

CUTERA INC
Form 10-K
March 13, 2008
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, 2007

Commission file number: 000-50644

Cutera, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

77-0492262
(I.R.S. Employer

Identification Number)

3240 Bayshore Blvd.

Brisbane, California 94005

(415) 657-5500

Edgar Filing: CUTERA INC - Form 10-K

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

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

| Title of Each Class | Name of Each Exchange on Which Registered |
|---|---|
| Common Stock, \$0.001 par value per share | The NASDAQ Stock Market, LLC |

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 (Do not check if a smaller reporting company)

Smaller reporting company

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, 2007 (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 \$338 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 29, 2008 was 12,742,303.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates by reference certain information from the registrant's definitive proxy statement for the 2008 Annual Meeting of Stockholders.

Table of Contents

TABLE OF CONTENTS

| | Page |
|--|-------------|
| <u>PART I</u> | |
| Item 1. <u>Business</u> | 3 |
| Item 1A. <u>Risk Factors</u> | 19 |
| Item 1B. <u>Unresolved Staff Comments</u> | 33 |
| Item 2. <u>Properties</u> | 33 |
| Item 3. <u>Legal Proceedings</u> | 33 |
| Item 4. <u>Submission of Matters to a Vote of Security Holders</u> | 33 |
| <u>PART II</u> | |
| Item 5. <u>Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u> | 34 |
| Item 6. <u>Selected Financial Data</u> | 36 |
| Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> | 37 |
| Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u> | 51 |
| Item 8. <u>Financial Statements and Supplementary Data</u> | 52 |
| Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u> | 82 |
| Item 9A. <u>Controls and Procedures</u> | 82 |
| Item 9B. <u>Other Information</u> | 83 |
| <u>PART III</u> | |
| Item 10. <u>Directors, Executive Officers and Corporate Governance</u> | 84 |
| Item 11. <u>Executive Compensation</u> | 84 |
| Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u> | 84 |
| Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u> | 84 |
| Item 14. <u>Principal Accounting Fees and Services</u> | 84 |
| <u>PART IV</u> | |
| Item 15. <u>Exhibits and Financial Statement Schedules</u> | 85 |

Table of Contents

PART I

ITEM 1. BUSINESS

We are a global medical device company headquartered in Brisbane, California 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 physicians and other qualified practitioners to perform safe and effective aesthetic procedures for their customers.

CoolGlide- Our first product platform, CoolGlide, was launched in March 2000. This product offers laser applications for hair removal, treatment of a range of vascular lesions, including leg and facial veins, and Laser Genesis a skin rejuvenation procedure that reduces fine lines, reduces pore size and improves skin texture.

Xeo- In 2003, we introduced the Xeo platform, which can combine pulsed light and laser applications in a single system. The Xeo is a fully upgradeable platform on which a customer can use every application that we offer to remove unwanted hair, treat vascular lesions and rejuvenate the skin by treating discoloration, improving texture, reducing pore size and treating fine lines and laxity.

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

Solera systems use either infrared (Solera Titan) or pulsed light (Solera Opus) and can be used to remove unwanted hair, treat vascular lesions and rejuvenate the skin. The Solera Opus can support one or more pulsed light applications in a single system.

Each of our products consists of one or more hand pieces and a console that incorporates a universal graphic user interface, a laser or other light-based module, control system software and high voltage electronics. However, depending on the application, the laser or light-based module is sometimes instead contained in the hand piece. A description of each of our hand pieces, and the aesthetic conditions they are designed to treat, are contained in the section entitled Products, below.

We offer our customers the ability to select the systems and applications that best fit their practice and to subsequently upgrade their systems to add new applications. This upgrade path allows our customers to cost-effectively build 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, smoking and sun damage, can result in aesthetically unpleasant changes in the appearance of the skin. These changes can include:

Undesirable hair growth;

Enlargement or swelling of blood vessels due to circulatory changes that become visible at the skin's surface in the form of unsightly veins;

Deterioration of collagen, which weakens the skin, leading to uneven texture, increased pore size, wrinkles and laxity; and

Uneven pigmentation or sun spots due to long-term sun exposure.
People with unwanted hair or any of 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 2006 there were 9.1 million minimally-invasive aesthetic procedures performed, an 8% increase over 2005 and a 66% 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 43 to 61 in calendar 2007, represented approximately 26% of the U.S. population as of July 1 2005. 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. These technical developments have reduced the required treatment and recovery times, which in turn have 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 from all specialties 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, many other non-core practitioners, such as gynecologists, primary care physicians, physicians offering aesthetic treatments in spa environments, and other qualified practitioners are performing aesthetic 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 and minimally-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 many hours of treatment. In addition, electrolysis can cause blemishes and infection related to needle use.

Leg and Facial Veins- The current aesthetic treatment methods for leg and facial veins include sclerotherapy and laser and other 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 over 607,000 sclerotherapy procedures were performed in 2006.

Skin Rejuvenation- Skin rejuvenation treatments include a broad range of popular alternatives, including Botox and collagen injections, chemical peels, microdermabrasions, radiofrequency treatments and lasers and other light-based treatments. 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

Table of Contents

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.

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 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 2006, 4.1 million injections of Botox and over 1.2 million injections of collagen and other soft-tissue fillers were administered, and 1 million chemical peels and over 800,000 microdermabrasion procedures were performed.

In radiofrequency 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 may resolve over time, and the risk of burning the treatment area.

Laser and other light-based non-surgical treatments for hair removal, veins and skin rejuvenation are discussed in the following section and in the section entitled *Our Applications and Procedures*, below.

Laser and Other Light-Based Aesthetic Treatments

Laser and other light-based aesthetic treatments can achieve therapeutic results by 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. Ablative skin resurfacing procedures are considered invasive or minimally invasive, depending on how much of the epidermis is removed during a treatment.

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 can 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. They can also use these technologies to safely remove portions of the epidermis and deliver heat to the dermis as a means of generating new collagen growth.

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

Table of Contents

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.

Technology and Design of Our Systems

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 solutions include:

Multiple Applications Available in a Single System- Our multi-application systems enable practitioners to perform multiple aesthetic procedures using a single device. These procedures include hair removal, treatment of unsightly veins and skin rejuvenation, including the treatment of discoloration, laxity, fine lines and uneven texture. 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 practitioners to customize treatments for each patient and condition. Our proprietary pulsed light hand pieces for the treatment of discoloration, hair removal and vascular treatments optimize the wavelength used for treatments and incorporate a monitoring system to increase safety. Our Titan hand pieces utilize a novel light source that had not been previously used for aesthetic treatments. And our Pearl hand piece, with proprietary YSGG technology, represents the first application of the 2790 nm wavelength for a minimally invasive cosmetic dermatology.

Upgradeable Platform- We design our products to allow our customers to cost-effectively upgrade to our multi-application systems, which provides our customers with the option to add additional applications to their existing systems and provides us with a source of recurring revenue. We believe that product upgradeability allows our customers 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 use our products to treat spider and reticular veins, which are unsightly small veins in the leg, as well as small facial veins. And they can treat color, texture, pore size, fine lines and wrinkles on any type of skin with our skin rejuvenation systems. The ability to customize treatment parameters enables practitioners to offer safe and effective therapies to a broad base of their patients.

Ease of Use- We design our products to be easy to use. Our proprietary hand pieces are lightweight and ergonomic, minimizing user fatigue, and allow for clear views of the treatment area, reducing the possibility of unintended damage and increasing the speed of application. Our control console contains a universal graphic user interface with three simple, independently adjustable controls from which to select a wide range of treatment parameters to suit each patient's profile. The clinical navigation user interface on the Xeo platform provides recommended clinical treatment parameter ranges based on patient criteria entered. And our Pearl hand piece includes a scanner with multiple scan patterns to allow simple and fast treatments of the face. Risks involved in the use of our products include risks common to other laser and other light-based aesthetic procedures, including the risk of burns, blistering and skin discoloration.

Table of Contents

Strategy

Our mission is to maintain and expand our position as a leading, worldwide provider of light-based aesthetic devices by executing the following strategies:

Continuing to Develop New Products- We have introduced at least one new product every year since 2000. In 2007, we introduced Pearl a minimally invasive, 2790 nm YSGG laser for treating fine lines, uneven texture and dyschromia. We plan to continue developing our existing technology platforms and develop other platforms with the intent of offering new applications for our customers.

Increasing Sales of Existing Products in the United States- We believe that the U.S. market for aesthetic systems is continuing to grow. In 2007 we expanded our U.S. direct sales force and continued to leverage our 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.

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 international market penetration and building global brand-recognition. In 2007, we increased our direct international sales force and expanded our distributor territories to approximately 34 countries in 2007. 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 2007 and 2006, approximately 79% and 78%, 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 that can be performed by their existing systems.

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. We offer post-warranty services to our customers either through extended service contracts to cover preventive maintenance or replacement parts and labor, or through direct billing for parts and labor. These post-warranty services serve as additional sources of recurring revenue.

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: | | | | Hair Removal: | Vascular Lesions: | Dyschromia: | Skin Rejuvenation Texture, Fine Lines: | Skin Laxity: |
|----------------------|--------------|-------|-------------------|------------------|----------------------|-------------|---|-----------------|
| System Platforms: | Products: | Year: | Energy Source: | | | | | |
| CoolGlide | CV | 2000 | a | x | | | | |
| | Excel | 2001 | a | | x | | | |
| | Vantage | 2002 | a | | | | x | |
| Xeo: | Nd:YAG | 2003 | a | x | x | | x | |
| | OPS600 | 2003 | b | | | x | | |
| | LP560 | 2004 | b | | | x | | |
| | Titan S | 2004 | c | | | | | x |
| | ProWave 770 | 2005 | b | x | | | | |
| | AcuTip 500 | 2005 | b | | x | | | |
| | Titan V / XL | 2006 | c | | | | | x |
| | LimeLight | 2006 | b | | | | x | |
| Solera | Pearl | 2007 | d | | | x | x | |
| | Titan S | 2004 | c | | | | | x |
| | ProWave 770 | 2005 | b | x | | | | |
| | OPS 600 | 2005 | b | | | x | | |
| | LP560 | 2005 | b | | | x | | |
| | AcuTip 500 | 2005 | b | | x | | | |
| | Titan V / XL | 2006 | c | | | | | x |
| LimeLight | 2006 | b | | | x | | | |

Energy Source: a. 1064nm Nd:YAG laser. b. flashlamp. c. Infrared laser and, d. 2790 nm YSGG laser

Each of our products consists of a control console and one or more hand piece, 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, a flashlamp and 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 hand piece while the Solera Titan console is designed specifically to drive the Titan hand pieces. 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.

Table of Contents

Hand Pieces

1064 nm Nd:YAG Hand piece- Our 1064nm Nd:YAG hand piece delivers laser energy to the treatment area for hair removal, leg and facial vein treatment, and skin rejuvenation procedures to treat skin texture and fine lines, and reduce pore size. The 1064nm Nd:YAG hand piece consists of an energy-delivery component, consisting of an optical fiber and lens, and a copper cooling plate with imbedded temperature monitoring. The hand piece weighs approximately 14 ounces, which is light enough to be held with one hand. The lightweight nature and ergonomic design of the hand piece 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 1064nm Nd:YAG hand piece 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 hand piece is available in either a fixed 10 millimeter spot size, for our CoolGlide CV system, or a user-controlled variable 3, 5, 7 or 10 millimeter spot size, for our CoolGlide Excel and CoolGlide Vantage systems.

Pulsed Light Hand Pieces- The LP560, ProWave 770, AcuTip 500 and LimeLight hand pieces are designed to produce a pulse of light over a wavelength spectrum to treat discoloration, including pigmented lesions, such as age and sun spots, hair removal and superficial facial vessels. The hand pieces 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 AcuTip 500 eliminates long and short wavelengths, transmitting only the therapeutic range required for safe and effective treatment. The filter in the LP560, ProWave 770 and LimeLight 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 hand pieces protect the epidermis by regulating the temperature of the hand piece window through the embedded temperature monitor. These hand pieces are available on the Xeo and Solera platforms.

Titan Hand Pieces- The Titan hand pieces are designed to produce a sustained pulse of light over a wavelength spectrum tailored to provide heating in the dermis to treat skin laxity (although it is cleared in the United States by the U.S. Food and Drug Administration, or FDA, only for deep dermal heating). The hand piece 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 two different Titan hand pieces Titan V and Titan XL.

Titan V- Titan V has a treatment tip that extends beyond the hand piece 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- Titan XL, like the Titan V, has a treatment tip that extends beyond the housing for improved visibility. It also has a larger treatment spot size to treat larger body areas faster, such as the arms, abdomen and legs.

The Titan hand pieces can be used on the Xeo and Solera platforms. The Titan hand piece requires a periodic refilling process, which includes the replacement of the optical source, after a set number of pulses have been used. This provides us with a source of recurring revenue.

Pearl Hand Piece- The Pearl hand piece, introduced in 2007, is designed to treat fine lines, uneven texture and dyschromia through the application of proprietary YSGG laser technology. This hand piece can safely remove a small portion of the epidermis, while coagulating the remaining epidermis, leading to new collagen growth. The Pearl hand piece consists of a custom monolithic laser source, scanner and power monitoring electronics. The scanner includes multiple scan patterns to allow simple and fast treatments of the face. The hand piece includes an attachment for a smoke evacuator, allowing the practitioner to use one hand during treatment.

Table of Contents

Our Applications and Procedures

Our products are designed to allow the practitioner to select an appropriate combination of energy level, spot size and pulse duration for each treatment. 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 1064 nm 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. Our 1064nm Nd:YAG hand piece allows our customers to treat all skin types, while our ProWave 770 hand piece, with its pulsed light technology, treats the majority of skin types quickly and effectively.

To remove hair using a 1064nm Nd:YAG hand piece, the treatment site on the skin is first cleaned and shaved. The practitioner then applies a thin layer of gel to glide across the skin, and next applies the hand piece directly to the skin to cool the area to be treated and then delivers a laser pulse to the pre-cooled area. To remove hair using the ProWave 770 hand piece, 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 hand pieces, delivery of the energy destroys the hair follicles and prevents hair re-growth. 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.

Vascular Lesions- 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 1064nm Nd:YAG hand piece'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 hand piece, with its 6 millimeter spot size, uses pulsed-light technology and is designed for the treatment of facial vessels.

The vein treatment procedure when using the 1064nm Nd:YAG hand piece is performed in a substantially similar manner to the laser hair removal procedure. The laser hand piece is used to cool the treatment area both before and after the laser pulse has been applied. With the AcuTip 500 hand piece, 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 and other light-based technologies allow our customers to perform non-invasive and minimally-invasive treatments that reduce redness, pore size, fine lines and laxity, improve skin texture, and treat other aesthetic conditions. Our products are each designed to minimize the risk of damage to the surrounding tissue.

Texture; Fine Lines- When using a 1064nm Nd:YAG laser to improve skin texture, reduce pore size and treat fine lines, cooling is not applied and the hand piece 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.

When treating texture and fine lines with a Pearl hand piece, the hand piece is held at a controlled distance from the skin and the scanner delivers a preset pattern of spots to the treatment area. Cooling is not applied to the

Table of Contents

epidermis during the treatment. The energy delivered by the hand piece ablates a portion of the epidermis while leaving a coagulated portion that will gently peel off over the course of a few days. Heat is also delivered into the dermis which can result in the production of new collagen. Treatment of the full face can usually be performed in 15 to 30 minutes. Patients receive on average between one and three treatments at monthly intervals.

Dyschromia- Our pulsed-light technologies allow our customers to safely and effectively treat red and brown dyschromia, which is skin discoloration, pigmented lesions and rosacea. The practitioner delivers a narrow spectrum of light to the surface of the skin through our LP560 or LimeLight hand pieces. These hand pieces 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 with a pulsed-light technology, the hand piece is placed directly on the skin and then the light pulse is triggered. The cells forming the pigmented lesion absorb the light energy, 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.

Practitioners can also treat dyschromia and other skin conditions with our Pearl hand piece. During these treatments, the heat delivered by the Pearl hand piece will remove the outer layer of the epidermis while coagulating a portion of the epidermis. That coagulated portion will gently peel off over the course of a few days, revealing a new layer of skin underneath. Treatment of the full face can usually be performed in 15 to 30 minutes. Patients receive on average between one and three treatments at monthly intervals.

Skin Laxity- 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 hand piece. This hand piece includes our proprietary light source and wavelength filter which tailors the delivered spectrum of light to provide heating at the desired depth in the skin.

In treating skin laxity, the hand piece 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 re-growth. 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.

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 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 some cases, where substantial upgrades are necessary, the customer will receive a fully-refurbished system before sending their prior system back to our headquarters.

Post-Warranty Service and Titan Hand piece Refills

Each Titan hand piece includes a disposable component, which provides us with a source of recurring revenue from our existing customers. We offer post-warranty services to our customers either through extended service

Table of Contents

contracts to cover preventive maintenance or replacement parts and labor, or through direct billing for parts and labor. These post-warranty services serve as additional sources of recurring revenue from our installed base.

Sales and Marketing

In the United States and Canada, we market and sell our products primarily through a combined North American direct sales organization. We divide the U.S. and Canada markets into discreet sales territories, and generally each direct sales employee in our North American sales organization is assigned a specific sales territory. The number and size of North American sales territories vary from time to time according to business needs. Due to attrition, recruiting efforts and other factors, the total number of North American sales territories at any given time could be slightly higher than the total number of North American direct sales employees. As of December 31, 2007, we had 60 North American sales territories, of which 5 were in Canada and 55 were in the U.S. As of December 31, 2007, two of our U.S. sales territories were not staffed. In addition to direct sales employees, we have a distribution relationship with 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, 2007, 2006 and 2005, revenue from PSS was \$14.6 million, \$15.4 million and \$12.4 million, respectively.

International sales are generally made through a direct international sales force of 29 employees, which includes five employees in Canada, as well as a worldwide distributor network in approximately 34 countries as of December 31, 2007. As of December 31, 2007, we had direct sales offices located in Australia, Canada, France, Japan, Spain, Switzerland and the United Kingdom. Our international revenue represented 37%, 31% and 28% of total revenue for the years ended December 31, 2007, 2006 and 2005, respectively.

We also sell certain items like Titan hand piece refills and marketing brochures via the internet.

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 and are responsive to our customers' financing preferences. To increase market penetration, in addition to marketing to the core specialties 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 spa environments and other qualified practitioners.

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 hand pieces, 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, Syneron and Thermage, as well as private companies, including, Alma, Aesthera, Lumenis, Reliant, Sciton and several other companies.

Table of Contents

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, customers and products, as well as worldwide distribution channels that are comparable to or 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, service 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, 2007, our research and development activities were conducted by a staff of 21 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 2007, 2006 and 2005, were \$7.2 million, \$6.5 million and \$5.4 million, respectively.

Service 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, 2007, we had a 37-person global service department. Internationally, we provide direct service support through our Australia, Canada, France, Japan, and Switzerland offices, and also through the network of distributors in approximately 34 countries and third-party service providers. We provide initial warranties on our products to cover parts and service and offer extended service plans that vary by the type of product and the level of service desired. Our standard warranty on system sales covers parts and service for a standard period of one or two years. From time to time, we also have promotions whereby we include a supplemental warranty with the sale of our products. Customers are notified before their initial warranty expires and are able to choose from two different extended service plans covering preventative maintenance or replacement parts and labor. One plan covers the cost of parts and labor, and the second plan provides preventive maintenance, each for a fixed fee paid in advance. In the event a customer does not purchase an extended service plan, we will offer to service the customer's system and charge the customer for time and materials. We have invested substantial financial and management resources to develop a worldwide infrastructure to meet the service 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

Table of Contents

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. There were no significant findings as a result of this audit and our responses have been accepted by the FDA. Our failure to maintain compliance with the QSR requirements could result in the shut down of our manufacturing operations and the recall of our products, which would have a material adverse effect on 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, and non-disclosure, confidentiality and invention assignment agreements to protect our intellectual property rights. As of December 31, 2007, we had nine issued U.S. patents and twenty-six pending U.S. patent applications. Cutera, CoolGlide, Solera, Xeo, AcuTip, Limelight, Pearl, ProWave 770 and Titan 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.

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.

Table of Contents

Government Regulation

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

Product design and development;

Product testing;

Product manufacturing;

Product safety;

Product labeling;

Product storage;

Recordkeeping;

Pre-market clearance or approval;

Advertising and promotion;

Production; and

Product sales and distribution.

FDA's Pre-market Clearance and Approval Requirements

Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either prior 510(k) clearance or pre-market approval from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risks are placed in either class I or II, which requires the manufacturer to submit to the FDA a pre-market notification requesting permission to commercially distribute the device. This process is generally known as 510(k) clearance. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in class III, requiring pre-market approval. All of our current products are class II devices.

510(k) Clearance Pathway

Edgar Filing: CUTERA INC - Form 10-K

When a 510(k) clearance is required, we must submit a pre-market notification demonstrating that our proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of Pre-Market Approval, 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.

Table of Contents

The following table details the indications for which we received a 510(k) clearance and when these clearances were received.

| FDA Marketing Clearances: | Date Received: |
|---|-----------------------|
| Laser-based products: | |
| - treatment of vascular lesions | June 1999 |
| - hair removal | March 2000 |
| - permanent hair reduction | January 2001 |
| - treatment of benign pigmented lesions and pseudofolliculitis barbae, commonly referred to as razor bumps, and for the reduction of red pigmentation in scars | June 2002 |
| - treatment of wrinkles | October 2002 |
| Pulsed-light technologies: | |
| - treatment of pigmented lesions | March 2003 |
| - hair removal and vascular treatments | March 2005 |
| Infrared Titan technology for deep dermal heating for the temporary relief of minor muscle and joint pain and for the temporary increase in local circulation where applied* | February 2004 |
| Solera tabletop console: | |
| - for use with the Titan hand piece | October 2004 |
| - for use with our pulsed-light hand pieces | January 2005 |
| Pearl product for the treatment of wrinkles | March 2007 |

* 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 do not plan on submitting any further applications for this clearance for Titan.

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

Table of Contents

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

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.

Table of Contents

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;

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 a number of countries encompassing most of the major countries in Europe. The 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.

Table of Contents

Employees

As of December 31, 2007, we had 273 employees, of which 121 were in sales and marketing, 67 in manufacturing operations, 37 in technical service, 21 in research and development and 27 in general and administrative. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel. None of our employees is represented by a labor union, and we believe our employee relations are good.

Available Information

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 practicable 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

The initiatives that we are implementing in an effort to improve our sales productivity, revenue and income could be unsuccessful, which could harm our business and may further depress the price of our stock.

In an effort to improve our revenue and income levels, we have implemented several strategic initiatives, including the following:

We increased the number of our North American sales professionals and added additional sales managers.

We launched our new Pearl product worldwide.

We dedicated additional sales professionals to work in conjunction with PSS, and increased our focus and attention on our PSS relationship.

We believe these initiatives should improve our revenue and income. However, these initiatives may not be successful for several reasons: they may lead to employee turnover; there are no assurances that we can hire and train new sales employees; we may not be able to successfully market our new products; and our efforts to improve our sales productivity may result in instability to our operations, causing harm to our business and a further decline in our stock price.

Our revenue and earnings are difficult to predict and our decision to not provide public guidance could harm our business, and our stock price might become more volatile and could decline.

We historically provided guidance to the investment community regarding our anticipated future operating performance, both for the coming quarters and fiscal year. However, beginning with the release of our earnings for the quarter ended September 30, 2007, we have discontinued our practice of providing financial guidance because the following factors have made it difficult for us to accurately forecast our revenue and earnings:

Edgar Filing: CUTERA INC - Form 10-K

Some of our publicly-traded competitors have reported reduced growth rates for the second half of calendar 2007, which could indicate signs of a slowing market growth rate;

There has been a slower-than-expected adoption of our new Pearl product by new customers;

Table of Contents

The sales productivity of our recently-hired North American sales professionals has not increased to our expected level;

We have short sales cycles in our business; and

Many of our customer orders in any given quarter are received during the last month of a quarter, which results in uncertainties in our ability to ship our products by the end of the quarter.

Due to our decision to not provide public guidance, if, in the future, our actual results are below the expectations of third party financial analysts, our business could be harmed, the volatility of our stock price could increase, and our stock price could decline significantly as a result.

Our North American sales team has many new sales professionals and managers. If we are unable to effectively train, retain and manage these employees, our ability to manage and expand our business will be harmed, which would impair our future revenue and profitability.

As of December 31, 2007, as a result of our sales-expansion efforts and sales employee turnover in 2007, a significant number of our sales professionals and sales managers on our North American sales team had been in their respective roles for less than a year. Our experience is that new sales professionals are at higher risk for employee turnover and generally take two to three quarters to achieve effective productivity levels. Our success largely depends on our ability to manage and improve the productivity levels of our sales professionals and worldwide distribution network. If we fail to manage, or do not improve the productivity of, any material part of that network, including the North American sales team, this could lead to reduced revenue and employee turnover, which could materially harm our business. If we experience significant levels of attrition among our sales professionals or our sales managers, our revenue and profitability may be adversely affected as a result.

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

For the quarter and year ended December 31, 2007, approximately 42% and 37%, respectively, of our revenue was derived from international customers, which is 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 underperform, 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 if we are unable to engage distributors in particular geographic areas, we may not be able to realize 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;

Table of Contents

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 were unsuccessful at finding a solution, our revenue may decline.

We may incur substantial expenses if our practices are shown to have violated the Telephone Consumer Protection Act.

We had previously used facsimiles to disseminate commercial information about our business to customers and potential customers. In February 2008, we adopted a policy of sending commercial facsimiles only to our customers and others with whom we have an existing business relationship.

Under the federal Telephone Consumer Protection Act, or TCPA, recipients of unsolicited facsimile advertisements may be entitled to damages of \$500 per violation for inadvertent violations and \$1,500 per violation for knowing or willful violations.

In January 2008, a TCPA class action lawsuit was filed against us in the Illinois Circuit Court, Cook County, by Bridgeport Pain Control Center, LTD., seeking monetary damages, injunctive relief, costs and other relief. The complaint alleges that we violated the TCPA by sending unsolicited advertisements by facsimile to the plaintiff and other recipients without the prior express invitation or permission of the recipients. On February 22, 2008, we removed the case to federal court in the Northern District of Illinois, and filed our response to the complaint on February 29, 2008. Although we are continuing to investigate the number of facsimiles transmitted during the period for which the plaintiff in the lawsuit seeks class certification and the number of these facsimiles that were unsolicited within the meaning of the TCPA, we expect the number of unsolicited facsimiles could be large.

We intend to defend this lawsuit vigorously, including the plaintiff's allegations seeking class certification, but litigation is subject to numerous uncertainties and we are unable to predict the ultimate outcome of this matter. Even if we prevail in this lawsuit, other individual or class action claims may be brought against us alleging violations of the TCPA. Moreover, the amount of any potential liability in connection with this lawsuit will depend, to a large extent, on whether a class in this type of action is certified and, if one is certified, on the scope of the class, neither of which we can predict at this time.

We have not recorded a liability related to this lawsuit. However, we may determine in the future that an accrual is required, and we may be required to pay damages in respect of this lawsuit out of our transmission of facsimiles, any of which could materially and adversely affect our results of operations, cash flows and financial condition. Regardless of the outcome, this lawsuit may cause us to incur significant expenses and divert the attention of our management and key personnel from our business operations.

We have not tendered this lawsuit to our insurance carrier, may not do so, and, even if we do so, coverage may be disputed. Even if coverage is determined to apply, since the potential liability under this claim could be substantial, our coverage may not be sufficient to satisfy any damages or expenses that we may be required to pay.

Table of Contents

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

Our industry is subject to intense competition. 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, Sciton and several other companies. Additional competitors may enter the market, and we are likely to compete with new companies in the future. 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.

In addition, some of our current and potential competitors have significantly greater financial, research and development, business 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. 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, service and price. Our competitors could form strategic alliances with other companies to develop products and solutions that effectively compete with our products. For example, Palomar and Syneron have each entered into agreements with Proctor and Gamble for the proposed development of home-use aesthetic devices. And Syneron entered into an agreement with Obagi Medical Products to study the effects of using Obagi's skin care products during treatments with Syneron aesthetic devices. Business combinations and alliances by our competitors could increase competition, 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 or acquire new products and successfully introduce them or our revenue may decline.

Some of our competitors release new products more often and more successfully than we do. For example, in the second half of 2007, revenue from sales of our new Pearl product to new customers did not meet our

Table of Contents

expectations, although revenue from sales of Pearl upgrades to existing customers grew significantly and was the primary reason for the 217% and 104% increases in upgrade revenue in the third and fourth quarter of 2007, compared to the corresponding periods in 2006, respectively. We believe that, to increase revenue from sales of new products and related product upgrades, we need to continue developing our clinical support and increasing market awareness of the benefits of those new products. If we fail to successfully commercialize any of our products, our business could be harmed.

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 hand pieces 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 could decline as our customers and prospects purchase our competitors' products.

Our ability to compete effectively depends upon our ability to innovate, to develop, acquire 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 and skin rejuvenation, including the treating of diffuse redness, skin laxity, fine lines, skin texture, pore size and pigmented lesions. Currently, these applications represent the majority of laser and other energy-based aesthetic procedures. To continue growing in the future, we must develop and acquire new and innovative aesthetic applications, identify new markets for our existing technology, and develop and acquire new technology from various platforms. To successfully expand our product offerings, we must, among other things:

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

Convince our customers and prospective 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. 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. Even with a significant investment in research and development, we may be unable to continue to develop or acquire 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

Table of Contents

reimbursable through government or private health insurance, with the costs borne by the patient. The decision to utilize our products may therefore be influenced by a number of factors, including:

The cost of procedures performed using our products;

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

The success of our sales and marketing efforts;

Consumer confidence, which may be impacted by political and macroeconomic conditions, such as recession, continuing increases in oil prices, high unemployment rates, increased interest rates and subprime mortgage failures; and

The education of our customers and patients on the benefits and uses of our products, compared to competitors' products and technologies.

Also, some of our publicly-traded competitors have reported reduced growth rates for the second-half of calendar 2007, which could indicate signs of a slowing demand for aesthetic procedures.

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, which could have a material adverse effect on our business, financial condition, revenue and result of operations.

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. PSS sales professionals work in coordination with our sales force to locate new customers for our products throughout the United States. For the years ended December 31, 2007, 2006, and 2005, approximately 14%, 15% and 16% of our revenue came from PSS, respectively. Although we have dedicated additional sales professionals to work closely with, and increase the focus and attention on, our PSS relationship, it may take time for the increase in resources to result in an improvement in revenue from our PSS relationship. In addition, we can provide no assurances that the increased focus on PSS will translate into increased revenue for us. Further, 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 and results of operations.

Two securities class action lawsuits were filed against us in April and May 2007, respectively, based upon the decreases in our stock price following the announcement of our preliminary first quarter 2007 revenue and earnings, and the announcement of our revised 2007 guidance. Defending ourselves against this litigation could distract management and harm our business.

Two class action lawsuits were filed against us following declines in our stock price in the spring of 2007. On November 1, 2007, the court ordered the two cases consolidated. We will incur legal costs as a result of this litigation. Although we retain director and officer liability insurance, there can be no guarantee that such insurance will cover the claims that are made or will insure us fully for all losses on covered claims. This litigation may distract our management and consume resources that would otherwise have been directed toward running our business. Each of these factors could harm our business.

We hold auction-rate securities in our portfolio of investments. Due to failed auctions for some of our auction rate investments in February 2008, we are unable to readily liquidate our auction rate securities into cash, future earnings could be reduced if we have to take an impairment charge, our business could be harmed and our stock price could decline significantly as a result.

We invest our excess cash primarily in money market funds and in highly liquid debt instruments of the U.S. government and its agencies, U.S. municipalities, and in bonds of high-quality corporate issuers. At

Table of Contents

December 31, 2007, we had marketable securities of \$95.9 million, of which \$21.5 million was invested in auction rate securities. Of the \$21.5 million of auction rate securities, we classified \$7.4 million under the caption of "Marketable investments- long term portion" in the Consolidated Balance Sheet.

As of February 29, 2008 we had \$13.6 million of our investment portfolio invested in auction rate securities. These auction rate securities provide liquidity via an auction process that resets the applicable interest rate at predetermined calendar intervals, generally every 35 days though auctions for some of the securities are held every 360 days.

During the period from January 1, 2008 to February 29, 2008, auctions for \$9.6 million of our investments in auction rate securities failed due to the current overall credit concerns in capital markets. Upon an auction failure, the interest rates do not reset at a market rate but instead reset based on a formula contained in the security, which rate is generally higher than the current market rate. The failure of the auctions impacts our ability to readily liquidate our auction rate securities into cash until a future auction of these investments is successful or the auction rate security is refinanced by the issuer into another type of debt instrument.

If in the future we are unable to liquidate our investments in auction rate securities and / or there is an other-than-temporary impairment in their market value, our future earnings could be reduced if we have to take an impairment charge, our business could be harmed and our stock price could decline significantly as a result.

The price of our common stock may fluctuate substantially. We have a limited number of shares of common stock outstanding, a large portion of which is held by a small number of investors, which could result in the increase in volatility of our stock price.

As of December 31, 2007, approximately 50% of our outstanding shares of common stock was held by ten institutional investors. As a result of our relatively small public float, our common stock may be less liquid than the stock of companies with broader public ownership. Among other things, trading of a relatively small volume of our common stock may have a greater impact on the trading price for our shares than would be the case if our public float were larger.

The public market price of our common stock has in the past fluctuated substantially and, given the current concentration of stockholders, may continue to do so in the future. The market price for our common stock could also be affected by a number of other factors, including:

Sales of large blocks of our common stock, including sales by our executive officers, directors and our large institutional investors;

Quarterly variations in our, or our competitors', results of operations;

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

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

The announcement of the departure of a key employee or executive officer;

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

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

Edgar Filing: CUTERA INC - Form 10-K

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

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 as a team with acquiring companies or products. If we decide to expand our product offerings beyond laser and other energy-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 could 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 material acquisitions or collaborative projects.

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

Our competitors or other patent holders may assert that our present or future products and the methods we employ are covered by their patents. In addition, we do not know whether our competitors own or will obtain patents that they may claim 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 selling the applicable products and our business would suffer as a result. In addition, 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.

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.

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, 2007, we had nine issued U.S. patents. Some of our 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.

Table of Contents

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 and our business could 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, if there are federal or state level regulatory changes or if we are found to have violated applicable FDA marketing rules, 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.

Medical devices may be marketed in the United States only for the indications for which they are approved or cleared by the FDA. For example, we have FDA clearance to market our Titan product in the United States only for deep dermal heating, and are therefore prevented from promoting or advertising Titan in the United States for any other indications. If we fail to comply with these regulations, it could result in enforcement action by the FDA which could lead to such consequences as warning letters, adverse publicity, criminal enforcement action and/or third-party civil litigation, each of which could adversely affect us.

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. If we fail to comply with applicable regulatory requirements, it 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, it could harm our business.

Table of Contents

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

We are currently required to demonstrate and maintain compliance with the FDA's Quality System Regulation, or QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. Because our products involve the use of lasers, our products also are covered by a performance standard for lasers set forth in FDA regulations. The laser performance standard imposes specific record-keeping, reporting, product testing and product labeling requirements. These requirements include affixing warning labels to laser products, as well as incorporating certain safety features in the design of laser products. The FDA enforces the QSR and laser performance standards through periodic unannounced inspections. 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.

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 potential customers may opt against purchasing laser and other energy-

Table of Contents

based products due to the cost or inability to procure insurance coverage. The unavailability of insurance coverage for our customers and prospects could adversely affect our ability to sell our products, and that could harm our financial condition.

Because we do not require training for users of our products, and sell our products at times 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 product training to the purchasers or operators of our products. In addition, we sometimes sell our systems to companies that rent our systems to third parties and that provide a technician to perform the procedures. 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 our business, and, in the event these result in product liability litigation, distract management and subject us to liability, including legal expenses.

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 could 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;

Table of Contents

A lack of long-term supply arrangements for key components with our suppliers;

Inability to obtain adequate supply in a timely manner, or on 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; and,

Delay in supplier deliveries.

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 that would reduce our revenue and increase our cost.

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

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

Loss of customer orders and delay in order fulfillment;

Damage to our brand reputation;

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

Inability to attract new customers;

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

Legal action.

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

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

Edgar Filing: CUTERA INC - Form 10-K

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 market is a material assumption of our growth strategy.

Table of Contents

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 lawsuits against non-core practitioners. If we do not achieve anticipated demand for our products in the non-core market, our revenue may be adversely impacted.

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.

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

Our profit margins may vary over time.

Our profit margins may be adversely affected by a number of factors, including decreases in our shipment volume, reductions in, or obsolescence of, our inventory, shifts in our product mix and increased expenses associated with repairing defective products covered by our warranty program. In addition, the competitive market environment in which we operate may adversely affect pricing for our products. Because we own most of our manufacturing capacity, a significant portion of our operating costs are fixed. If we experience a decrease in shipment volume, or have to reduce our pricing to remain competitive, or experience a greater than expected failure rate for any of our products, etc., our gross and operating margins will be adversely impacted.

We are subject to fluctuations in the exchange rate of the U.S. dollar and foreign currencies.

We do not actively hedge our exposure to currency rate fluctuations. While we transact business primarily in U.S. Dollars, and a significant proportion of our revenue is denominated in U.S. Dollars, a portion of our costs and revenue is denominated in other currencies, such as the Euro, Japanese Yen, Australian Dollar, Canadian Dollar and British Pound Sterling. As a result, changes in the exchange rates of these currencies to the U.S. Dollar will affect our net income.

We are exposed to fluctuations in the market values of our portfolio investments and in interest rates.

Our investment portfolio consists of both high investment grade corporate and municipal securities that have a maximum effective maturity of up to two years. In addition to bonds, we invest in variable rate demand notes and auction-rate-securities whose interest rates reset generally every 35 days though auctions for some of the securities are held every 360 days. The longer the duration of a security, the more susceptible it is to changes in market interest rates and bond yields. As yields increase, those securities with a lower yield-at-cost show a mark-to-market unrealized loss. For example, assuming a hypothetical increase in interest rates of one percentage point, the fair value of our total investment portfolio as of December 31, 2007 would have potentially decreased by \$443,000, resulting in an unrealized loss that would subsequently adversely impact our earnings. As a result, changes in the market interest rates will affect our future net income.

Table of Contents

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.

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 years' items, unanticipated decreases in the amount of revenue or earnings in countries with low statutory tax rates, changes in the valuation of our deferred tax assets and liabilities, future levels of research and development spending, deductions for employee stock option exercises being different from what we projected, and changes in overall levels of income before taxes.

The quarterly royalty payments under our patent license 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 independent public accountant's interpretation of the applicable royalty rate for any new products, or combination of products, and the net revenue from 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.

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 currently anticipate paying cash dividends on our common stock. 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 5,790 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 two leases in Japan expire in May 2008 and July 2010, respectively, 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

Two securities class action lawsuits were filed against us and two of our executive officers in April 2007 and May 2007, respectively, in the U.S. District Court for the Northern District of California following declines in our stock price. The plaintiffs claim to represent purchasers of our common stock from January 31, 2007 through May 7, 2007. The complaints generally allege that materially false statements and omissions were made regarding our financial prospects, and seek unspecified monetary damages. On November 1, 2007, the Court ordered the two cases consolidated. On December 17, 2007, the plaintiffs filed a consolidated, amended complaint, and on January 31, 2008, we filed a motion to dismiss that complaint. A hearing on our motion is scheduled with the Court for May 1, 2008. We intend to defend this consolidated case vigorously. Although we retain director and officer liability insurance, there is no assurance that such insurance will cover the claims that are made or will insure us fully for all losses on covered claims. Since the outcome of this litigation is unpredictable, and the amount that could be payable is not reasonably estimable, since we believe that a significant adverse result for us is not probable, no expense has been recorded with respect to the contingent liability associated with this matter.

A Telephone Consumer Protection Act, or TCPA, class action lawsuit was filed against us in January 2008 in the Illinois Circuit Court, Cook County, by Bridgeport Pain Control Center, LTD., seeking monetary damages, injunctive relief, costs and other relief. The complaint alleges that we violated the TCPA by sending unsolicited advertisements by facsimile to the plaintiff and other recipients without the prior express invitation or permission of the recipients. Under the TCPA, recipients of unsolicited facsimile advertisements may be entitled to damages of \$500 per violation for inadvertent violations and \$1,500 per violation for knowing or willful violations. On February 22, 2008, we removed the case to federal court in the Northern District of Illinois, and filed our response to the complaint on February 29, 2008. Although we are continuing to investigate the number of facsimiles transmitted during the period for which the plaintiff in the lawsuit seeks class certification and the number of these facsimiles that were unsolicited within the meaning of the TCPA, we expect that the number of unsolicited facsimiles could be large. We intend to defend this case vigorously, including the plaintiff's allegations seeking class certification. Since the outcome of this litigation is unpredictable, and since the amount that could be payable is not reasonably estimable, no expense has been recorded with respect to the contingent liability associated with this matter. However, we may determine in the future that an accrual is required, and we may be required to pay damages in respect of this lawsuit, any of which could materially and adversely affect our results of operations, cash flows and financial condition. We have not tendered this lawsuit to our insurance carrier, may not do so, and, even if we do so, coverage may be disputed. Even if coverage is determined to apply, since the potential liability under this lawsuit could be substantial, our insurance coverage may not be sufficient to satisfy any damages or expenses that we may be required to pay.

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. As of February 29, 2008, the closing sale price of our common stock was \$12.68 per share.

Common Stockholders

We had 10 stockholders of record as of February 29, 2008. Since many stockholders choose to hold their shares under the name of their brokerage firm, we believe, the actual number of stockholders was approximately 5,700.

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 | | | |
|-------------|---------------------|------------|-------------|------------|
| | 2007 | | 2006 | |
| | High | Low | High | Low |
| 4th Quarter | \$ 27.04 | \$ 14.44 | \$ 29.93 | \$ 25.32 |
| 3rd Quarter | 26.55 | 20.84 | 26.59 | 18.86 |
| 2nd Quarter | 38.39 | 23.40 | 27.94 | 16.49 |
| 1st Quarter | 37.48 | 27.06 | 31.24 | 24.99 |

Table of Contents**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.

Issuer Purchases of Equity Securities

| Period | Total Number of Shares Purchased | Average Price Paid per Share | Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs * | Millions of Dollars Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs |
|-------------------|---|---|---|---|
| June 1 30, 2007 | 123,800 | \$ 24.36 | 123,800 | 21,984 |
| July 1 31, 2007 | 234,283 | \$ 23.94 | 234,283 | 16,376 |
| August 1 31, 2007 | 749,773 | \$ 21.84 | 749,773 | |
| | 1,107,856 | \$ 22.57 | 1,107,856 | |

* On May 15, 2007, the Company's Board of Directors approved a stock repurchase program under which the Company was authorized to use up to \$25 million to repurchase shares of its common stock. The Company entered into a pre-arranged, Rule 10b5-1 trading plan with a broker to facilitate the repurchases of its shares. Acquisitions were made in accordance with the trading plan, at prevailing prices, subject to market conditions and other factors. This repurchase program terminated on August 31, 2007, when the Company had acquired \$25 million worth of shares of its common stock. The stock repurchased under the plan was cancelled and returned to authorized share status.

Securities Authorized for Issuance under Equity Compensation Plans

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

Table of Contents**ITEM 6. SELECTED FINANCIAL DATA**

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

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

| | Year ended December 31, | | | | |
|--|-------------------------|------------|-----------|-----------|-----------|
| | 2007 | 2006 | 2005 | 2004 | 2003 |
| Net revenue | \$ 101,726 | \$ 100,692 | \$ 75,620 | \$ 52,641 | \$ 39,088 |
| Cost of revenue | 35,002 | 29,859 | 19,792 | 14,689 | 12,317 |
| Gross profit | 66,724 | 70,833 | 55,828 | 37,952 | 26,771 |
| Operating expenses: | | | | | |
| Sales and marketing | 38,277 | 32,890 | 25,021 | 19,326 | 13,792 |
| Research and development | 7,169 | 6,473 | 5,353 | 4,549 | 3,448 |
| General and administrative | 11,721 | 15,192 | 8,782 | 8,924 | 4,367 |
| Litigation settlement | | 18,935 | | | |
| Total operating expenses | 57,167 | 73,490 | 39,156 | 32,799 | 21,607 |
| Income (loss) from operations | 9,557 | (2,657) | 16,672 | 5,153 | 5,164 |
| Interest and other income, net | 4,207 | 3,596 | 2,034 | 632 | 30 |
| Income before income taxes | 13,764 | 939 | 18,706 | 5,785 | 5,194 |
| Provision (benefit) for income taxes | 3,260 | (1,184) | 4,905 | 2,025 | 2,088 |
| Net income | \$ 10,504 | \$ 2,123 | \$ 13,801 | \$ 3,760 | \$ 3,106 |
| Net income available to common stockholders used in basic net income per share | \$ 10,504 | \$ 2,123 | \$ 13,801 | \$ 3,284 | \$ 963 |
| Net income per share: | | | | | |
| Basic | \$ 0.80 | \$ 0.17 | \$ 1.20 | \$ 0.38 | \$ 0.46 |
| Diluted | \$ 0.74 | \$ 0.15 | \$ 1.00 | \$ 0.31 | \$ 0.35 |
| Weighted-average number of shares used in per share calculations: | | | | | |
| Basic | 13,153 | 12,558 | 11,535 | 8,573 | 2,106 |
| Diluted | 14,228 | 14,278 | 13,864 | 12,222 | 8,835 |

| | As of December 31, | | | | |
|--|--------------------|-----------|----------|----------|-----------|
| | 2007 | 2006 | 2005 | 2004 | 2003 |
| Consolidated Balance Sheet Data (in thousands): | | | | | |
| Cash and cash equivalents | \$ 11,054 | \$ 11,800 | \$ 5,260 | \$ 7,070 | \$ 10,290 |
| Marketable investments | 88,510 | 96,285 | 86,736 | 59,200 | |
| Working capital | 106,894 | 111,999 | 98,318 | 68,519 | 14,205 |
| Total assets | 138,653 | 133,875 | 111,958 | 80,549 | 24,198 |
| Redeemable convertible preferred stock | | | | | 7,372 |

Edgar Filing: CUTERA INC - Form 10-K

| | | | | | |
|---------------------------|---------|---------|--------|--------|-------|
| Retained earnings | 34,279 | 23,866 | 21,743 | 7,942 | 4,182 |
| Total stockholders equity | 109,353 | 109,732 | 97,177 | 68,456 | 7,875 |

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, 2007. 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 future financial performance, the ability to grow our business, expectations regarding new products and applications, expectations for improvements in our sales and distribution network, future capital expenditures and requirements and the impact of exchange rate volatility. 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 19, 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 Management's Discussion and Analysis, or MD&A, is organized as follows:

Executive summary- This section provides a general description 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.

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, 2007.

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 for practitioners worldwide. We offer easy-to-use products on three platforms CoolGlide, Xeo and Solera which enable physicians and other qualified practitioners to offer safe and effective aesthetic treatments to their customers.

Our corporate headquarters and U.S. operations are located in Brisbane, California, where we conduct our manufacturing, warehousing, research, regulatory, sales, service marketing and administrative activities. In the United States, we market, sell and service our products primarily through a direct sales force of 53 employees as of December 31, 2007 and through a distribution relationship with PSS World Medical Shared Services, Inc., a wholly-owned subsidiary of PSS World Medical, or PSS, which has over 700 sales professionals serving physician offices throughout the United States. In addition, we also sell certain items, like Titan hand piece refills and marketing brochures, via the web.

International sales are generally made through a direct sales force of 29 employees and through a worldwide distributor network in approximately 34 countries as of December 31, 2007. Outside the United States, we have a direct sales presence in Australia, Canada, France, 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 hand piece refills. Product revenue represents the sale of a system, which consists of one or more hand pieces and a console that incorporates a universal graphic user interface, a laser and/or other light-based module, control system software and high voltage electronics. However, depending on the application, the laser or other light-based module is sometimes instead contained in the hand piece. 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 to their system 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 hand piece refill revenue is associated with our Titan hand piece, which requires a periodic refilling process, which includes the replacement of the optical source after a set number of pulses have been used.

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 the aesthetic laser market.

Continuing introduction of new aesthetic products and applications.

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

Generating service, upgrade and Titan hand piece refill revenue from our growing installed base of customers.

In 2007, compared to 2006, our U.S. revenue declined 8% and our international revenue grew 22%. In contrast, in 2006, compared to 2005, our U.S. revenue grew 28%, while our international revenue grew 46%. The weaker U.S. revenue growth from 2006 to 2007, as compared from 2005 to 2006, was primarily attributable to lower sales productivity of our recently-hired North American sales professionals and to slower-than-expected adoption of our new Pearl product by new customers. Also, some of our public competitors have reported reduced growth rates for the second half of the year ended December 31, 2007, which may indicate signs of a slowing market growth rate that could have contributed to a decrease in our U.S. revenue growth rate. The stronger international revenue growth in 2007, compared to U.S. revenue growth for that same period, was primarily attributable to continuing investments in building our international sales distribution channels. These efforts have resulted in increased revenue from several of our geographic locations, with growth primarily sourced from Australia, Japan, many European countries and Latin America. As a result of this stronger international revenue growth, international revenue as a percentage of total revenue increased to 37% in 2007, compared with 31% in 2006.

For 2007, our gross margin declined to 66%, compared to 70% in 2006. This decrease was primarily attributable to lower introductory margins for our Pearl-enabled systems and upgrades that started shipping in June 2007, reduced leverage of our manufacturing and service expenses due to lower than expected revenue, and \$764,000 of higher patent royalty expense. Since the patent license was signed in the second quarter of 2006, royalty expenses were incurred for sales made during the last three quarters of 2006, and for all four quarters of 2007.

Sales and Marketing expenses for 2007, compared to 2006, increased by \$5.4 million, or 16%, due primarily to expenses associated with the expansion of our worldwide sales force and management team. Sales and marketing expenses as a percentage of total revenue increased to 38% in 2007, compared to 33% in 2006, due primarily to lower sales productivity from the recently expanded North American sales team.

Research and Development expenses for 2007, compared with 2006, increased by \$696,000, or 11%, due primarily to increased expenses related to the development, testing and clinical research of our Pearl product, which started shipping in June 2007. As a percentage of total revenue, research and development expenses increased to 7% in 2007, compared to 6% in 2006.

Table of Contents

General and administrative expenses for 2007, compared with 2006, decreased by \$3.5 million, or 23%, to \$11.7 million and were 12% of net revenue. This decrease was primarily attributable to the following expenses incurred in 2006 but not in 2007: \$3.3 million of legal expenses related to the patent litigation matter settled in the second quarter ended June 30, 2006 and a charge of approximately \$505,000 relating to a liability for sales taxes in certain jurisdictions that we had determined we did not have a taxable presence. In April and May 2007, two securities class action lawsuits were filed against us and were later consolidated into one lawsuit. In 2007 we incurred approximately \$131,000 in legal fees to defend this class action lawsuit. However, given that we retain director and officer liability insurance with a deductible, this litigation is not expected to have a material impact on our expenses in 2008. In January 2008, a TCPA class action lawsuit was filed against us. For additional details relating to these lawsuits see Part I, Item 3 Legal Proceedings.

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 future performance 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 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, continue to develop new products and technologies, obtain regulatory clearances, protect our intellectual property, manufacture our products cost effectively, or 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.

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. To the extent that there are material differences between these estimates and actual results, our financial condition or results of operations will be affected.

Our critical accounting policies that are affected by accounting estimates are as follows:

Cash Equivalents and Marketable Securities

We maintain investment portfolio holdings of various issuers, types and maturities. We consider all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. At December 31, 2007, all other investment securities are classified as available-for-sale and consequently are recorded on the balance sheet at fair value with unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) within stockholders' equity. Management assesses whether declines in the fair value of investment securities are other than temporary. If the decline in fair value is judged to be other than temporary, the cost basis of the individual security is written down to fair value and the amount of the write down is included in earnings. In determining whether a decline is other than temporary, management considers the following factors:

Length of the time and the extent to which the market value has been less than cost;

The financial condition and near-term prospects of the issuer; and

Table of Contents

Our intent and ability to retain our investment in the issuer for a period of time sufficient to allow for any anticipated recovery in market value.

To date we have had no declines in fair value that have been identified as other than temporary.

Stock-based Compensation Expense

We account for stock-based compensation in accordance with Statement of Financial Accounting Standards, or SFAS 123(R), *Share-Based Payment (revised 2004)*. SFAS 123(R) 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, 2007 and 2006 reflect the impact of SFAS 123(R). In accordance with the modified prospective transition method, our consolidated financial statements for periods prior to 2006 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 years ended December 31, 2007 and 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 *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), 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. Given the Black-Scholes option valuation model requires the use of subjective assumptions including expected stock price volatility, expected term of stock option, risk-free interest rate and forfeiture rates, if any of the assumptions used change significantly, stock-based compensation expense may differ materially in the future from that recorded in the current period.

Prior to the adoption of SFAS 123(R) with effect from January 1, 2006, 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 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 or determinable; and

Collectability 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 collectability of those fees. In instances where final

Table of Contents

acceptance of the product is specified by the customer or collectability 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. 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.

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. We provide for excess and obsolete inventories 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 provisions are measured as the difference between the cost of inventory and estimated market value and charged to cost of revenue to establish a lower cost basis for the inventories. We balance the need to maintain strategic inventory levels with the risk of obsolescence due to changing technology and customer demand levels. Unfavorable changes in market conditions may result in a need for additional inventory provisions that could adversely impact our gross margins. Conversely, favorable changes in demand could result in higher gross margins when product that has previously been reserved is sold.

Warranty Obligations

We provide a standard one-year or two-year warranty coverage on our systems. 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. 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 uncertain tax positions and determining our provision for income taxes on earnings. Effective January 1, 2007, we adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement No. 109*, or FIN 48. FIN 48 contains a two-step approach to recognizing and measuring uncertain tax positions accounted for in accordance with SFAS No. 109, *Accounting for Income Taxes*. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. Although we believe we have adequately reserved for our uncertain tax positions, no assurance can be given that the final tax outcome of these matters will not be different. We adjust these reserves

Table of Contents

in light of changing facts and circumstances, such as the closing of a tax audit or the refinement of an estimate. To the extent that the final tax outcome of these matters is different than the amounts recorded, such differences will impact the provision for income taxes in the period in which such determination is made. The provision for income taxes includes the impact of reserve provisions and changes to reserves that are considered appropriate, as well as the related net interest.

Our effective tax rates have differed from the statutory rate primarily due to the tax impact of tax-exempt interest income, foreign operations, research and development tax credits, state taxes, and certain benefits realized related to stock option activity. 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. The effective tax rate was 24%, (126)% and 26% for the years ended December 31, 2007, 2006 and 2005, respectively. For 2006, given that the litigation settlement expense of \$18.9 million resulted in a significantly lower level of income before income taxes, the impact of deductible permanent items including, tax-exempt interest income, R&D tax credits 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.

Our future effective tax rates could be adversely affected by earnings being lower than anticipated in countries where we have lower statutory rates and being higher than anticipated in countries where we have higher statutory rates, or by changes in tax laws including whether the U.S. Congress ratifies the federal R&D tax credit for 2008 regulations, accounting principles, or interpretations thereof. In addition, we are subject to the examination of our income tax returns by the Internal Revenue Service and other tax authorities. We regularly assess the likelihood of adverse outcomes resulting from these examinations to determine the adequacy of our provision for income taxes.

Contingencies

We have been, and may in the future become, subject to legal proceedings related to securities litigation, intellectual property and other operational matters such as the TCPA infringement matter described in Item 3- Legal Proceedings. Based on the information available at the balance sheet dates and through consultation with our legal counsel, we assess the likelihood of any adverse judgments or outcomes for these matters, as well as potential ranges of probable loss. If losses are probable and reasonably estimable, we will record a reserve in accordance with Statement of Financial Accounting Standards No. 5, Accounting for Contingencies. Currently we have no such reserves recorded. Any reserves recorded in the future may change due to new developments in each matter.

Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board, or FASB, issued SFAS No. 157, *Fair Value Measurements*, or SFAS 157, which defines fair value, establishes guidelines for measuring fair value and expands disclosures regarding fair value measurements. SFAS 157 does not require any new fair value measurements but rather eliminates inconsistencies in guidance found in various prior accounting pronouncements. SFAS 157 is effective for us beginning January 1, 2008. We are currently evaluating the impact of SFAS 157 on our consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, or SFAS 159. SFAS 159 permits companies to choose to measure certain financial instruments and certain other items at fair value. The standard requires that unrealized gains and losses on items for which the fair value option has been elected be reported in earnings. SFAS 159 is effective for us beginning January 1, 2008. We are currently evaluating the impact that SFAS 159 will have on our consolidated financial statements.

Table of Contents

In December 2007, the FASB issued SFAS No. 141R, *Business Combinations*, or SFAS 141R. This issuance retains the fundamental requirements in SFAS 141 that the acquisition method of accounting (which SFAS 141 called the purchase method) be used for all business combinations and for an acquirer to be identified for each business combination. SFAS 141R defines the acquirer as the entity that obtains control of one or more businesses in the business combination and establishes the acquisition date as the date that the acquirer achieves control. SFAS 141R is effective for us beginning January 1, 2009. Though this pronouncement is not expected to have an effect on our consolidated financial position, annual results of operations or cash flows, if we were to acquire another entity, we would be required to account for it in accordance with this pronouncement.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements*, (SFAS 160). This issuance amends Accounting Research Bulletin 51 to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. SFAS 160 clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. SFAS 160 is effective for us beginning January 1, 2009. Though this pronouncement is not expected to have an effect on our consolidated financial position, annual results of operations or cash flows, if we were to acquire another entity, we would be required to account for it in accordance with this pronouncement.

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, | | |
|--------------------------------------|-------------------------|-----------|------------|
| | 2007 | 2006 | 2005 |
| Operating Ratios: | | | |
| Net revenue | 100% | 100% | 100% |
| Cost of revenue | 34% | 30% | 26% |
| Gross profit | 66% | 70% | 74% |
| Operating expenses: | | | |
| Sales and marketing | 38% | 33% | 33% |
| Research and development | 7% | 6% | 7% |
| General and administrative | 12% | 15% | 12% |
| Litigation settlement | % | 19% | % |
| Total operating expenses | 57% | 73% | 52% |
| Income (loss) from operations | 9% | (3)% | 22% |
| Interest and other income, net | 4% | 4% | 3% |
| Income before income taxes | 13% | 1% | 25% |
| Provision (benefit) for income taxes | 3% | (1)% | 7% |
| Net income | 10% | 2% | 18% |

Table of Contents**Total Revenue**

| (Dollars in thousands) | Year ended December 31, | | | | |
|--|-------------------------|----------|------------|----------|-----------|
| | 2007 | % Change | 2006 | % Change | 2005 |
| Revenue mix by geography: | | | | | |
| United States | \$ 64,084 | (8)% | \$ 69,895 | 28% | \$ 54,506 |
| Asia | 17,898 | 13% | 15,781 | 19% | 13,220 |
| Europe | 9,258 | 28% | 7,239 | 66% | 4,351 |
| Rest of the world | 10,486 | 35% | 7,777 | 120% | 3,543 |
| Total international revenue | 37,642 | 22% | 30,797 | 46% | 21,114 |
| Consolidated total revenue | \$ 101,726 | 1% | \$ 100,692 | 33% | \$ 75,620 |
| United States as a percentage of total revenue | 63% | | 69% | | 72% |
| International as a percentage of total revenue | 37% | | 31% | | 28% |
| Revenue mix by product category: | | | | | |
| Products | \$ 74,502 | (12)% | \$ 84,695 | 34% | \$ 63,349 |
| Product upgrades | 13,342 | 122% | 6,006 | (9)% | 6,630 |
| Service | 9,128 | 55% | 5,890 | 52% | 3,881 |
| Titan hand piece refills | 4,754 | 16% | 4,101 | 133% | 1,760 |
| Consolidated total revenue | \$ 101,726 | 1% | \$ 100,692 | 33% | \$ 75,620 |

In 2007, compared to 2006, our U.S. revenue declined 8% and our international revenue grew 22%. In contrast, in 2006, compared to 2005, our U.S. revenue grew by 28%, while our international revenue grew by 46%. The weaker U.S. revenue growth from 2006 to 2007, as compared to 2005 to 2006, was primarily attributable to lower sales productivity of our recently-hired North American sales professionals and to slower-than-expected adoption of our new Pearl product by new customers. Also, some of our public competitors have reported reduced growth rates for the year ended December 31, 2007, which may indicate signs of a slowing market growth rate that could have contributed to a decrease in our U.S. revenue growth rate. The stronger international revenue growth in 2007, compared to U.S. revenue growth for that same period, was primarily attributable to continuing investments in building our international sales distribution channels. These efforts have resulted in increased revenue from several of our geographic locations, with growth primarily sourced from Australia, Japan, many European countries and Latin America. As a result of continued stronger international revenue growth, international revenue as a percentage of total revenue increased to 37% in 2007, compared with 31% and 28% in 2006 and 2005, respectively.

Product revenue decreased 12% in 2007, compared with 2006, but increased by 34% in 2006, compared with 2005. This reduction in product revenue growth was due primarily to slower-than-expected adoption of our Pearl product by new customers in 2007 and to lower sales productivity of the North American sales professionals that were hired in 2007. Upgrade revenue increased by 122% in 2007, compared with 2006, due primarily to an increase in existing customers choosing to upgrade their systems with our new Pearl application introduced in 2007. Service revenue continued to increase as a result of an increase in our installed base of customers purchasing extended service contracts. Titan hand piece refills revenue increased by 16% in 2007, compared with 2006, and 133% in 2006, compared with 2005. The reduction in growth of revenue from Titan hand piece refills is due in part to us providing an increased number of shots per hand piece with the introduction of Titan V in 2006 15,000 shots, compared to 10,000 shots in the original Titan S hand piece. In addition, we believe some of our customers, particularly high-volume Titan users, may be using fewer shots than before, due in part to the introduction of other new applications for skin rejuvenation in the marketplace, including our Pearl product.

Table of Contents**Gross Profit**

| (Dollars in thousands) | Year Ended December 31, | | | | |
|---|-------------------------|----------|------------|----------|------------|
| | 2007 | % Change | 2006 | % Change | 2005 |
| Gross margin | \$ 66,724 | (6)% | \$ 70,833 | 27% | \$ 55,828 |
| <i>As a percentage of total revenue</i> | <i>66%</i> | | <i>70%</i> | | <i>74%</i> |

Our cost of revenue consists primarily of material, labor, employee stock-based compensation, royalty expense, warranty, and manufacturing overhead expenses. For 2007, our gross margin declined to 66%, compared to 70% in 2006. This decrease was primarily attributable to lower introductory margins for our Pearl-enabled systems and upgrades that started shipping in June 2007, reduced leverage of our manufacturing and service expenses due to lower than expected revenue in 2007, and \$764,000 of higher patent royalty expense. Royalty expenses were incurred for a full-year in 2007, but for only the last three quarters in 2006.

The decline in gross margin to 70% in 2006, compared to 74% in 2005, was primarily attributable to the royalty expense recorded with effect from April 1, 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.

Sales and Marketing

| (Dollars in thousands) | Year Ended December 31, | | | | |
|---|-------------------------|----------|------------|----------|------------|
| | 2007 | % Change | 2006 | % Change | 2005 |
| Sales and marketing | \$ 38,277 | 16% | \$ 32,890 | 31% | \$ 25,021 |
| <i>As a percentage of total revenue</i> | <i>38%</i> | | <i>33%</i> | | <i>33%</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. In 2007, the \$5.4 million, or 16%, increase in sales and marketing expenses was due primarily to \$2.7 million of higher personnel expenses associated with the expansion of our worldwide sales force and management team, \$1.2 million of higher advertising and promotional expenses, and \$756,000 of higher employee travel and entertainment expenses related to the increased sales headcount. Sales and marketing expenses as a percentage of total revenue, increased to 38% in 2007, compared with 33% in 2006, due primarily to lower sales productivity from the recently expanded North American sales team.

Of the \$7.9 million increase in sales and marketing expenses in 2006, compared with 2005, \$6.0 million was attributable to personnel expenses associated primarily with increased headcount and higher stock-based compensation expenses due to the adoption of SFAS 123(R) with effect from January 1, 2006 and \$1.6 million of higher advertising and promotional expenses. Sales and marketing expenses as a percentage of total revenue was 33% in both 2006 and 2005.

Research and Development (R&D)

| (Dollars in thousands) | Year Ended December 31, | | | | |
|---|-------------------------|----------|-----------|----------|-----------|
| | 2007 | % Change | 2006 | % Change | 2005 |
| Research and development | \$ 7,169 | 11% | \$ 6,473 | 21% | \$ 5,353 |
| <i>As a percentage of total revenue</i> | <i>7%</i> | | <i>6%</i> | | <i>7%</i> |

Research and development expenses consist primarily of personnel cost, stock-based compensation expenses and clinical, regulatory and material costs. In 2007, compared with 2006, research and development expenses increased by \$696,000, or 11%, due primarily to \$463,000 of higher consulting and other services expense and \$303,000 of higher expensed tools, equipment and materials used primarily in the research and development

Table of Contents

activities related to our Pearl product. As a result of the increased expenses, R&D expenses as a percentage of total revenue increased to 7% in 2007, compared to 6% in 2006.

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. Due primarily to \$25.1 million of higher revenue in 2006, compared with 2005, research and development expenses as a percentage of revenue decreased to 6% in 2006, compared with 7% in 2005.

General and Administrative (G&A)

| (Dollars in thousands) | Year Ended December 31, | | | | 2005 |
|---|-------------------------|----------|------------|----------|------------|
| | 2007 | % Change | 2006 | % Change | |
| General and administrative | \$ 11,721 | (23)% | \$ 15,192 | 73% | \$ 8,782 |
| <i>As a percentage of total revenue</i> | <i>12%</i> | | <i>15%</i> | | <i>12%</i> |

General and administrative expenses consist primarily of personnel costs, stock-based compensation expenses, legal fees, accounting fees and other general and administrative expenses. General and administrative expenses for 2007, compared with 2006, decreased by \$3.5 million, or 23%, to \$11.7 million and were 12% of net revenue. This decrease was primarily attributable to the following expenses incurred in 2006 but not in 2007: \$3.3 million of legal expenses related to the patent litigation matter settled in the second quarter ended June 30, 2006 and a charge of approximately \$505,000 relating to a liability for sales taxes in certain jurisdictions that we had determined we did not have a taxable presence.

The \$6.4 million, or 73%, increase in G&A expenses in 2006, compared with 2005, was primarily attributable to \$2.6 million of higher legal expenses associated primarily with the then-active Palomar patent 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 a charge of approximately \$505,000 recorded in 2006 relating to a liability for sales taxes in certain jurisdictions that we previously determined we did not have a taxable presence. Due to these reasons, G&A expenses as a percentage of revenue increased from 12% in 2005 to 15% in 2006.

In April and May 2007, two securities class action lawsuits were filed against us and were later consolidated into one lawsuit. In 2007 we incurred approximately \$131,000 in legal fees to defend this securities class action lawsuit. However, given that we retain director and officer liability insurance with a deductible, this litigation is not expected to have a material impact to our Consolidated Statement of Operations for 2008. In January 2008, a TCPA class action lawsuit was filed against us. For additional details relating to these lawsuits see Part I, Item 3 Legal Proceedings.

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 obtained as part of the settlement agreement.

Table of Contents**Interest and Other Income, Net**

| (Dollars in thousands) | Year Ended December 31, | | | | |
|---------------------------------------|-------------------------|----------|----------|----------|----------|
| | 2007 | % Change | 2006 | % Change | 2005 |
| <i>Interest and other income, net</i> | \$ 4,207 | 17% | \$ 3,596 | 77% | \$ 2,034 |

The \$611,000, or 17%, net increase in interest and other income in 2007 and the \$1.6 million, or 77%, net increase in 2006, compared to the respective prior years, was primarily attributable to improved tax-exempt interest yields on investments in government bonds and an increased average amount invested. Our cash, cash equivalents and marketable investment balances were at \$107.0 million, \$108.1 million and \$92.0 million as of December 31, 2007, 2006 and 2005, respectively.

Provision (Benefit) for Income Taxes

| (Dollars in thousands) | Year Ended December 31, | | | | |
|--------------------------------------|-------------------------|-----------|---------|-------------|-----------|
| | 2007 | Change | 2006 | Change | 2005 |
| Income before income taxes | \$ 13,764 | \$ 12,825 | \$ 939 | \$ (17,767) | \$ 18,706 |
| Provision (benefit) for income taxes | 3,260 | 4,444 | (1,184) | (6,089) | 4,905 |
| <i>Effective tax rate</i> | 24% | | (126)% | | 26% |

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 certain benefits realized related to stock option activity. The effective tax rate was 24% and (126)% for the years ended December 31, 2007 and 2006, respectively. The change in the effective tax rate for 2007, compared with 2006, was primarily attributable to the litigation settlement expense in 2006, and the increased benefit associated with deductible permanent items R&D tax credits relating to both fiscal 2006 and 2007 and tax-exempt interest income in 2007.

The significant change in the effective tax rate for 2006, compared with 2005, was primarily due to the \$18.9 million litigation settlement expense. 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.

Net Income and Net Income Per Diluted Share

| (Dollars in thousands, except per share data) | Year Ended December 31, | | | | |
|---|-------------------------|----------|----------|----------|-----------|
| | 2007 | % Change | 2006 | % Change | 2005 |
| Net income | \$ 10,504 | 395% | \$ 2,123 | (85)% | \$ 13,801 |
| Net income per diluted share | \$ 0.74 | 393% | \$ 0.15 | (85)% | \$ 1.00 |

The \$8.4 million increase in net income, and \$0.59 increase in net income per diluted share, in 2007, compared with 2006, was primarily due to \$11.7 million of patent litigation settlement expense of \$18.9 million, net of the marginal tax impact of \$7.2 million, being incurred in 2006 but not in 2007. The \$11.7 million improvement was offset in part by lower gross margins, higher operating expenses and a higher effective income tax rate.

The \$11.7 million decrease in net income, and \$0.85 decrease in net income per diluted share, in 2006, compared with 2005, was due primarily to \$11.7 million of patent litigation settlement expense of \$18.9 million, net of the marginal tax impact of \$7.2 million, resulting from the June 2006 settlement of all patent litigation brought against us by Palomar and MGH.

Table of Contents**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, 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, | | |
|---|--------------------|------------|------------|
| | 2007 | 2006 | Decrease |
| Cash, cash equivalents and marketable securities: | | | |
| Cash and cash equivalents | \$ 11,054 | \$ 11,800 | \$ (746) |
| Marketable investments | 88,510 | 96,285 | (7,775) |
| Total | \$ 99,564 | \$ 108,085 | \$ (8,521) |

Cash Flows

In summary, our cash flows were as follows:

| (Dollars in thousands) | Year ended December 31, | | |
|--|-------------------------|-----------|------------|
| | 2007 | 2006 | 2005 |
| Cash flows provided by (used in): | | | |
| Operating activities | \$ 16,890 | \$ 12,466 | \$ 20,388 |
| Investing activities | (426) | (11,355) | (28,342) |
| Financing activities | (17,210) | 5,429 | 6,144 |
| Net increase (decrease) in cash and cash equivalents | \$ (746) | \$ 6,540 | \$ (1,810) |

Cash Flows From Operating Activities

Cash provided by operating activities in 2007 was \$16.9 million and consisted of net income of \$10.5 million, adjustments for non-cash items of \$4.7 million and cash provided by working capital and other activities of \$1.7 million. Adjustments for non-cash items primarily consisted of: (i) \$5.6 million of stock-based compensation expense; (ii) \$4.2 million of tax benefit from employee stock option exercises; (iii) partially offset by \$3.6 million of excess tax benefits related to stock-based compensation expenses reclassified from operating activities to financing activities in accordance with FAS 123(R); and (iv) offset by a \$2.7 million increase in deferred tax assets resulting from an increase in accrued liabilities and unutilized deductions for stock-based compensation expenses. Working capital activities primarily consisted of: (i) an increase of \$3.8 million in deferred revenue due to the growth in service contracts sold to our expanding customer installed base; (ii) partially offset by cash used to increase inventories by \$2.6 million to support a broader product offering and due to lower than expected revenue in the fourth quarter 2007; and (iii) an increase in accounts receivable by \$1.1 million resulting from a higher uncollected balance relating to fourth quarter 2007 revenue.

Cash provided by operating activities in 2006 was \$12.5 million and consisted of net income of \$2.1 million, adjustments for non-cash items of \$3.4 million and cash provided by working capital and other activities of \$7.0 million. Adjustments for non-cash items primarily consisted of: (i) \$4.5 million of stock-based compensation expense; (ii) \$1.8 million of tax benefit from employee stock option exercises; (iii) partially offset by a \$2.8 million increase in deferred tax assets resulting from increased accrued liabilities, R&D credits, and unutilized deductions for stock based compensation; and (iv) \$1.0 million of excess tax benefits related to stock-based

Table of Contents

compensation expenses which was reclassified from operating activities to financing activities in accordance with FAS 123(R). Working capital activities primarily consisted of: (i) \$4.2 million of cash provided by an increase in accrued liabilities due in part to higher accrued warranty and royalty expenses resulting from the increase in revenue in 2006; (ii) \$3.6 million of cash provided by an increase in deferred revenue due to the continued growth in service contracts sold to our expanding customer installed base; (iii) offset partially by \$3.0 million cash used to increase accounts receivable due to the strong revenue growth in the fourth quarter ended December 31, 2006.

Cash provided by operating activities in 2005 was \$20.4 million. This was primarily attributable to net income of \$13.8 million, adjustments for non-cash items of \$9.4 million and cash used in working capital and other activities of \$2.8 million. Adjustments for non-cash items primarily consisted of tax benefits related to employee stock option exercises of \$7.4 million and stock-based compensation expenses of \$1.4 million. Working capital activities primarily consisted of (i) \$1.1 million cash generated from an increase in deferred revenue resulting from an increase in customer service contracts sold; (ii) offset by cash used to increase inventory by \$3.1 million to support anticipated shipments and a broader product offering; and (iii) an increase in other assets of \$2.9 million that resulted from income taxes paid prior to the fourth quarter of 2005 becoming refundable due to an increase in employee stock option deductions in the fourth quarter of 2005.

Cash Flows From Investing Activities

We used \$426,000 of cash in investing activities in 2007. Of this amount, \$594,000 was used to invest the cash generated from operations in marketable securities, \$1.0 million was used to purchase capital equipment for R&D and manufacturing operations as well as a trade show booth for marketing, and \$20,000 was used to purchase an intangible asset.

We used \$11.4 million of cash in investing activities in 2006. Of this amount, \$9.5 million was used to invest the cash generated from operations in marketable securities, \$1.2 million was used to purchase an ongoing patent sublicense and \$642,000 was used to purchase capital equipment for R&D and manufacturing departments.

In 2005, net cash used in investing activities was \$28.3 million. 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 capital equipment and \$165,000 was used to purchase intangibles associated with the set up of a new office in Zurich, Switzerland through the acquisition of a distributor.

Cash Flows From Financing Activities

Net cash used in financing activities in 2007 was \$17.2 million, which primarily related to \$25.0 million of cash used to repurchase shares of our common stock pursuant to our stock repurchase program, which was partially offset by \$4.1 million of cash generated from the issuance of stock pursuant to our stock option and stock purchase plans and \$3.7 million of excess tax benefits related to stock-based compensation expenses reclassified from operating activities to financing activities in accordance with FAS 123(R).

Cash provided by financing activities in 2006 was \$5.4 million which was attributable to \$4.4 million of proceeds from the issuance of stock through our stock option and employee stock purchase plans and \$1.0 million of excess tax benefits related to stock-based compensation expenses reclassified from operating activities to financing activities in accordance with FAS 123(R).

Cash provided by financing activities in 2005 was \$6.1 million which was attributable to the proceeds from the issuance of stock through our stock option and employee stock purchase plans.

Table of Contents***Adequacy of cash resources to meet future needs***

We had cash and marketable investments of \$107.0 million as of December 31, 2007. Of this amount, we had \$21.5 million invested in auction rate securities that were rated AAA or better by a major credit rating agency and are either commercially insured or guaranteed by the Federal Family Education Loan Program (FFELP). As of December 31, 2007, of the \$21.5 million of auction rate securities, the Company classified \$7.4 million under the caption of "Marketable investments- long term portion" in the Consolidated Balance Sheet.

As of February 29, 2008 we had \$13.6 million of our investment portfolio invested in auction-rate securities. These auction rate securities provide liquidity via an auction process that resets the applicable interest rate at predetermined calendar intervals, generally every 35 days though auctions for some of the securities are held every 360 days. During the period from January 1, 2008 to February 29, 2008, auctions for \$9.6 million of our investments in auction rate securities failed due to the current overall credit concerns in capital markets. Upon an auction failure, the interest rates do not reset at a market rate but instead reset based on a formula contained in the security prospectus, which rate is generally higher than the current market rate. The failure of the auctions impacts our ability to readily liquidate our auction rate securities into cash until a future auction of these investments is successful or the auction rate security is refinanced by the issuer into another type of debt instrument. Based on our ability to access our cash and other short-term investments, our expected operating cash flows, and our other sources of cash, we do not anticipate the current lack of liquidity on these investments will affect our ability to operate our business as usual.

Contractual Cash Obligations

The following summarizes our contractual obligations as of December 31, 2007 for minimum lease payments related to facility leases.

| | Total | Payments Due by Period (\$ 000 s) | | | |
|--|----------|-----------------------------------|--------------|--------------|----------------------|
| | | Less Than 1 Year | 1-3 Years | 3-5 Years | More Than 5 Years |
| Contractual Obligations | | | | | |
| Operating leases | \$ 7,921 | \$ 1,198 | \$ 2,442 | \$ 2,736 | \$ 1,545 |
| <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, 2007, we were not involved in any unconsolidated transactions.

Income Tax Liability

As a result of the adoption of FIN 48, as of December 31, 2007, we have included in our condensed consolidated balance sheet \$367,000 in Accrued Liabilities and \$1.2 million in long-term Income Tax Liability with respect to unrecognized tax benefits and accrued interest. At this time, we are unable to make a reasonably reliable estimate of the timing of payments in individual years beyond 12 months due to uncertainties in the timing of tax audit outcomes. As a result, this amount is not included in the Contractual Obligations table above.

Indemnifications

In the normal course of business, we enter into agreements that contain a variety of representations, warranties, and indemnification obligations. For example, we have entered into indemnification agreements with each of our directors and executive officers. In 2007, two of our executive officers were named as defendants in securities class action litigation see Part I, Item 3 Legal Proceedings. Our exposure under the various indemnification

Table of Contents

obligations, including those under the indemnification agreements with our directors and executive officers, is unknown since the outcome of the securities litigation is unpredictable and the amount that could be payable thereunder is not reasonably estimable, and since other indemnification obligations involve future claims that may be made against us. We have not accrued or paid any amounts for any such indemnification obligations. However, we may record charges in the future as a result of these potential indemnification obligations, including those related to the securities class action litigation.

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 including variable rate demand notes, auction rate securities and bonds of the U.S. Government, its agencies, and municipalities, and high-quality corporate issuers. By policy, we 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, 2007 would have potentially declined by \$443,000.

While we transact business primarily in U.S. Dollars, and a significant proportion of our revenue is denominated in U.S. Dollars, a portion of our revenue and operating expenses are denominated in other currencies, such as the Euro, Japanese Yen, Australian Dollar, Canadian Dollar and British Pound Sterling. Though our exposure to exchange rate volatility has not been significant to date, future fluctuations in the value of the U.S. dollar may affect the price competitiveness of our products and/or adversely impact our gross margins and operating margins. 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> | 53 |
| <u>Consolidated Balance Sheets</u> | 54 |
| <u>Consolidated Statements of Operations</u> | 55 |
| <u>Consolidated Statements of Stockholders' Equity</u> | 56 |
| <u>Consolidated Statements of Cash Flows</u> | 57 |
| <u>Notes to Consolidated Financial Statements</u> | 58 |

The following Consolidated Financial Statement Schedule of the Registrant and its subsidiaries for the years ended December 31, 2007, 2006 and 2005 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> | 81 |

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.:

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, 2007 and 2006, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2007 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. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements and financial statement schedule, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements, on the financial statement schedule, and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note 1 to the consolidated financial statements, the Company changed the manner in which it accounts for share-based compensation in 2006 and the manner in which it accounts for uncertain tax positions in 2007.

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 12, 2008

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

| | December 31, | |
|--|---------------------|-------------------|
| | 2007 | 2006 |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 11,054 | \$ 11,800 |
| Marketable investments | 88,510 | 96,285 |
| Accounts receivable, net of allowance for doubtful accounts in 2007 and 2006 of \$9 and \$34, respectively | 10,692 | 9,601 |
| Inventories | 7,533 | 5,220 |
| Deferred tax asset | 8,058 | 5,792 |
| Other current assets | 1,955 | 2,702 |
| Total current assets | 127,802 | 131,400 |
| Property and equipment, net | 1,361 | 1,029 |
| Marketable investments, long term portion | 7,429 | |
| Intangibles, net | 1,227 | 1,446 |
| Deferred tax asset, net of current portion | 834 | |
| Total assets | \$ 138,653 | \$ 133,875 |
| Liabilities and Stockholders Equity | | |
| Liabilities: | | |
| Accounts payable | \$ 2,350 | \$ 2,212 |
| Accrued liabilities | 13,587 | 13,675 |
| Deferred revenue | 4,971 | 3,514 |
| Total current liabilities | 20,908 | 19,401 |
| Deferred rent | 1,639 | 1,424 |
| Deferred revenue, net of current portion | 5,593 | 3,258 |
| Income tax liability | 1,160 | 60 |
| Total liabilities | 29,300 | 24,143 |
| Commitments and contingencies (Note 10 and 11) | | |
| Stockholders equity: | | |
| 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: 12,738,449 and 12,939,389 shares in 2007 and 2006, respectively | | |
| Additional paid-in capital | 74,871 | 86,242 |
| Deferred stock-based compensation | | (331) |
| Retained earnings | 34,279 | 23,866 |
| Accumulated other comprehensive income (loss) | 190 | (58) |
| Total stockholders equity | 109,353 | 109,732 |

Edgar Filing: CUTERA INC - Form 10-K

| | | |
|--|------------|------------|
| Total liabilities and stockholders' equity | \$ 138,653 | \$ 133,875 |
|--|------------|------------|

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, | | |
|---|--------------------------------|---------------|---------------|
| | 2007 | 2006 | 2005 |
| Net revenue | \$ 101,726 | \$ 100,692 | \$ 75,620 |
| Cost of revenue | 35,002 | 29,859 | 19,792 |
| Gross profit | 66,724 | 70,833 | 55,828 |
| Operating expenses: | | | |
| Sales and marketing | 38,277 | 32,890 | 25,021 |
| Research and development | 7,169 | 6,473 | 5,353 |
| General and administrative | 11,721 | 15,192 | 8,782 |
| Litigation settlement | | 18,935 | |
| Total operating expenses | 57,167 | 73,490 | 39,156 |
| Income (loss) from operations | 9,557 | (2,657) | 16,672 |
| Interest and other income, net | 4,207 | 3,596 | 2,034 |
| Income before income taxes | 13,764 | 939 | 18,706 |
| Provision (benefit) for income taxes | 3,260 | (1,184) | 4,905 |
| Net income | \$ 10,504 | \$ 2,123 | \$ 13,801 |
| Net income per share: | | | |
| Basic | \$ 0.80 | \$ 0.17 | \$ 1.20 |
| Diluted | \$ 0.74 | \$ 0.15 | \$ 1.00 |
| Weighted-average number of shares used in per share calculations: | | | |
| Basic | 13,153 | 12,558 | 11,535 |
| Diluted | 14,228 | 14,278 | 13,864 |

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 | | Additional Paid-in Capital | Deferred Stock-Based Compensation | Retained Earnings | Accumulated Other Comprehensive Income (loss) | Total Stockholders Equity |
|--|--------------|--------|----------------------------------|---|----------------------|---|---------------------------------|
| | Shares | Amount | | | | | |
| 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: | | | | | | | |
| 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 |
| Issuance of common stock for employee purchase plan | 42,868 | | 954 | | | | 954 |
| Exercise of stock options | 854,147 | 1 | 3,321 | | | | 3,322 |
| Issuance of common stock in settlement of restricted stock units, net of shares withheld for employee taxes. | 9,901 | | (138) | | | | (138) |
| Repurchase of common stock | (1,107,856) | (1) | (24,999) | | | | (25,000) |
| Share-based compensation expense | | | 5,305 | 322 | | | 5,627 |
| Change in deferred stock-based compensation, net of terminations | | | (9) | 9 | | | |
| Tax benefit from exercises of stock-based payment awards | | | 4,195 | | | | 4,195 |

Edgar Filing: CUTERA INC - Form 10-K

| | | | | | | | | |
|---|------------|-------|-----------|----|-----------|-----|-----|------------|
| Adjustment to retained earnings upon adoption of FIN 48 | | | | | (91) | | | (91) |
| Components of other comprehensive income: | | | | | | | | |
| Net income | | | | | 10,504 | | | 10,504 |
| Other comprehensive income | | | | | | 248 | | 248 |
| Comprehensive income | | | | | | | | 10,752 |
| Balance at December 31, 2007 | 12,738,449 | \$ 13 | \$ 74,871 | \$ | \$ 34,279 | \$ | 190 | \$ 109,353 |

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, | | |
|---|-------------------------|------------|-----------|
| | 2007 | 2006 | 2005 |
| Cash flows from operating activities: | | | |
| Net income | \$ 10,504 | \$ 2,123 | \$ 13,801 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | | |
| Depreciation and amortization | 913 | 869 | 689 |
| Change in deferred tax asset/liability | (2,662) | (2,765) | (735) |
| Stock-based compensation | 5,627 | 4,542 | 1,442 |
| Tax benefit from employee stock options | 4,195 | 1,808 | 7,437 |
| Excess tax benefit related to stock-based compensation expense | (3,652) | (1,032) | |
| Other | 248 | (53) | 595 |
| Changes in assets and liabilities: | | | |
| Accounts receivable | (1,066) | (2,980) | 475 |
| Inventory | (2,592) | (65) | (3,146) |
| Other current assets | 747 | 1,026 | (2,850) |
| Accounts payable | 138 | 860 | 157 |
| Accrued liabilities | 367 | 4,175 | 937 |
| Deferred rent | 215 | 328 | 448 |
| Deferred revenue | 3,792 | 3,630 | 1,138 |
| Income tax liability | 116 | | |
| Net cash provided by operating activities | 16,890 | 12,466 | 20,388 |
| Cash flows from investing activities: | | | |
| Acquisition of property and equipment | (1,000) | (642) | (539) |
| Purchase of intangibles | (20) | (1,218) | (165) |
| Proceeds from sales of marketable investments | 69,103 | 23,522 | 18,324 |
| Proceeds from maturities of marketable investments | 31,508 | 99,439 | 49,948 |
| Purchase of marketable investments | (100,017) | (132,456) | (95,910) |
| Net cash used in investing activities | (426) | (11,355) | (28,342) |
| Cash flows from financing activities: | | | |
| Proceeds from exercise of stock options and employee stock purchase plan | 4,138 | 4,397 | 6,144 |
| Repurchase of common stock | (25,000) | | |
| Excess tax benefit related to stock-based compensation expense | 3,652 | 1,032 | |
| Net cash provided by (used in) financing activities | (17,210) | 5,429 | 6,144 |
| Net increase (decrease) in cash and cash equivalents | (746) | 6,540 | (1,810) |
| Cash and cash equivalents at beginning of year | 11,800 | 5,260 | 7,070 |
| Cash and cash equivalents at end of year | \$ 11,054 | \$ 11,800 | \$ 5,260 |
| Supplemental and non-cash disclosure of cash flow information: | | | |
| Change in deferred stock-based compensation, net of terminations | \$ (9) | \$ (1,271) | \$ 1,387 |
| Cash paid (received) for income taxes | \$ (808) | \$ (1,990) | \$ 1,837 |

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 primary care physicians and other qualified practitioners to offer safe and effective aesthetic treatments to their customers.

Headquartered in Brisbane, California, the Company has wholly-owned subsidiaries in Australia, Canada, France, Japan, Spain, Switzerland and United Kingdom that market, sell and service its 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.

The Company invests its cash primarily in money market funds and in highly liquid debt instruments of U.S. municipalities, the U.S. government and its agencies, and in bonds of high-quality corporate issuers. All highly liquid investments with stated maturities of three months or less from date of purchase are classified as cash equivalents; all highly liquid investments with stated maturities of greater than three months are classified as marketable investments. The Company determines the appropriate classification of its investments in marketable securities at the time of purchase and re-evaluates such designation at each balance sheet date. The Company's marketable securities have been classified and accounted for as available-for-sale. The Company may, or may not, hold securities with stated maturities greater than 12 months until maturity. In response to changes in the availability of and the yield on alternative investments as well as liquidity requirements, it occasionally sells these securities prior to their stated maturities. As these securities are viewed by the Company as available to support current operations, based on the provisions of Accounting Research Bulletin No. 43, Chapter 3A, Working Capital-Current Assets and Liabilities, securities with maturities beyond 12 months (such as auction rate securities and variable rate demand notes) are classified as current assets under the caption marketable investments in the accompanying Consolidated Balance Sheets. These securities are carried at fair value, with the unrealized gains and losses, net of taxes, reported as a component of stockholders' equity, except for unrealized losses determined to be other than temporary which are recorded as interest income and other, net, in accordance with the Company's policy and FASB Staff Position (FSP) Nos. FAS 115-1 and FAS 124-1, The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments. Any realized gains or losses on the sale of marketable securities are determined on a specific identification method, and such gains and losses are reflected as a component of interest income and other, net. As of December 31, 2007 and 2006, the Company had not incurred any losses that were other-than-temporary.

As of December 31, 2007, the Company held \$21.5 million in auction rate securities which are variable rate debt instruments, which bear interest rates that reset generally every 35 days though auctions for some of the securities are held every 360 days. The auction rate securities owned by the Company were rated AAA or better by a major credit rating agency and are either commercially insured or guaranteed by the Federal Family

Table of Contents

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Education Loan Program (FFELP). The underlying securities have contractual maturities which are generally greater than ten years. The auction rate securities are classified as available-for-sale and are recorded at fair value. Typically, the carrying value of auction rate securities approximates fair value due to the frequent resetting of the interest rates. In the accompanying Consolidated Balance Sheets, the Company has classified these investments as current assets under the caption "Marketable investments" and classified \$7.4 million of un-sold auction-rate securities as of February 29, 2008, under the caption "Marketable investments- long term portion" - see Note 12- Subsequent Event.

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 as of the balance sheet dates because of their generally short maturities. The fair value of marketable investments is based on quoted market prices.

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 banks in each of the international locations in which it operates. 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, believes that 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 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 including variable rate demand notes, auction rate securities and bonds of the U.S. Government, its agencies and municipalities, and in bonds of high-quality corporate issuers. By policy, the Company 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 technology 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.

Table of Contents

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 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, 2007, there have been no such impairments.

Warranty Obligations.

The Company provides standard one-year or two-year warranty coverage on its systems. 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 of the standard warranty coverage 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.

Table of Contents

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Revenue Recognition.

The Company recognizes distributor and non-distributor revenue in accordance with the SEC's Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition*. Product revenue, including upgrade revenue, and revenue from Titan hand piece 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;

The remaining obligations are insignificant; and

Collectability is reasonably assured.

Transfer of title and risk of ownership 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. For sales transactions when collectability is not reasonably assured, the Company recognizes revenue upon receipt of cash payment. Sales to customers and distributors do not include any return or exchange rights. In addition the Company's distributor agreements obligate the distributor to pay the Company for the sale regardless of whether the distributor is able to resell the product. Shipping and handling charges are invoiced to customers based on the amount of products sold. Shipping and handling fees are recorded as revenue and the related expense as a component of cost of revenue.

The Company also offers customers extended service contracts. 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, 2007, 2006 and 2005 was \$9.1 million, \$5.9 million and \$3.9 million, respectively

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, 2007, 2006 and 2005 were \$2.1 million, \$1.5 million and \$1.2 million, 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 years ended December 31, 2007 and 2006 reflect the impact of SFAS 123(R). In accordance with the modified prospective transition method, the Company's consolidated financial statements for periods prior to the year ended December 31, 2006 have not been restated to reflect, and do not include, the

Edgar Filing: CUTERA INC - Form 10-K

impact of SFAS 123(R). 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

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

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 4 for a further discussion on stock-based compensation.

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 years ended December 31, 2007 and 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. With respect to Restricted Stock Units (RSUs) issued by the Company in 2005, the Company measures them based on the fair market values of the underlying stock on the dates of grant and recognizes the share-based compensation to expense using the straight-line method over the vesting period.

Upon the vesting of RSUs, stock is issued on the dates of vesting, net of the statutory withholding requirements to be paid by the Company on behalf of its employees. As a result, the actual number of shares issued is less than the actual number of RSUs vested. Furthermore, in accordance with SFAS 123(R), the liability for withholding amounts to be paid by the Company is recorded as a reduction to additional paid-in capital when paid.

In compliance with SFAS 123R, the Company included as part of its cash flows from financing activities the benefits of tax deductions in excess of the tax-effected compensation of the related stock-based awards for the options exercised and RSUs vested during the years ended December 31, 2007 and 2006, whereas the excess tax benefits previously generated in 2005 under the then applicable accounting rules, are reported as a cash flow from operating activities. Total cash flow remains unchanged from what would have been reported under prior accounting rules. During the year ended December 31, 2007 and 2006, the amount of cash received from exercise of stock options was \$4.1 million and \$4.4 million, respectively, and the total direct tax benefit realized, including the excess tax benefit, from stock based award activity was \$4.2 million and \$1.8 million, respectively. The Company elected to account for the indirect effects of stock-based awards primarily the research and development tax credit through the statement of operations.

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 and was \$0, \$0 and \$262,000 for the year ended December 31, 2007, 2006 and 2005, respectively

Income Taxes.

The Company accounts for income taxes under the liability method in accordance with SFAS No. 109, *Accounting for Income Taxes*, which requires that deferred tax assets and liabilities be recognized using

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

enacted statutory 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.

In addition, effective January 1, 2007, the Company adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement No. 109*, or FIN 48, which requires the Company to calculate tax liabilities dealing with uncertainties in the application of complex tax regulations and recognizes liabilities for anticipated tax audit issues in the U.S. and other tax jurisdictions pursuant to FIN 48. Under FIN 48, the impact of an uncertain income tax position on income tax expense must be recognized at the largest amount that is more-likely-than-not to be sustained. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. The Company has provided taxes and related interest and penalties due for potential adjustments that may result from examinations of open U.S. Federal, state and foreign tax years. If the Company ultimately determines that payment of these amounts are not more-likely-than-not, 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 gains and losses 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, 2007. 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, 2007.

Recent Accounting Pronouncements.

In September 2006, the Financial Accounting Standards Board (FASB) issued SFAS No. 157, *Fair Value Measurements* (SFAS 157), which defines fair value, establishes guidelines for measuring fair value and expands disclosures regarding fair value measurements. SFAS 157 does not require any new fair value measurements but rather eliminates inconsistencies in guidance found in various prior accounting pronouncements. SFAS 157 is effective for the Company beginning January 1, 2008. The Company is currently evaluating the impact of SFAS 157 on its consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159). SFAS 159 permits companies to choose to measure certain financial instruments and certain other items at fair value. The standard requires that unrealized gains and losses on items for which the fair

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

value option has been elected be reported in earnings. SFAS 159 is effective for the Company beginning January 1, 2008. The Company is currently evaluating the impact that SFAS 159 will have on its consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141R, *Business Combinations*, (SFAS 141R). This issuance retains the fundamental requirements in SFAS 141 that the acquisition method of accounting (which SFAS 141 called the purchase method) be used for all business combinations and for an acquirer to be identified for each business combination. SFAS 141R defines the acquirer as the entity that obtains control of one or more businesses in the business combination and establishes the acquisition date as the date that the acquirer achieves control. SFAS 141R is effective for the Company beginning January 1, 2009. Though this pronouncement is not expected to have an effect on the Company's consolidated financial position, annual results of operations or cash flows, if it were to acquire another entity, it would be required to account for it in accordance with this pronouncement.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements*, (SFAS 160). This issuance amends Accounting Research Bulletin 51 to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. SFAS 160 clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. SFAS 160 is effective for the Company beginning January 1, 2009. Though this pronouncement is not expected to have an effect on the Company's consolidated financial position, annual results of operations or cash flows, if it were to acquire another entity, it would be required to account for it in accordance with this pronouncement.

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.

| Security Description | December 31, 2007 | | | Fair Market Value |
|--|-------------------|------------------------|-------------------|-------------------|
| | Amortized Cost | Gross Unrealized Gains | Unrealized Losses | |
| Checking and money market funds | \$ 11,054 | \$ | \$ | \$ 11,054 |
| U.S. government agencies and municipal securities (Marketable investments) | 95,749 | 190 | | 95,939 |
| | \$ 106,803 | \$ 190 | \$ | \$ 106,993 |

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

As of December 31, 2007, the Company had \$21.5 million invested in auction rate securities, of which \$7.4 million was classified under the caption of "Marketable investments- long term portion" in the accompanying Consolidated Balance Sheet. These auction rate securities were rated AAA by a major credit rating agency, and are guaranteed by U.S. federal agencies or commercial insurance carriers. See note 12- Subsequent event.

| Security Description | Amortized Cost | December 31, 2006 | | Fair Market Value |
|---|-------------------|------------------------------|----------------------|-------------------------|
| | | Gross Unrealized Gains | Unrealized Losses | |
| Checking and money market funds | \$ 11,800 | \$ | \$ | \$ 11,800 |
| U.S. government agencies and municipal securities (Marketable investments) | 96,343 | | (58) | 96,285 |
| | \$ 108,143 | \$ | \$ (58) | \$ 108,085 |

The contractual maturities of cash, cash equivalents and marketable-investments as of December 31, 2007, are as follows (in thousands):

| December 31, 2007 | Amount |
|------------------------------|------------|
| Due in less than one year | \$ 52,667 |
| Due in 1 to 3 years | 14,651 |
| Due in 3 to 5 years | |
| Due in 5 to 10 years | |
| Due in greater than 10 years | 39,675 |
| | \$ 106,993 |

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, 2007 and 2006, one customer accounted for 35% and 28% of the Company's total accounts receivable balance, respectively.

Inventories:

Inventories consist of the following (in thousands):

| | December 31, | |
|----------------|--------------|----------|
| | 2007 | 2006 |
| Raw materials | \$ 3,313 | \$ 2,816 |
| Finished goods | 4,220 | 2,404 |

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

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

| | December 31, | |
|------------------|--------------|----------|
| | 2007 | 2006 |
| Tax receivable | \$ 227 | \$ 1,739 |
| Prepaid expenses | 900 | 698 |
| Deposits | 828 | 265 |
| | \$ 1,955 | \$ 2,702 |

Property and Equipment, net:

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

| | December 31, | |
|---|--------------|----------|
| | 2007 | 2006 |
| Leasehold improvements | \$ 152 | \$ 140 |
| Office equipment and furniture | 2,541 | 1,926 |
| Machinery and equipment | 1,987 | 1,663 |
| | 4,680 | 3,729 |
| Less: Accumulated depreciation and amortization | (3,319) | (2,700) |
| | \$ 1,361 | \$ 1,029 |

Depreciation and amortization expense related to property and equipment was \$674,000, \$628,000 and \$594,000 for the years ended December 31, 2007, 2006 and 2005, respectively.

Intangible Assets:

Intangible assets were 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, 2007 and 2006 were as follows:

| | Gross Carrying Amount | Accumulated Amortization Amount | Net Amount |
|---|-----------------------------|---------------------------------------|---------------|
| December 31, 2007 (in thousands) | | | |
| Patent sublicense | \$ 1,218 | \$ 241 | \$ 977 |
| Technology sublicense | 538 | 302 | 236 |
| Other intangibles | 185 | 171 | 14 |

Edgar Filing: CUTERA INC - Form 10-K

| | | | |
|---|----------|--------|----------|
| Total | \$ 1,941 | \$ 714 | \$ 1,227 |
| 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 |

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

For the year ended December 31, 2007, 2006 and 2005, amortization expense for intangible assets was \$239,000, \$241,000 and \$95,000, respectively.

Based on intangible assets recorded at December 31, 2007, 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, | Amount |
|---------------------------------|-----------------|
| 2008 | 202 |
| 2009 | 196 |
| 2010 | 192 |
| 2011 | 192 |
| 2012 | 158 |
| 2013 and thereafter | 287 |
| Total | \$ 1,227 |

Accrued Liabilities:

Accrued liabilities consist of the following (in thousands):

| | December 31, | |
|------------------------------|---------------------|------------------|
| | 2007 | 2006 |
| Payroll and related expenses | \$ 5,547 | \$ 5,101 |
| Warranty | 2,725 | 3,055 |
| Royalty | 1,047 | 1,304 |
| Professional fees | 328 | 202 |
| Income tax payable | 1,134 | 785 |
| Sales and marketing accruals | 588 | 698 |
| Sales tax | 809 | 1,107 |
| Customer deposits | 208 | 781 |
| Other | 1,201 | 642 |
| | \$ 13,587 | \$ 13,675 |

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, Canada, France, 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 provides a warranty with its products, depending on the type of product. After the original 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, | |
|---|----------------------------|----------|
| | 2007 | 2006 |
| Balance at beginning of year | \$ 3,055 | \$ 2,043 |
| Add: Accruals for warranties issued during the year | 5,087 | 5,552 |
| Less: Settlements made during the year | (5,417) | (4,540) |
| Balance at end of year | \$ 2,725 | \$ 3,055 |

Deferred Service Contract Revenue (in thousands):

| | Year Ended December 31, | |
|------------------------------|----------------------------|----------|
| | 2007 | 2006 |
| Balance at beginning of year | \$ 6,652 | \$ 3,117 |
| Add: Payments received | 10,498 | 7,455 |
| Less: Revenue recognized | (6,586) | (3,920) |
| Balance at end of year | \$ 10,564 | \$ 6,652 |

Costs incurred under service contracts during the years ended December 31, 2007, 2006 and 2005 amounted to \$2.4 million, \$1.6 million and \$1.1 million, respectively, and are recognized as incurred.

NOTE 4 STOCKHOLDERS EQUITY, STOCK PLANS AND STOCK-BASED COMPENSATION EXPENSE:**Stock Option Plans.**

As of December 31, 2007, 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 258,788 reserved shares to the 2004 ESPP on January 1, 2007. 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 the offering period. The Company issued 42,868 and 40,651 shares of common stock under the 2004 ESPP in fiscal years 2007 and 2006, respectively. At December 31, 2007, 745,124 shares remained available for future issuance.

Table of Contents

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 originally 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.

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 on the first day of such year; (b) 2 million shares; or, (c) an amount determined by the Board of Directors. On January 1, 2007, the Company added 646,969 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 to employees 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. In June 2007, the Company granted options to non-employee Board of Directors that become exercisable 100% on the first anniversary of the vesting commencement date. Unvested options that have been exercised are subject to repurchase upon termination of the holder's status as an employee, director or consultant. The contractual term of the options granted 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 RSUs to certain members of the Company's management. The RSUs generally vest in four equal, annual installments on the anniversaries of the date of grant. The Company measured the fair market values of the underlying stock on the dates of grant and recognizes the share-based compensation expense using the straight-line method over the vesting period.

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 | Weighted- Average Exercise Price | Options Outstanding Weighted- Average Remaining Contractual Life (in years) | Aggregate Intrinsic Value (in \$ millions)* |
|---|----------------------------------|------------------------|---|---|--|
| Balances, December 31, 2006 | 1,682,746 | 2,985,531 | \$ 10.16 | | |
| Additional shares reserved | 646,969 | | | | |
| Options granted | (397,500) | 397,500 | \$ 24.68 | | |
| Options exercised | | (854,147) | \$ 3.89 | | |
| Options cancelled or forfeited | 111,309 | (111,309) | \$ 21.94 | | |
| Restricted stock units cancelled or forfeited | 4,125 | | | | |
| Balances, December 31, 2007 | 2,047,649 | 2,417,575 | \$ 14.22 | 5.03 | \$ 12.6 |
| Exercisable as of December 31, 2007 | | 1,494,100 | \$ 8.99 | 4.44 | \$ 12.3 |

* Based on the closing stock price of \$15.70 for the Company's common stock on December 31, 2007, the last day of trading for the 2007 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 2007 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, 2007. 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, 2007 and 2006 was \$23.9 million and \$13.5 million, respectively.

The options outstanding and exercisable at December 31, 2007 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 | 433,333 | 1.70 | 433,333 | \$ 0.10 |
| \$ 0.50 \$ 4.25 | 340,690 | 4.12 | 340,690 | 2.89 |
| \$ 5.50 \$13.80 | 313,736 | 6.14 | 266,322 | 11.75 |
| \$14.00 \$17.99 | 262,804 | 6.84 | 167,076 | 15.41 |
| \$20.25 \$22.53 | 223,623 | 7.47 | 87,819 | 20.25 |
| \$23.75 \$23.75 | 311,535 | 5.38 | 118,922 | 23.75 |
| \$24.46 \$24.46 | 283,000 | 4.44 | | |

Edgar Filing: CUTERA INC - Form 10-K

| | | | | | | |
|---------|---------|--|-----------|------|-----------|---------|
| \$24.60 | \$26.32 | | 206,562 | 7.18 | 65,354 | 26.04 |
| \$27.36 | \$27.36 | | 32,292 | 4.53 | 14,584 | 27.36 |
| \$34.45 | \$34.45 | | 10,000 | 6.69 | | |
| \$ 0.10 | \$34.45 | | 2,417,575 | 5.03 | 1,494,100 | \$ 8.99 |

As of December 31, 2006, there were 1,864,435 outstanding options that were exercisable at a weighted average exercise price of \$4.30.

Table of Contents

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Restricted Stock Unit Awards

Information with respect to outstanding restricted stock unit activity is as follows:

| | Number of Shares | Weighted Average Grant- Date Fair Value | Aggregate Fair Value ⁽¹⁾ (in thousands) |
|---|------------------------|---|---|
| Outstanding at December 31, 2006 | 46,686 | \$ 20.25 | |
| Granted | | \$ | |
| Vested ⁽²⁾ | (15,189) | \$ 20.25 | \$ 398 ⁽³⁾ |
| Forfeited | (4,125) | \$ 20.25 | |
| Outstanding at December 31, 2007 | 27,372 | \$ 20.25 | |

(1) Represents the value of the Company's stock on the date that the restricted stock units vest.

(2) The number of restricted stock units vested includes shares that the Company withheld on behalf of the employees to satisfy the statutory tax withholding requirements.

(3) On the grant date, the fair value for these vested awards was \$308,000.

Stock-Based Compensation.

Effective January 1, 2006, the Company adopted the provisions of SFAS No. 123(R), as discussed in Note 1: Summary of Significant Accounting Policies. Total fair value of vested and expensed stock options, restricted stock units and ESPP shares for the twelve months ended December 31, 2007 was \$5.6 million offset by the related tax benefit of \$2.0 million. The Company issues new shares upon the exercise of options, restricted stock units and ESPP shares.

Total fair value of vested and expensed stock options, restricted stock units and ESPP shares for the year ended December 31, 2007 and 2006 was as follows:

| | Year Ended December 31, | |
|--|----------------------------|----------|
| | 2007 | 2006 |
| Stock Options | \$ 4,982 | \$ 3,885 |
| RSUs | 294 | 326 |
| ESPP | 351 | 331 |
| Total share-based compensation expense | 5,627 | 4,542 |
| Tax effect on share-based compensation at the marginal tax rates | (1,963) | (1,568) |

Edgar Filing: CUTERA INC - Form 10-K

| | | |
|--------------------------------------|----------|----------|
| Net share-based compensation expense | \$ 3,664 | \$ 2,974 |
|--------------------------------------|----------|----------|

As of December 31, 2007, the unrecognized compensation cost, net of expected forfeitures, related to stock options, RSUs and ESPP was \$7.7 million, \$382,000 and \$100,000, which will be recognized using the straight-line attribution method over an estimated weighted-average amortization period of 2.4 years, 1.4 years and 0.3 years, respectively.

Table of Contents**CUTERA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****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 |
|--|---|
| Net income, as reported | \$ 13,801 |
| Add: Stock-based employee compensation expense included in reported net income, net of related tax effects | 857 |
| Less: Total stock-based employee compensation determined under fair-valued based method for all awards, net of related tax effects | (2,126) |
| Pro forma net income | \$ 12,532 |
| Net income per share: | |
| Basic: as reported | \$ 1.20 |
| Basic: pro forma | \$ 1.09 |
| Diluted: as reported | \$ 1.00 |
| Diluted: pro forma | \$ 0.91 |

Valuation Assumptions and Fair Value of Stock Option and ESPP Grants.

For share-based compensation recognized in 2007 and 2006 as a result of the adoption of SFAS No. 123(R), as well as pro forma disclosures according to the original provisions of SFAS No. 123 for periods prior to the adoption of SFAS No. 123(R), the Company uses the Black-Scholes option pricing model to estimate the fair value of options granted under its equity incentive plans and rights to acquire stock granted under its employee stock purchase plan. The Company based the weighted average estimated values of employee stock option grants and rights granted under the employee stock purchase plan, as well as the weighted average assumptions used in calculating these values, on estimates at the date of grant, as follows:

| | Stock Options | | | Stock Purchase Plan | | |
|--|----------------------|-------------|----------------------------|----------------------------|-------------|----------------------------|
| | 2007 | 2006 | 2005 ⁽¹⁾ | 2007 | 2006 | 2005 ⁽¹⁾ |
| Estimated fair value of grants during the year | \$ 11.42 | \$ 14.16 | \$ 9.44 | \$ 9.20 | \$ 8.97 | \$ 6.08 |
| Expected life (in years) | 3.76 | 5.05 | 3.81 | 0.62 | 0.75 | 0.75 |

Edgar Filing: CUTERA INC - Form 10-K

| | | | | | | |
|-------------------------|------|------|------|------|------|------|
| Risk-free interest rate | 4.9% | 4.9% | 3.9% | 4.7% | 4.4% | 3.5% |
| Volatility | 56% | 64% | 67% | 59% | 58% | 51% |
| Dividend yield | % | % | % | % | % | % |

(1) Estimated values and assumptions used in calculating fair value prior to the adoption of SFAS No. 123(R).

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

The Company bases the expected volatility on implied volatility, because it has determined that implied volatility is more reflective of market conditions and a better indicator of expected volatility, than its limited historical volatility since the Initial Public Offering, or IPO, of its common stock. The Company uses the simplified method of calculating expected life described in SAB 107, due to significant differences in the vesting and contractual life of current option grants compared to its historical grants, as well as limited data of historical exercise patterns since the IPO of its common stock.

NOTE 5: COMMON STOCK REPURCHASES*Common Stock Repurchase Program*

On May 15, 2007, the Company's Board of Directors approved a stock repurchase program under which the Company was authorized to use up to \$25 million over a period of up to one year to repurchase shares of its common stock. Under this program, the Company entered into a pre-arranged Rule 10b5-1 trading plan with a broker to facilitate the repurchase of its shares. Acquisitions were made in accordance with the trading plan, at prevailing prices, subject to market conditions and other factors. This repurchase program terminated on August 31, 2007, when the Company had acquired \$25 million worth of shares of its common stock. In the year ended December 31, 2007, the Company repurchased 1,107,856 shares of its common stock at an average price of \$22.57. The stock repurchased under the plan was cancelled and returned to authorized share status.

Restricted Stock Unit Withholdings

The Company issues restricted stock units as part of its equity incentive plans, which are described more fully in Note 4 Stockholders' Equity, Stock Plans and Stock-Based Compensation Expense. For the majority of restricted stock units granted, the number of shares issued on the date the restricted stock units vest is net of the statutory withholding requirements paid on behalf of the employees. During 2007, the Company withheld 5,288 shares of common stock to satisfy approximately \$139,000 of its employees' tax obligations. The Company paid this amount in cash to the appropriate taxing authorities. Although shares withheld are not issued, they are treated as common stock repurchases for accounting and disclosure purposes, as they reduce the number of shares that would have been issued upon vesting.

NOTE 6 INCOME TAXES:

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

| | 2007 | December 31, 2006 | 2005 |
|-----------|----------|----------------------|----------|
| Current: | | | |
| Federal | \$ 4,904 | \$ 1,024 | \$ 4,393 |
| State | 626 | 176 | 433 |
| Foreign | 260 | 382 | 231 |
| | 5,790 | 1,582 | 5,057 |
| Deferred: | | | |
| Federal | (2,052) | (2,457) | (103) |
| State | (416) | (309) | (81) |
| Foreign | (62) | | 32 |
| | (2,530) | (2,766) | (152) |

Edgar Filing: CUTERA INC - Form 10-K

| | | | |
|--------------------------------------|----------|------------|----------|
| Provision (benefit) for income taxes | \$ 3,260 | \$ (1,184) | \$ 4,905 |
|--------------------------------------|----------|------------|----------|

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

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

| | December 31, | |
|-------------------------------|---------------------|-----------------|
| | 2007 | 2006 |
| Credits | \$ 857 | \$ 1,216 |
| Accrued warranty | 1,075 | 1,204 |
| Other accruals and reserves | 3,450 | 1,912 |
| Stock-based compensation | 2,780 | 1,460 |
| Other | 419 | |
| Foreign | 130 | |
| Deferred tax asset | 8,711 | 5,792 |
| Depreciation and amortization | 181 | (60) |
| Net deferred tax asset | \$ 8,892 | \$ 5,732 |

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

| | Year Ended December 31, | | |
|---|--------------------------------|------------------|---------------|
| | 2007 | 2006 | 2005 |
| Tax at federal statutory rate | 35.00% | 35.00% | 35.00% |
| State, net of federal benefit | 4.58 | 4.98 | 4.48 |
| Meals and entertainment | 0.92 | 11.80 | 0.45 |
| Benefit for research and development credit | (10.62) | (109.81) | (7.89) |
| Stock-based compensation | 1.90 | 19.89 | (3.17) |
| Tax-exempt interest | (9.61) | (112.08) | (3.26) |
| Other | 1.51 | 24.07 | 0.61 |
| Provision (benefit) for income taxes | 23.68% | (126.15)% | 26.22% |

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 \$1.7 million at December 31, 2007, 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, 2007, the Company had cumulative net operating loss carry-forwards for federal and state income tax reporting purposes of approximately \$1.2 million and \$3.0 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 \$525,000 as a credit to additional paid in capital as and when such excess tax benefits are ultimately realized.

As of December 31, 2007, the Company had cumulative carry-forwards for research and development credits for federal and state income tax purposes of approximately \$1.6 and \$2.1 million, respectively. These federal research and development tax credits expire through the year

2024. The state research and development credits

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

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 \$767,000 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 \$2.4 million as a credit to additional paid in capital as and when such excess tax benefits are ultimately realized.

Uncertain Tax Positions

Effective January 1, 2007, the Company adopted the provisions of FIN 48. This Interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS No. 109 and prescribes a recognition threshold of more-likely-than-not to be sustained upon examination. The Company recorded the cumulative effect of applying the provisions of the Interpretation as an adjustment to the Company's retained earnings balance as of January 1, 2007. The total amount of unrecognized tax benefits as of the date of adoption was approximately \$1 million. The Company reduced its January 1, 2007 retained earnings by approximately \$91,000. Upon adoption of FIN 48, the Company's policy to include interest and penalties related to gross unrecognized tax benefits within the provision for income taxes did not change.

The following table summarizes the activity related to the Company's gross unrecognized tax benefits from January 1, 2007 to December 31, 2007 (in thousands):

| | |
|--|-----------------|
| Balance as of January 1, 2007 | \$ 1,067 |
| Increases related to prior year tax positions | 588 |
| Decreases related to prior year tax positions | (59) |
| Increases related to current year tax positions | |
| Decreases related to settlements with taxing authorities | |
| Decreases related to lapsing of statute of limitations | (96) |
| Balance as of December 31, 2007 | \$ 1,500 |

The Company's total unrecognized tax benefits that, if recognized, would affect its effective tax rate were \$542,000 and \$664,000 as of January 1, 2007 and December 31, 2007. As of December 31, 2007, the Company had accrued \$109,000 for payment of interest. Interest included in the provision for income taxes was not material in all the periods presented. The Company has not accrued any penalties related to its uncertain tax positions as it believes that it is more likely than not that there will not be any assessment of penalties. The Company expects that the amount of unrecognized tax benefits will change by approximately \$300,000 within the next 12 months due the expiration of statutes. In general, the Company's income tax returns are subject to examination by U.S. federal tax authorities for tax years 2004 onward and by various U.S. state and foreign tax authorities for tax years 2003 onward. The Company is currently under audit by the Internal Revenue Service for the year ended December 31, 2005 and by some other state tax authorities for other year(s). The Company has reserved for potential adjustments to its provision for income taxes that may result from examinations by, or any negotiated agreements with, these tax authorities, and it believes that the final outcome of these examinations or agreements will not have a material affect on its results of operations. If events occur which indicate payment of these amounts is unnecessary, the reversal of the liabilities would result in the recognition of tax benefits in the period it determines the liabilities are no longer necessary. If the Company's estimates of the federal, state, and foreign income tax liabilities are less than the ultimate assessment, a further charge to expense would result.

Table of Contents**CUTERA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****NOTE 7 NET INCOME PER SHARE:**

Basic net income per share is calculated by dividing net income 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 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, | | |
|---|-------------------------|----------|-----------|
| | 2007 | 2006 | 2005 |
| Numerator: | | | |
| Net income- Basic and Diluted | \$ 10,504 | \$ 2,123 | \$ 13,801 |
| Denominator: | | | |
| Weighted-average number of common shares outstanding used in computing basic net income per share | 13,153 | 12,558 | 11,535 |
| Dilutive potential common shares used in computing diluted net income per share | 1,075 | 1,720 | 2,329 |
| Total weighted-average number of shares used in computing diluted net income per share | 14,228 | 14,278 | 13,864 |

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 share for the periods presented because including them would have had an anti-dilutive effect (in thousands):

| | Year Ended December 31, | | |
|--------------------------------------|-------------------------|------|------|
| | 2007 | 2006 | 2005 |
| Common stock options and ESPP shares | 829 | 621 | 7 |

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, 2007, 2006 and 2005, the Company made discretionary contributions of \$597,000, \$557,000 and \$420,000, 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, 2007. The Company's contributions for its foreign employees were not material in each of the years ended December 31, 2007, 2006 and 2005.

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- and other light-based systems for physicians and other qualified 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 the product is delivered.

For the years ended December 31, 2007, 2006 and 2005, the Company had one customer that represented 14%, 15% and 16%, respectively, of net revenue.

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

| | 2007 | 2006 | 2005 |
|---|------------|------------|-----------|
| Revenue mix by geography: | | | |
| United States | \$ 64,084 | \$ 69,895 | \$ 54,506 |
| Asia | 17,898 | 15,781 | 13,220 |
| Europe | 9,258 | 7,239 | 4,351 |
| Rest of the world | 10,486 | 7,777 | 3,543 |
| Consolidated total | \$ 101,726 | \$ 100,692 | \$ 75,620 |
| Revenue mix by product category: | | | |
| Products | \$ 74,502 | \$ 84,695 | \$ 63,349 |
| Product upgrades | 13,342 | 6,006 | 6,630 |
| Service | 9,128 | 5,890 | 3,881 |
| Titan hand piece refills | 4,754 | 4,101 | 1,760 |
| Consolidated total | \$ 101,726 | \$ 100,692 | \$ 75,620 |

NOTE 10 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 5,790 square feet, 3,100 square feet and 1,240 square feet, in Japan, Switzerland and France, respectively. The leases in Japan expire in May 2008, May 2009, and July 2010, respectively, and the leases in, Switzerland and France expire in July 2008 and December 2009, respectively.

As of December 31, 2007, 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):

Edgar Filing: CUTERA INC - Form 10-K

| Year Ending December 31, | Amount |
|---------------------------------------|-----------------|
| 2008 | \$ 1,198 |
| 2009 | 1,210 |
| 2010 | 1,232 |
| 2011 | 1,309 |
| 2012 | 1,427 |
| 2013 and thereafter | 1,545 |
| Future minimum rental payments | \$ 7,921 |

Table of Contents

CUTERA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

For the years ended December 31, 2007, 2006 and 2005, gross rent expense was \$1.5 million, \$1.3 million and \$1.3 million, respectively.

Income Taxes

The Company is currently under audit by the Internal Revenue Service for the year ended December 31, 2005 and other state tax authorities. It has reserved for potential adjustments to its provision for income taxes that may result from examinations by, or any negotiated agreements with, these tax authorities, and it believes that the final outcome of these examinations or agreements will not have a material affect on its results of operations. If events occur which indicate payment of these amounts is unnecessary, the reversal of the liabilities would result in the recognition of tax benefits in the period the Company determines the liabilities are no longer necessary. If the Company's estimates of the federal, state, and foreign income tax liabilities are less than the ultimate assessment, a further charge to expense would result.

Purchase Commitments.

The Company maintains certain open inventory purchase commitments with its suppliers to ensure a smooth and continuous supply for key components. The Company's liability in these purchase commitments is generally restricted to a forecasted time-horizon as agreed between the parties. These forecasted time-horizons can vary among different suppliers. The Company's open inventory purchase commitments were not material at December 31, 2007.

Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations, warranties, and indemnification obligations. For example, the Company has entered into indemnification agreements with each of its directors and executive officers. In 2007, two of the Company's executive officers were named as defendants in securities class action litigation see Note 11 Litigation and Litigation Settlement. The Company's exposure under its various indemnification obligations, including those under the indemnification agreements with its directors and executive officers, is unknown since the outcome of that securities litigation is unpredictable and the amount that could be payable thereunder is not reasonably estimable, and since other indemnification obligations involve future claims that may be made against the Company. The Company has not accrued or paid any amounts for any such indemnification obligations. However, the Company may record charges in the future as a result of these potential indemnification obligations, including those related to the securities class action litigation.

NOTE 11 LITIGATION AND LITIGATION SETTLEMENT:

Litigation

Two securities class action lawsuits were filed against the Company and two of its executive officers in April 2007 and May 2007, respectively, in the U.S. District Court for the Northern District of California following declines in the Company's stock price. The plaintiffs claim to represent purchasers of the Company's common stock from January 31, 2007 through May 7, 2007. The complaints generally allege that materially false statements and omissions were made regarding the Company's financial prospects, and seek unspecified monetary damages. On November 1, 2007, the Court ordered the two cases consolidated. On December 17, 2007, the plaintiffs filed a consolidated, amended complaint, and on January 31, 2008, the Company filed a motion to dismiss that complaint. A hearing on the motion is scheduled with the Court for May 1, 2008. The Company retains director and officer liability insurance, though there is no assurance that such insurance will cover the claims that are made or will insure the Company fully for all losses on covered claims. The Company intends to defend this case vigorously. Since the outcome of this litigation is unpredictable, not reasonably estimable, and

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

since the Company believes that a significant adverse result is not probable, no expense has been recorded with respect to the contingent liability associated with this matter.

A Telephone Consumer Protection Act, or TCPA, class action lawsuit was filed against the Company in January 2008 in the Illinois Circuit Court, Cook County, by Bridgeport Pain Control Center, LTD., seeking monetary damages, injunctive relief, costs and other relief. The complaint alleges that the Company violated the TCPA by sending unsolicited advertisements by facsimile to the plaintiff and other recipients without the prior express invitation or permission of the recipients. Under the TCPA, recipients of unsolicited facsimile advertisements may be entitled to damages of \$500 per violation for inadvertent violations and \$1,500 per violation for knowing or willful violations. On February 22, 2008, the Company removed the case to federal court in the Northern District of Illinois, and filed its response to the complaint on February 29, 2008. Although the Company is continuing to investigate the number of facsimiles transmitted during the period for which the plaintiff in the lawsuit seeks class certification and the number of these facsimiles that were unsolicited within the meaning of the TCPA, the Company expects that the number of unsolicited facsimiles could be large. The Company intends to defend this case vigorously, including the plaintiff's allegations seeking class certification. Since the outcome of this litigation is unpredictable, and since the amount that could be payable is not reasonably estimable, the Company has not recorded any expense with respect to the contingent liability associated with this matter. However, the Company may determine in the future that an accrual is required, and it may be required to pay damages in respect of this lawsuit, any of which could materially and adversely affect their results of operations, cash flows and financial condition. The Company has not tendered this lawsuit to its insurance carrier, may not do so, and, even if it does so, coverage may be disputed. Even if coverage is determined to apply, since the potential liability under this lawsuit could be substantial, the insurance coverage may not be sufficient to satisfy any damages or expenses that the Company may be required to pay.

Litigation Settlement

In June 2006, the Company settled its patent litigation with Palomar Medical Technologies and Massachusetts General Hospital- with Palomar granting the Company an irrevocable sublicense to the subject patents. In connection with this settlement, the Company recorded a litigation settlement charge of \$18.9 million relating to past royalties, interest and legal settlement costs and \$1.2 million as an intangible asset representing the value of the on-going sublicense agreement which expires in February 2015.

Other Legal Matters

In addition to the foregoing lawsuits, the Company is named from time to time as a party to product liability and contractual lawsuits in the normal course of its business. As of December 31, 2007, the Company was not a party to any material pending litigation.

NOTE 12 SUBSEQUENT EVENT

During the first quarter of fiscal 2008, the Company continued to hold auction rate securities in its long term investment portfolio, as described in footnote 2 to these financial statements. On February 29, 2008 the Company had \$13.6 million invested in auction rate securities, of which \$9.6 million failed to settle at auction. All auction rate securities owned by the Company on February 29, 2008 are backed by federal student loans which are guaranteed by the Federal Family Educational Loan Program (FFELP) and continue to carry AAA ratings. The Company continues to earn interest on the investments that failed to settle at auction, at the maximum contractual rate. As of December 31, 2007 the carrying value of these investments approximated fair value based on successful auctions, preceding and subsequent to year-end. The Company will continue to monitor the value of its auction rate securities each reporting period for a possible impairment if a decline in fair value occurs.

Table of Contents**SUPPLEMENTARY FINANCIAL DATA (UNAUDITED)****(In thousands, except per share amounts)**

| Quarter ended: | Dec 31, 2007 | Sept 30, 2007 | June 30, 2007 | March 31, 2007 | Dec 31, 2006 | Sept 30, 2006 | June 30, 2006 | March 31, 2006 |
|---|-------------------------|--------------------------|--------------------------|---------------------------|-------------------------|--------------------------|--------------------------|---------------------------|
| Net revenue | \$ 26,453 | \$ 28,143 | \$ 23,873 | \$ 23,257 | \$ 30,481 | \$ 25,059 | \$ 24,395 | \$ 20,757 |
| Cost of revenue | 9,704 | 9,607 | 7,910 | 7,781 | 8,349 | 7,931 | 7,768 | 5,811 |
| Gross profit | 16,749 | 18,536 | 15,963 | 15,476 | 22,132 | 17,128 | 16,627 | 14,946 |
| Operating expenses: | | | | | | | | |
| Sales and marketing | 9,438 | 10,586 | 9,190 | 9,063 | 7,865 | 8,174 | 8,305 | 8,546 |
| Research and development | 1,735 | 1,764 | 1,923 | 1,747 | 1,935 | 1,679 | 1,552 | 1,307 |
| General and administrative | 2,725 | 3,078 | 2,900 | 3,018 | 3,578 | 2,992 | 4,248 | 4,375 |
| Litigation settlement | | | | | | 544 | 18,391 | |
| Total operating expense | 13,898 | 15,428 | 14,013 | 13,828 | 13,378 | 13,389 | 32,496 | 14,228 |
| Income (loss) from operations | 2,851 | 3,108 | 1,950 | 1,648 | 8,754 | 3,739 | (15,869) | 718 |
| Interest and other income, net | 1,001 | 1,096 | 1,108 | 1,002 | 981 | 829 | 830 | 956 |
| Income (loss) before income taxes | 3,852 | 4,204 | 3,058 | 2,650 | 9,735 | 4,568 | (15,039) | 1,674 |
| Provision (benefit) for income taxes | 229 | 1,112 | 1,024 | 895 | 2,620 | 1,618 | (5,990) | 567 |
| Net income (loss) | \$ 3,623 | \$ 3,092 | \$ 2,034 | \$ 1,755 | \$ 7,115 | \$ 2,950 | \$ (9,049) | \$ 1,107 |
| Net income (loss) per share basic | \$ 0.28 | \$ 0.24 | \$ 0.15 | \$ 0.13 | \$ 0.56 | \$ 0.23 | \$ (0.73) | \$ 0.09 |
| Net income (loss) per share diluted | \$ 0.27 | \$ 0.22 | \$ 0.14 | \$ 0.15 | \$ 0.50 | \$ 0.21 | \$ (0.73) | \$ 0.08 |
| Weight-average number of shares used in per share calculations: | | | | | | | | |
| Basic | 12,714 | 13,026 | 13,610 | 13,216 | 12,749 | 12,675 | 12,444 | 12,257 |
| Diluted | 13,561 | 13,970 | 14,666 | 14,629 | 14,346 | 14,238 | 12,444 | 14,174 |
| Cash, cash equivalents and marketable investments | \$ 106,993 | \$ 99,536 | \$ 115,415 | \$ 111,239 | \$ 108,085 | \$ 90,672 | \$ 81,965 | \$ 95,511 |

Table of Contents**SCHEDULE II****CUTERA, INC.****VALUATION AND QUALIFYING ACCOUNTS****(in thousands)****For the Year Ended December 31, 2007, 2006 and 2005**

| | Balance at Beginning of Year | Additions | Deductions | Balance at End of Year |
|--|---|------------------|-------------------|---------------------------------------|
| Allowance for doubtful accounts receivable | | | | |
| Year ended December 31, 2005 | \$ 487 | \$ 8 | \$ 318 | \$ 177 |
| Year ended December 31, 2006 | \$ 177 | \$ 221 | \$ 364 | \$ 34 |
| Year ended December 31, 2007 | \$ 34 | \$ 222 | \$ 247 | \$ 9 |
| Reserve for excess and obsolete inventories | | | | |
| Year ended December 31, 2005 | \$ 378 | \$ 905 | \$ 291 | \$ 992 |
| Year ended December 31, 2006 | \$ 992 | \$ 90 | \$ 231 | \$ 851 |
| Year ended December 31, 2007 | \$ 851 | \$ 279 | \$ 79 | \$ 1,051 |

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, 2007. The effectiveness of our internal control over financial reporting as of December 31, 2007 has been audited by PricewaterhouseCoopers LLP, an Independent Registered Public Accounting Firm, as stated in their report, which is included herein.

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

The Company has established that the 2008 Annual Meeting of Stockholders will be held at their principal executive offices located at 3240 Bayshore Blvd., Brisbane, CA 94005-1021 on June 12, 2008 at 10.00 a.m. and the record date for the purposes of voting in that meeting shall be April 18, 2008.

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 2008 Annual Meeting of Stockholders with the Securities and Exchange Commission within 120 days after the end of our fiscal year ended December 31, 2007.

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 ⁽⁵⁾ | 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 86). |
| 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.

Edgar Filing: CUTERA INC - Form 10-K

- (4) Incorporated by reference from our Quarterly Report on Form 10-Q filed on November 8, 2006.
- (5) Incorporated by reference from our 2006 Annual Report on Form 10-K filed on March 16, 2007.

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 13th day of March, 2008.

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 13, 2008 |
| <i>/s/</i> RONALD J. SANTILLI Ronald J. Santilli | Chief Financial Officer and Executive Vice President (Principal Financial and Accounting Officer) | March 13, 2008 |
| <i>/s/</i> DAVID A. GOLLNICK David A. Gollnick | Executive Vice President of Research and Development and Director | March 13, 2008 |
| David B. Apfelberg | Director | |
| <i>/s/</i> ANNETTE J. CAMPBELL-WHITE Annette J. Campbell-White | Director | March 13, 2008 |
| <i>/s/</i> MARK LORTZ Mark Lortz | Director | March 13, 2008 |
| <i>/s/</i> TIM O SHEA Tim O Shea | Director | March 13, 2008 |
| <i>/s/</i> JERRY P. WIDMAN | Director | March 13, 2008 |

Jerry P. Widman

86