March 31, 2006	Dec 31, 2005	Sept 30, 2005	June 30, 2005	March 31, 2005
Net revenue	\$ 30,481	\$ 25,059	\$ 24,395	\$ 20,757	\$ 23,953	\$ 18,950	\$ 17,570	\$ 15,147
Cost of revenue	8,349	7,931	7,768	5,811	6,149	4,746	4,883	4,014
Gross profit	22,132	17,128	16,627	14,946	17,804	14,204	12,687	11,133
Operating expenses:								
Sales and marketing	7,865	8,174	8,305	8,546	7,167	6,222	5,832	5,800
Research and development	1,935	1,679	1,552	1,307	1,421	1,334	1,412	1,185
General and administrative	3,578	2,992	4,248	4,375	2,263	1,924	2,283	2,312
Litigation settlement		544	18,391					
Total operating expense	13,378	13,389	32,496	14,228	10,851	9,480	9,527	9,297
Income (loss) from operations	8,754	3,739	(15,869)	718	6,953	4,724	3,160	1,836
Interest and other income, net	981	829	830	956	683	549	516	286
Income (loss) before income taxes	9,735	4,568	(15,039)	1,674	7,636	5,273	3,676	2,122
Provision (benefit) for income taxes	2,620	1,618	(5,990)	567	1,825	1,472	972	636
Net income (loss)	\$ 7,115	\$ 2,950	\$ (9,049)	\$ 1,107	\$ 5,811	\$ 3,801	\$ 2,704	\$ 1,486
Net income (loss) attributable to common stockholders used in basic earnings per share:	\$ 7,115	\$ 2,950	\$ (9,049)	\$ 1,107	\$ 5,811	\$ 3,801	\$ 2,704	\$ 1,486
Net income (loss) per share basic	\$ 0.56	\$ 0.23	\$ (0.73)	\$ 0.09	\$ 0.48	\$ 0.33	\$ 0.24	\$ 0.13
Net income (loss) per share diluted	\$ 0.50	\$ 0.21	\$ (0.73)	\$ 0.08	\$ 0.41	\$ 0.27	\$ 0.20	\$ 0.11
Weight-average number of shares used in per share calculations:								
Basic	12,749	12,675	12,444	12,257	12,026	11,661	11,345	11,093
Diluted	14,346	14,238	12,444	14,174	14,291	13,924	13,585	13,532
Cash, cash equivalents and marketable investments	\$ 108,085	\$ 90,672	\$ 81,965	\$ 95,511	\$ 91,996	\$ 82,216	\$ 74,719	\$ 69,109

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

	Balance at Beginning of Year	Additions	Deductions	Balance at End of Year
Allowance for doubtful accounts receivable				
Year ended December 31, 2004	\$ 307	\$ 293	\$ 113	\$ 487
Year ended December 31, 2005	\$ 487	\$ 8	\$ 318	\$ 177
Year ended December 31, 2006	\$ 177	\$ 221	\$ 364	\$ 34
Reserve for excess and obsolete inventories				
Year ended December 31, 2004	\$ 178	\$ 300	\$ 100	\$ 378
Year ended December 31, 2005	\$ 378	\$ 905	\$ 291	\$ 992
Year ended December 31, 2006	\$ 992	\$ 90	\$ 231	\$ 851

Table of Contents

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Attached as exhibits to this Annual Report are certifications of the Company's Chief Executive Officer (CEO) and Chief Financial Officer (CFO), which are required in accordance with Rule 13a-14 of the Securities Exchange Act of 1934, as amended (Exchange Act). This Controls and Procedures section includes the information concerning the controls evaluation referred to in the certifications, and it should be read in conjunction with the certifications for a more complete understanding of the topics presented.

The Company conducted an evaluation of the effectiveness of the design and operation of its disclosure controls and procedures (as defined in the Rules 13a-15(e) and 15d-15(e) under the Exchange Act) (Disclosure Controls) as of the end of the period covered by this Report required by Exchange Act Rules 13a-15(b) or 15d-15(b). The controls evaluation was conducted under the supervision and with the participation of the Company's management, including the CEO and CFO. Based on this evaluation, the CEO and our CFO have concluded that as of the end of the period covered by this report the Company's disclosure controls and procedures were effective at a reasonable assurance level.

Definition of Disclosure Controls

Disclosure Controls are controls and procedures designed to reasonably assure that information required to be disclosed in the Company's reports filed under the Exchange Act, such as this Report, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure Controls are also designed to reasonably assure that such information is accumulated and communicated to the Company's management, including the CEO and CFO, as appropriate to allow timely decisions regarding required disclosure. The Company's Disclosure Controls include components of its internal control over financial reporting, which consists of control processes designed to provide reasonable assurance regarding the reliability of its financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles in the U.S. To the extent that components of the Company's internal control over financial reporting are included within its Disclosure Controls, they are included in the scope of the Company's annual controls evaluation.

Management's Report on Internal Control over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Under the supervision and with the participation of the Company's management, including the CEO and CFO, the Company conducted an evaluation of the effectiveness of its internal control over financial reporting based on criteria established in the framework in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, the Company's management concluded that the Company's internal control over financial reporting was effective as of December 31, 2006. The assessment by the Company's management of the effectiveness of the Company's internal control over financial reporting as of December 31, 2006 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears on page 46 of this Report.

Limitations on the Effectiveness of Controls

The Company's management, including the CEO and CFO, does not expect that the Company's disclosure controls or internal control over financial reporting will prevent all error and all fraud. A control system, no

Table of Contents

matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Changes in Internal Control over Financial Reporting

There were no changes in the Company's internal control over financial reporting that occurred during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable.

Table of Contents

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because we will file a Definitive Proxy Statement (the Proxy Statement) for our 2007 Annual Meeting of Stockholders with the Securities and Exchange Commission within 120 days after the end of our fiscal year ended December 31, 2006.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item is incorporated herein by reference to the Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated herein by reference to the Proxy Statement.

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

The information required by this Item is incorporated herein by reference to the Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item is incorporated herein by reference to the Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item is incorporated herein by reference to the Proxy Statement.

Table of Contents

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

Exhibit No.	Description
3.2 ⁽¹⁾	Amended and Restated Certificate of Incorporation of the Registrant (Delaware).
3.4 ⁽¹⁾	Bylaws of the Registrant.
4.1 ⁽⁴⁾	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	2004 Employee Stock Purchase Plan.
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.
10.10 ⁽²⁾	Settlement Agreement and Non-Exclusive Patent License, each between the Registrant and Palomar Medical Technologies, Inc. dated June 2, 2006.
10.11 ⁽³⁾	Form of Performance Unit Award Agreement.
10.13 ⁽⁴⁾	Distribution Agreement between the Registrant and PSS World Medical Shared Services, Inc., a subsidiary of PSS World Medical dated October 1, 2006.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (see page 79).
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 Current Report on Form 8-K filed on June 2, 2006.
 - (3) Incorporated by reference from our Quarterly Report on Form 10-Q filed on November 14, 2005.
 - (4) Incorporated by reference from our Quarterly Report on Form 10-Q filed on November 8, 2006.

Confidential Treatment has been requested for certain portions of this exhibit.

Table of Contents**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of The Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Brisbane, State of California, on the 16th day of March 2007.

CUTERA, INC.

By: */s/* KEVIN P. CONNORS
Kevin P. Connors
President and Chief Executive Officer

Power of Attorney

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

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

Signature	Title	Date
<i>/s/</i> KEVIN P. CONNORS Kevin P. Connors	President, Chief Executive Officer and Director (Principal Executive Officer)	March 16, 2007
<i>/s/</i> RONALD J. SANTILLI Ronald J. Santilli	Chief Financial Officer and Vice President of Finance and Administration (Principal Financial and Accounting Officer)	March 16, 2007
<i>/s/</i> DAVID A. GOLLNICK David A. Gollnick	Vice President of Research and Development and Director	March 16, 2007
<i>/s/</i> DAVID B. APFELBERG David B. Apfelberg	Director	March 16, 2007
<i>/s/</i> ANNETTE J. CAMPBELL-WHITE Annette J. Campbell-White	Director	March 16, 2007
<i>/s/</i> MARK LORTZ Mark Lortz	Director	March 16, 2007
<i>/s/</i> TIM O SHEA Tim O Shea	Director	March 16, 2007
<i>/s/</i> JERRY P. WIDMAN	Director	March 16, 2007

Jerry P. Widman

79