

CUTERA INC  
Form 10-K  
March 16, 2009  
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, 2008

Commission file number: 000-50644

**Cutera, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**3240 Bayshore Blvd.**  
**Brisbane, California 94005**  
**(415) 657-5500**

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

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

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

<b>Title of Each Class</b>	<b>Name of Each Exchange on Which Registered</b>
<b>Common Stock, \$0.001 par value per share</b>	<b>The NASDAQ Stock Market, LLC</b>

**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, 2008 (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 \$73 million. For purposes of this disclosure, shares of common stock held by entities and individuals who own 5% or more of the outstanding common stock and shares of common stock held by each officer and director have been excluded in that such persons may be deemed to be affiliates as that term is defined under the Rules and Regulations of the Securities Exchange Act of 1934. This determination of affiliate status is not necessarily conclusive.

The number of shares of Registrant's common stock issued and outstanding as of February 28, 2009 was 13,287,768.

**DOCUMENTS INCORPORATED BY REFERENCE**

Part III incorporates by reference certain information from the registrant's definitive proxy statement for the 2009 Annual Meeting of Stockholders.

**Table of Contents****TABLE OF CONTENTS**

	Page
<b>PART I</b>	
Item 1. <u>Business</u>	3
Item 1A. <u>Risk Factors</u>	19
Item 1B. <u>Unresolved Staff Comments</u>	32
Item 2. <u>Properties</u>	32
Item 3. <u>Legal Proceedings</u>	32
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	33
<b>PART II</b>	
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>	53
Item 8. <u>Financial Statements and Supplementary Data</u>	55
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	86
Item 9A. <u>Controls and Procedures</u>	86
Item 9B. <u>Other Information</u>	87
<b>PART III</b>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	88
Item 11. <u>Executive Compensation</u>	88
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	88
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	88
Item 14. <u>Principal Accounting Fees and Services</u>	88
<b>PART IV</b>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	89

---

**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 other 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 practices 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 2007 there were nearly 10 million minimally-invasive aesthetic procedures performed, a 9% increase over 2006 and an 81% 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 44 to 62 in 2008, 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.

*Broader Base of Customers-* Managed care and government payer reimbursement restrictions in the United States, and similar payment related constraints outside the United States, may help motivate qualified practitioners from differing 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 core users such as dermatologists and plastic surgeons, many other non-core practitioners, such as gynecologists, family practitioners, primary care physicians, physicians offering aesthetic treatments in non-medical offices, and other qualified practitioners are offering 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 383,000 sclerotherapy procedures were performed in 2007.

*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, tighten skin 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



## **Table of Contents**

months to sustain their effect, thereby increasing the cost and inconvenience to patients. For example, the body absorbs Botox and collagen and patients require supplemental injections every three to six months to maintain the benefits of these treatments.

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 2007, 4.6 million injections of Botox and over 1.5 million injections of collagen and other soft-tissue fillers were administered, and 1.0 million chemical peels and over 890,000 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 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, pore size 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 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 and Pearl Fractional hand pieces, with proprietary YSGG technology, represent the first application of the 2790 nm wavelength for minimally-invasive cosmetic dermatology.

***Upgradeable Platform-*** We design our products to allow our customers to cost-effectively upgrade to our multi-application systems, which provide 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 laxity 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 and Pearl Fractional hand pieces include 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 goal 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 2008, we introduced Pearl Fractional a minimally invasive, 2790 nm YSGG laser for the fractional ablative market to be used for rejuvenation applications. 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-* Although the U.S. economy is currently in a recession, we believe that the U.S. market for aesthetic systems will continue to offer growth opportunities. In 2008, we restructured our U.S. direct sales force with the goals of managing expenses in line with our business, and improving productivity by retaining our key performers and expanding their sales territories. We also continued to leverage our relationship with PSS World Medical Shared Services, Inc., or PSS, a wholly-owned subsidiary of PSS World Medical. PSS operates medical supply distribution service centers with over 700 sales consultants 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, in 2008 we remained focused on building global brand-recognition by increased sales and marketing activities. In 2008, we increased our direct international sales force and ended the year with distributors in over 30 countries. We plan on continuing to manage our international direct sales employees, distributors and support staff to increase sales and strengthen customer relationships in the international markets.

*Maintaining a Broad Customer Base-* We believe there is growth opportunity in targeting our products to various market segments, including the core and non-core aesthetic practices. Dermatologists and plastic surgeons had generally been regarded as the core customers for laser and other light-based aesthetic equipment. However, due to increased consumer demand for aesthetic procedures, the development of safer and effective aesthetic equipment, and the attractive financial opportunities for practitioners, the customer base for aesthetic equipment expanded to non-core aesthetic practitioners, including gynecologists, primary care physicians, family practitioners, physicians offering aesthetic treatments in non-medical offices, and other qualified practitioners. Our goal is to continue marketing our products to a broad customer base, while maintaining a focus on the core 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 potentially 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 with their existing systems. In 2009, we plan on continuing to market upgrades to our installed base, including our Pearl and Pearl Fractional applications introduced in 2007 and 2008, respectively.

*Generating Revenue from Services and Refillable Hand Pieces-* Our Titan hand pieces and pulsed-light hand pieces are refillable products, which provide 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, Lines and Wrinkles:	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		
	Pearl	2007	d			x	x	
Pearl Fractional	2008	d				x		
Solera	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; d. 2790 nm YSGG laser

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

**Control Console**

Our control console includes a universal graphic user interface, control system software and high voltage electronics. All CoolGlide systems, and some models of the Xeo platform, include our laser module which consists of electronics, a visible aiming beam, a focusing lens, and an Nd:YAG and/or flashlamp 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 pieces 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 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**

***Pearl Fractional Hand Piece-*** The Pearl Fractional hand piece, introduced in 2008, also uses proprietary YSGG technology and is designed to treat wrinkles and deep dermal imperfections (although it is cleared in the United States by the FDA only for skin resurfacing and coagulation). This hand piece penetrates the deep dermis producing a series of microcolumns across the skin, which can result in the removal of damaged tissue and the production of new collagen. The Pearl Fractional 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.

### **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.

---

**Table of Contents**

***Texture; Lines and Wrinkles-*** 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 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.

When treating wrinkles and deep dermal imperfections with a Pearl Fractional 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 epidermis during the treatment. The energy delivered by the hand piece penetrates the deep dermis producing a series of microcolumns across the skin, which can result in the removal of damaged tissue and the production of new collagen. Treatment of the full face can usually be performed in less than an hour. Patients receive on average between one and three treatments at monthly intervals.

Our CE Mark allows us to market Pearl Fractional in the European Union, Australia and certain other countries outside the United States for the treatment of wrinkles and deep dermal imperfections. However, in the United States we have a 510(k) clearance for only skin resurfacing and coagulation.

***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.



## **Table of Contents**

Our CE Mark allows us to market 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, customers will receive fully-refurbished systems before sending their prior systems back to our headquarters.

### **Post-Warranty Service and Titan Hand Piece Refills**

Each Titan hand piece is a refillable product, 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 from our installed base.

### **Sales and Marketing**

In the United States we market and sell our products primarily through a direct sales organization. Generally, each direct sales employee is assigned a specific territory. As of December 31, 2008, we had a U.S. direct sales force of 35 employees. 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, 2008, 2007 and 2006, revenue from PSS was \$12.1 million, \$14.6 million and \$15.4 million, respectively. In January 2009, we had a company-wide reduction in force of approximately 10%, which included members of our direct sales force.

International sales are generally made through a direct international sales force of 31 employees, as well as a worldwide distributor network in over 30 countries as of December 31, 2008. As of December 31, 2008, we had direct sales offices in Australia, Canada, France, Japan, Spain, Switzerland and the United Kingdom. Our international revenue represented 50%, 37% and 31% of total revenue for the years ended December 31, 2008, 2007 and 2006, 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 introduce new products and applications that are innovative, that address the specific aesthetic procedures in demand, and that 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 also market to the non-core aesthetic practices consisting of gynecologists, primary care physicians, family practitioners, physicians offering aesthetic treatments in non-medical offices 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

## **Table of Contents**

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 our products to further enhance customer loyalty and uncover new sales opportunities.

### **Competition**

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

Competition among providers of laser and other light-based devices for the aesthetic market is characterized by extensive research efforts and innovative technology. 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. Some of these competitors have greater resources than we do or product applications for certain sub-markets in which we do not participate. 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 for our products.

### **Research and Development**

Our research and development group develops new products and applications and builds clinical support to address unmet or underserved market needs. As of December 31, 2008, our research and development activities were conducted by a staff of 22 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 2008, 2007 and 2006, were \$7.6 million, \$7.2 million and \$6.5 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, 2008, we had a 40-person global service department. Internationally, we provide direct service support through our Australia, Canada, France, Japan, Spain and Switzerland offices, and also through the network of distributors in over 30 countries and third-party service providers. We provide initial warranties on our products to cover parts and service and offer extended service plans that vary by the type of product and the level of service desired. Our standard warranty on system consoles 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 post-warranty service contract 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. 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. Our Titan hand pieces generally include a warranty for a set number of shots instead of for a period of time. We have invested substantial financial and management resources to develop a worldwide infrastructure to meet the service needs of our customers worldwide.

## **Table of Contents**

### **Manufacturing**

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

We purchase certain components and subassemblies from a limited number of suppliers. We have flexibility with our suppliers to adjust the number of components and subassemblies as well as the delivery schedules. The forecasts we use are based on historical demands and sales projections. Lead times for components and subassemblies may vary significantly depending on the size of the order, time required to fabricate and test the components or subassemblies, specific supplier requirements and current market demand for the components and subassemblies. We reduce the potential for disruption of supply by maintaining sufficient inventories and identifying additional suppliers. The time required to qualify new suppliers for some components, or to redesign them, could cause delays in our manufacturing. To date, we have not experienced significant delays in obtaining any of our components or subassemblies.

We use small quantities of common cleaning products in our manufacturing operations, which are lawfully disposed of through a normal waste management program. We do not forecast any material costs due to compliance with environmental laws or regulations.

We are required to manufacture our products in compliance with the FDA's Quality System Regulation, or QSR. The QSR covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. The FDA enforces the QSR through periodic unannounced inspections. Our single manufacturing facility located in Brisbane, CA, was inspected by the FDA in 2008. 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 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, 2008, we had eleven issued U.S. patents and twenty-eight 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 to these names and others in the United States and certain other countries. We intend to file for additional patents and trademarks to continue to strengthen our intellectual property rights.

We license certain patents from Palomar and pay ongoing royalties based on sales of applicable hair-removal products. The royalty rate on these products ranges from 3.75% to 7.50% of revenue. The patents are set to expire in February 2013 and February 2015. Our revenue from systems that do not include hair-removal capabilities (such as our Solera Titan) and revenue from service contracts are not subject to these royalties. In addition, in 2006 we capitalized \$1.2 million as an intangible asset representing the ongoing license for these patents, which is being amortized on a straight-line basis over their expected useful life of 9-10 years. We also have a technology sublicense purchased in 2002, and a trademark license which we purchased in 2007, which are being amortized over their expected useful lives of ten and two years, respectively.

## **Table of Contents**

Our employees and technical consultants are required to execute confidentiality agreements in connection with their employment and consulting relationships with us. We also require them to agree to disclose and assign to us all inventions conceived in connection with the relationship. We cannot provide any assurance that employees and consultants will abide by the confidentiality or assignability terms of their agreements. Despite measures taken to protect our intellectual property, unauthorized parties may copy aspects of our products or obtain and use information that we regard as proprietary.

### **Government Regulation**

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

Product design and development;

Product testing;

Product manufacturing;

Product safety;

Product labeling;

Product storage;

Recordkeeping;

Pre-market clearance or approval;

Advertising and promotion;

Production; and

Product sales and distribution.

### ***FDA's Pre-market Clearance and Approval Requirements***

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

current products are class II devices.

***510(k) Clearance Pathway***

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

	<b>Date Received:</b>
<b>FDA Marketing Clearances:</b>	
<b>Laser-based products:</b>	
- 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
<b>Pulsed-light technologies:</b>	
- treatment of pigmented lesions	March 2003
- hair removal and vascular treatments	March 2005
<b>Infrared Titan technology</b> 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
<b>Solera tabletop console:</b>	
- for use with the Titan hand piece	October 2004
- for use with our pulsed-light hand pieces	January 2005
<b>Pearl product for the treatment of wrinkles</b>	March 2007
<b>Pearl Fractional product for skin resurfacing and coagulation</b> <i>Pre-Market Approval (PMA) Pathway</i>	August 2008

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

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

***Product Modifications***

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

***Clinical Trials***

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

## **Table of Contents**

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

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

### ***Pervasive and Continuing Regulation***

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

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

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

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

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

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

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

---

**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, and in March 2006, we passed our ISO 13485 recertification audit.





---

## **Table of Contents**

### **Employees**

As of December 31, 2008, we had 244 employees, of which 101 were in sales and marketing, 55 in manufacturing operations, 40 in technical service, 22 in research and development and 26 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. In January 2009, we had a company-wide reduction in force of approximately 10%.

### **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 soon after they are filed with the SEC.

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

### **ITEM 1A. RISK FACTORS**

*We are in a difficult economic period, and the uncertainty in the economy may reduce customer demand for our products, cause potential customers to delay their purchase decisions and make it more difficult for some potential customers to obtain credit financing, all of which would adversely affect our business and may increase the volatility of our stock price.*

Current economic conditions are unstable and we are in a global recession. The general economic difficulties being experienced by our customers and the lack of availability of consumer credit for some of our customers are adversely affecting the market in which we operate. In times of economic uncertainty or recession, individuals often reduce the amount of money that they spend on discretionary items, including aesthetic procedures. This economic uncertainty may cause potential customers to delay their capital equipment purchase decisions, and may make it more difficult for some potential customers to obtain credit financing necessary to purchase our products or make timely payments to us, each of which can have a material adverse effect on our revenue, profitability and business and may increase the volatility of our stock price.

*We rely heavily on our sales professionals to market and sell our products worldwide. If we are unable to effectively train, retain and manage these employees, our ability to manage our business will be harmed, which would impair our future revenue and profitability.*

Our success largely depends on our ability to manage and improve the productivity levels of our sales professionals worldwide. Measures we implement in an effort to improve that productivity may not be successful. For example, in January 2009 we had a company-wide reduction of employees, including members of our direct sales force. Further, we restructured our sales commission program, and assigned some sales employees with new sales or management responsibilities. These measures may not improve productivity and may lead to reduced revenue and employee turnover, which could materially harm our business. If we experience significant levels of attrition or reductions in productivity among our sales professionals or our sales managers, our revenue and profitability may be adversely affected as a result.

*The initiatives that we are implementing in an effort to improve revenue and profitability could be unsuccessful, which could harm our business.*

In 2008, compared to 2007, our revenue decreased 18%, U.S. sales decreased 35% and international sales increased 11%. In an effort to improve our revenue and profitability, we have implemented several strategic

## **Table of Contents**

initiatives focusing on our worldwide sales and marketing infrastructure, product introductions and expense management. For example, in January 2009, we had a company-wide reduction in force of approximately 10% and we also reduced or eliminated certain employee benefit programs in an effort to manage expenses in line with expected revenue levels. These initiatives are intended to improve our revenue and profitability; however, they may instead result in employee turnover, instability to our operations and cause harm to our business.

*A lack of customer demand for our products in any of our markets would harm our revenue.*

Most of our products are marketed to established dermatology and plastic surgeon medical offices, as well as the non-core businesses, such as family practitioners, primary care physicians, gynecologists, and non-medical models. Our most recent product introductions, Pearl and Pearl Fractional, are targeted at dermatologists and plastic surgeons. Continuing to achieve and maintain penetration into each of our markets is a material assumption of our business strategy.

Demand for our products in any of our markets could be weakened by several factors, including:

The duration of the current worldwide recession;

Current lack of credit financing for some of our potential customers;

Poor financial performance of market segments that try introducing aesthetic procedures to their businesses;

The inability to differentiate our products from those of our competitors;

Reduced patient demand for elective aesthetic procedures;

Failure to build and maintain relationships with opinion leaders within the various market segments; and

An increase in malpractice lawsuits.

If we do not achieve anticipated demand for our products in each of our market segments, our revenue may be adversely impacted.

*To successfully market and sell our products internationally, we must address many issues that are unique to our international business.*

Our international revenue was \$41.7 million in 2008, which represented 50% of our total revenue. International revenue is a material component of our business strategy. We depend on third-party distributors and a direct sales force to sell our products internationally, and if they underperform we may be unable to increase or maintain our level of international revenue. To grow our business, we will need to improve productivity in current sales territories and expand into new territories. However, direct sales productivity may not improve and distributors may not accept our business or commit the necessary resources to market and sell our products to the level of our expectations. As a result, we may not be able to increase or maintain international revenue growth.

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;

## Edgar Filing: CUTERA INC - Form 10-K

Export restrictions, trade regulations and foreign tax laws;

Fluctuating foreign currency exchange rates;

Foreign certification and regulatory requirements;

20

**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;

Preference for locally-produced products; and

Reduced protection for intellectual property rights in some countries.

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, we may not be able to sell our products in a particular market and, as a result, our revenue may decline.

***We compete against companies that have longer operating histories, newer and different products, and greater resources, each of which may result in a competitive disadvantage to us and harm our business.***

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, Solta, and Syneron and as well as private companies such as Aesthera, Alma, Lumenis, Sciton and several other companies. We are likely to compete with new companies in the future. Competition with these companies could result in reduced selling prices, 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:

Success and timing of new product development and introductions;

Product performance;

Product pricing;

Quality of customer support;

Development of successful distribution channels, both domestically and internationally; and

Intellectual property protection.

Some of our competitors have newer or different products and more established 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

## Edgar Filing: CUTERA INC - Form 10-K

cost of 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 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. For example, Thermage acquired Reliant in December 2008 and thereby formed Solta. To compete effectively, we

---

**Table of Contents**

have to demonstrate that our products are attractive alternatives to other devices and treatments by differentiating our products on the basis of such factors as performance, brand name, service and price, and this is difficult to do in a crowded market. 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. Business combinations and alliances by our competitors could increase competition, which could harm our business.

***The aesthetic equipment market is characterized by rapid innovation. To compete effectively, we must develop and acquire new products, market them successfully, and 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, wrinkles, skin texture, pore size and pigmented lesions. Currently, these applications represent the majority of offered laser and other energy-based aesthetic procedures. To grow in the future, we must develop and acquire new and innovative aesthetic applications, identify new markets for our existing technologies, and develop and acquire new technologies for various platforms. To successfully expand our product offerings, we must, among other things:

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

Convince our customers and prospects that our new products or 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 generally been a significant component of our financial performance. Our business strategy is based, in part, on our expectation that we will continue to make regular product introductions that we can sell to new customers as systems and to existing customers as upgrades to their existing systems. Even with a significant investment in research and development, we may be unable to continue to develop, acquire or effectively launch and market new products and technologies regularly, or at all, which could adversely affect our business.

Some of our competitors release new products more often and more successfully than we do. For example, in the second half of 2008, revenue from sales of our new Pearl Fractional product to new and existing customers did not meet our expectations. We believe that, to increase revenue from sales of new products and related upgrades, we need to continue to develop our clinical support, further expand and nurture relationships with industry thought leaders and increase market awareness of the benefits of our new products. If we fail to successfully commercialize any of our new 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.





---

**Table of Contents**

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

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

Consumer disposable income, which may be impacted by political and economic conditions, such as concerns over the recession, high unemployment rates and the housing and credit market crisis;

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; and

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

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, 2008 and 2007, approximately 14% of our revenue came from PSS. Although we have dedicated sales professionals to work closely with, and increase the focus and attention on, our PSS relationship, there is no assurance that the 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.

***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. Except for Change of Control and Severance Agreements for our executive officers, 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 may 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.



---

**Table of Contents**

***We may incur substantial expenses if our practices are shown to have violated the Telephone Consumer Protection Act, and defending ourselves against the related litigation could distract management and harm our business.***

A class action lawsuit was filed against us in January 2008 alleging violations under the federal Telephone Consumer Protection Act and related Illinois state laws. Although we retain general liability insurance, one carrier has denied coverage, and the other has agreed to defend us subject to a reservation of rights. There can be no guarantee that any such insurance will cover the claims that are made, or will insure us for losses on covered claims.

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, 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, consume resources and divert the attention of our management and key personnel from our business operations. Each of these factors could harm our business.

***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. These consolidated cases have been on appeal since November 2008 after our motion to dismiss the plaintiffs' complaint was granted. 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 operating our business. Each of these factors could harm our business.

***We are exposed to fluctuations in the market values of our portfolio investments, specifically auction rate securities (ARS), and interest rates. Due to failed auctions of our auction rate investments since February 2008, we are unable to readily liquidate our ARS into cash, and in 2008, we took impairment charges. If these auctions continue to fail, we may have to take additional impairment charges, which could reduce future earnings, harm our business and cause our stock price to decline.***

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 (including ARS), and in bonds of high-quality corporate issuers. As of December 31, 2008, our balance in marketable securities was \$70.3 million. 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, 2008 would have potentially decreased by approximately \$858,000, 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 (loss).

Our marketable securities included \$9.9 million of ARS, of which \$9.6 are classified under the caption of "Long-term investments" in the Consolidated Balance Sheets. These ARS are designed to 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. However, since February 2008, auctions for each of our investments in ARS have 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

---

**Table of Contents**

auctions impacts our ability to readily liquidate our ARS into cash until a future auction of these investments is successful, a buyer is found outside of the auction process or the ARS is refinanced by the issuer into another type of debt instrument.

In 2008, we recorded other-than-temporary impairment charges of \$3.6 million relating to our ARS investments. If in the future we are unable to liquidate our investments in ARS, or there are further other-than-temporary impairments in their market value, we may have to take additional charges, which could reduce our future earnings, harm our business and cause our stock price to decline.

***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, 2008, approximately 63% of our outstanding shares of common stock were held by 10 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.

In 2008, the global equities market declined sharply and our industry was adversely affected. The public market price of our common stock has in the past fluctuated substantially and, due to the current concentration of stockholders and the continuing global recession, 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:

The duration of the current global economic recession, and other general market conditions unrelated to our operating performance;

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; and

The initiation of litigation by us or against us.

Actual or perceived instability in our stock price could reduce demand from potential buyers of our stock, thereby causing our stock price to decline.

***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

## Edgar Filing: CUTERA INC - Form 10-K

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.

---

## **Table of Contents**

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, 2008, we had eleven 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.

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 there from 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

---

## Table of Contents

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.

***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.

## Edgar Filing: CUTERA INC - Form 10-K

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.



---

**Table of Contents**

***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.

***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 and we may incur significant legal, accounting and banking fees in connection with such a transaction. In addition, if we purchase a company that is not profitable, our cash balances may be reduced or depleted. 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.

***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 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,

---

**Table of Contents**

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;

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.

## **Table of Contents**

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

*Any defects in the design, material or workmanship of our products may not be discovered prior to shipment to customers, which could result in warranty obligations that may reduce our future revenue and increase our cost.*

The design of our products is complex. To manufacture them successfully, we must procure quality components and employ individuals with a significant degree of technical expertise. If our designs are defective, if suppliers fail to deliver components to specification, or if our employees fail to properly assemble, test and package our products, 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 experience of materials usage may not provide us with enough data to accurately predict future demand. If our sales demand decreases significantly, or if we overestimate our component and material requirements, we will have excess inventories, which would increase our expenses. If our business expands, or 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.

*Our gross and operating margins may vary over time.*

Our gross and operating 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, our gross and operating margins will be adversely impacted.

*We offer payment terms for qualified customers, In the event that there is a default by any of these customers, this could affect our earnings and could result in an increase in our days sales outstanding.*

While we qualify customers to whom we offer payment terms, we cannot assure that the financial positions of these customers will not change adversely before we receive payment. In the event that there is a default by any of our customers to whom we have provided payment terms, this could affect our earnings and could result in an increase in our days sales outstanding.

---

**Table of Contents**

*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 (loss).

As a result of recent fluctuations in currency markets and the strong dollar relative to many other major currencies, our products priced in U.S. dollars may be more expensive relative to products of our foreign competitors, which could result in lower sales. In addition, the non-dollar denominated earnings of our foreign operations may be lower when reported by us in dollars.

*We may have exposure to additional tax liabilities which could negatively impact our income tax provision, net income, and cash flow.*

We are subject to income taxes and other taxes in both the U.S. and the foreign jurisdictions in which we currently operate or have historically operated. The determination of our worldwide provision for income taxes and current and deferred tax assets and liabilities requires judgment and estimation. In the ordinary course of our business, there are many transactions and calculations where the ultimate tax determination is uncertain. We are subject to regular review and audit by both domestic and foreign tax authorities as well as subject to the prospective and retrospective effects of changing tax regulations and legislation. Although we believe our tax estimates are reasonable, the ultimate tax outcome may materially differ from the tax amounts recorded in our consolidated financial statements and may materially affect our income tax provision, net income, and cash flows in the period in which such determination is made.

*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, as well as Change of Control and Severance Agreements entered into with each of our executive officers, 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.

**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 2013. In addition, we have leased office facilities in certain international countries as follows:

Country	Square Footage	Lease termination or Expiration
Japan	Approximately 5,790	Three leases which expire in May 2009, May 2010 and July 2010
Switzerland	Approximately 2,884	Lease can be terminated by either party at the end of any calendar quarter upon six months written notice
France	Approximately 1,240	Lease expires in December 2009
Spain	Approximately 175	Lease automatically renews at the end of each six-month period

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. On September 30, 2008, in response to our motion, the Court issued an order dismissing the plaintiffs amended complaint without prejudice. On October 28, 2008, the plaintiffs filed a Notice Of Intention Not to File A Second Amended Consolidated Complaint. On November 25, 2008, the Court closed the case on its own initiative. On November 26, 2008, the plaintiffs filed a Notice of Appeal to the U.S. Court of Appeals for the Ninth Circuit. We intend to continue to defend this case vigorously, regardless of the stage of litigation. 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 we do not believe that a significant adverse result in this litigation is probable and since the amount of potential damages in the event of an adverse result is not reasonably estimable, 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 nationwide during the four-year period preceding the lawsuit without the prior express invitation or permission of the recipients. Two state law claims, limited to Illinois recipients, allege a class period of three and five years, respectively. 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 it is unclear how many facsimiles were transmitted during the period for which the plaintiff seeks class certification and unclear how many of these facsimiles were unsolicited within the meaning of the TCPA, we

**Table of Contents**

expect that the number of unsolicited facsimiles could be large and potential liability may be substantial as a result. We retain general liability insurance, with one insurer covering the first two years of the four-year period preceding the lawsuit, and a second insurer covering the latter two years of that four-year period. The first carrier has agreed to defend us subject to a reservation of rights. The second carrier has declined coverage. We intend to defend this case vigorously, including the plaintiff's allegations seeking class certification, regardless of the stage of litigation. Since we do not believe that a significant adverse result in this litigation is probable and since the amount of potential damages in the event of an adverse result is not reasonably estimable, no expense has been recorded with respect to the contingent liability associated with this matter.

**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 28, 2009, the closing sale price of our common stock was \$6.37 per share.

***Common Stockholders***

We had 10 stockholders of record as of February 28, 2009. Since many stockholders choose to hold their shares under the name of their brokerage firm, we believe, the actual number of stockholders was approximately 5,200.

***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			
	2008		2007	
	High	Low	High	Low
4th Quarter	\$ 10.58	\$ 7.47	\$ 27.04	\$ 14.44
3rd Quarter	12.28	9.10	26.55	20.84
2nd Quarter	13.91	8.98	38.39	23.40
1st Quarter	15.53	11.70	37.48	27.06

## **Table of Contents**

### ***Performance Graph***

Below is a graph showing the cumulative total return to our stockholders during the period from March 31, 2004 through December 31, 2008, in comparison to the cumulative return on the NASDAQ Composite Index (U.S.) and the NASDAQ Medical Equipment Index during that same 57-month period. The results compare the return of a \$100 investment in Cutera stock and each of the indexes.

The information under *Performance Graph* is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference in any filing of Cutera under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this 10-K and irrespective of any general incorporation language in those filings.

### **Dividend Policy**

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

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

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

### **Securities Authorized for Issuance under Equity Compensation Plans**

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

**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.

	Year Ended December 31,				
	2008	2007	2006	2005	2004
<b>Consolidated Statements of Operations Data (in thousands, except per share data):</b>					
Net revenue	\$ 83,379	\$ 101,726	\$ 100,692	\$ 75,620	\$ 52,641
Cost of revenue	32,358	35,002	29,859	19,792	14,689
Gross profit	51,021	66,724	70,833	55,828	37,952
<b>Operating expenses:</b>					
Sales and marketing	35,354	38,277	32,890	25,021	19,326
Research and development	7,550	7,169	6,473	5,353	4,549
General and administrative	11,270	11,721	15,192	8,782	8,924
Litigation settlement			18,935		
Total operating expenses	54,174	57,167	73,490	39,156	32,799
Income (loss) from operations	(3,153)	9,557	(2,657)	16,672	5,153
Interest and other income, net	3,046	4,207	3,596	2,034	632
Other-than-temporary impairments of long-term investments	(3,554)				
Income (loss) before income taxes	(3,661)	13,764	939	18,706	5,785
Provision (benefit) for income taxes	(792)	3,260	(1,184)	4,905	2,025
Net income (loss)	\$ (2,869)	\$ 10,504	\$ 2,123	\$ 13,801	\$ 3,760
Net income (loss) available to common stockholders used in basic net income per share	\$ (2,869)	\$ 10,504	\$ 2,123	\$ 13,801	\$ 3,284
<b>Net income (loss) per share:</b>					
Basic	\$ (0.22)	\$ 0.80	\$ 0.17	\$ 1.20	\$ 0.38
Diluted	\$ (0.22)	\$ 0.74	\$ 0.15	\$ 1.00	\$ 0.31
<b>Weighted-average number of shares used in per share calculations:</b>					
Basic	12,770	13,153	12,558	11,535	8,573
Diluted	12,770	14,228	14,278	13,864	12,222
<b>Consolidated Balance Sheet Data (in thousands):</b>					
Cash and cash equivalents	\$ 36,540	\$ 11,054	\$ 11,800	\$ 5,260	\$ 7,070
Marketable investments	60,653	88,510	96,285	86,736	59,200
Long-term investments	9,627	7,429			
	106,820	106,993	108,085	91,996	66,270

## Edgar Filing: CUTERA INC - Form 10-K

Total cash and cash equivalents, marketable investments and long-term investments					
Working capital	101,644	106,894	111,999	98,318	68,519
Total assets	137,476	138,653	133,875	111,958	80,549
Retained earnings	31,410	34,279	23,866	21,743	7,942
Total stockholders' equity	112,108	109,353	109,732	97,177	68,456

## **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 our audited financial statements and notes thereto for the fiscal year ended December 31, 2008. 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. Throughout this Report, and particularly in this Item 7, the forward-looking statements are based upon our current expectations, estimates and projections and that reflect our beliefs and assumptions based upon information available to us at the date of this Report. In some cases, you can identify these statements by words such as may, might, will, should, expects, plans, anticipates, believes, estimates, predicts, potential or continue, and other similar terms. These forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties, and assumptions that are difficult to predict. Our actual results, performance or achievements could differ materially from those expressed or implied by the forward-looking statements. The forward-looking statements include, but are not limited to, statements relating to our future financial performance, the ability to grow our business, increase our revenue, manage expenses, generate additional cash, achieve and maintain profitability, develop and commercialize existing and new products and applications, improve the performance of our worldwide sales and distribution network, and to the outlook regarding long term prospects. We caution you 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.*

*Some of the important factors that could cause our results to differ materially from those in our forward-looking statements, and a discussion of other risks and uncertainties, are discussed in Item 1A Risk Factors commencing on page 19. We encourage you to read that section carefully as well as other risks detailed from time to time in our filings with the SEC.*

### **Introduction**

The Management's Discussion and Analysis, or MD&A, is organized as follows:

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

*Critical accounting policies and estimates-* This section describes the key accounting policies that are affected by critical accounting estimates.

*Recent accounting pronouncements-* This section describes the issuance and effect of new accounting pronouncements that may be applicable to us.

*Results of operations-* This section provides our analysis and outlook for the significant line items in 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, 2008.

### **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 products on three platforms CoolGlide, Xeo and Solera for use by physicians and other qualified practitioners to allow our customers 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



---

**Table of Contents**

United States, we market, sell and service our products primarily through direct sales and service employees 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 representatives serving physician offices throughout the United States. In addition, we also sell certain items, like Titan hand piece refills and marketing brochures, through the Internet.

International sales are generally made through direct sales employees and through a worldwide distributor network in over 30 countries. Outside the United States, we have a direct sales presence in Australia, Canada, France, Japan, Spain, Switzerland and the United Kingdom.

**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, such as with our Pearl and Pearl Fractional products, instead of in the console. 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 prepaid service 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 replacement of the optical source after a set number of pulses have been used.

**Significant Business Trends.** We believe that our ability to grow revenue has been, and will continue to be, primarily dependent on the following:

Investments made in our global sales and marketing infrastructure.

Continuing introduction of new aesthetic products and applications.

Continuing customer demand for our products and consumer demand for the applications they offer.

Marketing to physicians in the core dermatology and plastic surgeon specialties, as well as outside those specialties.

Generating Service, Product upgrade and Titan hand piece refill revenue from our growing installed base of customers. In 2008, compared to 2007, our U.S. revenue declined 35% and our international revenue grew 11%. In 2007, compared to 2006, our U.S. revenue declined 8%, while our international revenue grew 22%. We believe that the greater decline in U.S. revenue growth from 2007 to 2008, as compared from 2006 to 2007, was primarily attributable to a U.S. recession that is causing our prospective customers to delay their purchase decisions. We also believe that those prospects who do not have established medical offices are finding it more difficult to obtain credit financing. The weaker international revenue growth in 2008, compared to international revenue growth in 2007, was primarily attributable to the global recession, which adversely affected our international revenue in the second half of 2008. We experienced greater revenue growth in many of our international markets in 2008, compared with 2007, with particular strength in Australia and Japan. As a result of this continuing international revenue growth, international revenue as a percentage of total revenue increased to 50% in 2008, compared with 37% in 2007.

For 2008, our gross margin declined to 61%, compared to 66% in 2007. This decrease was primarily attributable to reduced leverage of our manufacturing and service expenses due to lower than expected revenue, and lower introductory margins for our Pearl Fractional-enabled systems and upgrades that started shipping in September 2008, and lower average selling prices for our Products and Product upgrades in 2008, compared with 2007.

---

## **Table of Contents**

Sales and marketing expenses as a percentage of net revenue increased to 42% in 2008, compared to 38% in 2007, but decreased in total dollars to \$35.4 million. The increase in percentage was primarily caused by lower revenue in 2008, compared with 2007. The decrease in total dollars in 2008, compared with 2007, was primarily caused by reduced personnel expenses in the United States due to lower sales commissions, resulting from lower revenue, and lower headcount.

Research and development expenses as a percentage of net revenue increased to 9% in 2008, compared to 7% in 2007, and increased in total dollars to \$7.6 million. These increases were primarily attributable to lower revenue in 2008, compared with 2007, and higher personnel expenses associated with increased headcount.

General and administrative expenses as a percentage of net revenue increased to 14% in 2008, compared to 12% in 2007, due primarily to lower revenue in 2008, compared with 2007. In absolute dollars, G&A expenses decreased by \$451,000 to \$11.3 million in 2008, compared with 2007.

### ***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, our future performance is dependent upon 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 execute on the aforementioned initiatives, our business would be adversely affected. 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 Consolidated Financial Statements and related disclosures in conformity with generally accepted accounting principles in the United States, or GAAP, requires us to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses. These estimates, judgments and assumptions are based on historical experience and on various other factors that we believe are reasonable under the circumstances. We periodically review our estimates and make adjustments when facts and circumstances dictate. To the extent that there are material differences between these estimates and actual results, our financial condition or results of operations will be affected. See Note 1 Summary of Significant Accounting Policies in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Form 10-K for a summary of our significant accounting policies.

Critical accounting estimates, as defined by the Securities and Exchange Commission (SEC), are those that are most important to the portrayal of our financial condition and results of operations and require our management's most difficult and subjective judgments and estimates of matters that are inherently uncertain. Our critical accounting estimates are as follows:

#### ***Revenue Recognition***

We recognize distributor and non-distributor revenue in accordance with the SEC's Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104). 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.





**Table of Contents**

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 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.

***Long-Term Auction Rate Securities Investments***

We hold a variety of interest bearing auction rate securities (ARS) that represent investments in pools of student loan assets. At the time of acquisition, these ARS investments were intended to provide liquidity via an auction process that resets the applicable interest rate at predetermined calendar intervals, allowing investors to either roll over their holdings or gain immediate liquidity by selling such interests at par. Since February 2008, uncertainties in the credit markets affected our ARS investments and auctions for our investments in these securities have failed to settle on their respective settlement dates. Consequently, the investments are not currently liquid and we will not be able to access these funds until a future auction of these investments is successful, a buyer is found outside of the auction process or the issuer refinances their debt. Maturity dates for these ARS investments range from 2028 to 2043.

As of December 31, 2008, we had \$9.6 million in long-term ARS investments. Given observable ARS market information was not available to determine the fair value of our ARS portfolio we compared the fair value of our securities to a discounted cash flow model as well as transaction data and bid-ask spread data for other similar illiquid securities from a secondary market. Expected future cash flows were calculated using estimates for interest rates ranging from 1.55% to 4.08%, timing and amount of cash flows through the maturity of the ARS. Our most significant assumption made in the present value calculations was the estimated required rates of return used to discount the estimated future cash flows. The rate selected to value each of the investments considered and assigned an expected yield premium based on several factors, including:

Lack of liquidity due to failing auctions;

Default risk arising from whether the security was issued by a federal backed agency (Federal Family Education Loan Program) or a municipal agency (Maine Education Loan Authority);

Underlying collateral coverage of the loan trust that issued the security;

Underlying credit rating; and

Liquidation preferences based on the capital structure of the loan trust.

For the year ended December 31, 2008, using this assessment of fair value, we determined there was a decline in the fair value of our ARS investments of approximately \$3.6 million, which was recognized as a pre-tax other-than-temporary impairment charge with a corresponding decrease in accumulated other comprehensive loss. The primary cause of the decline in fair value of our long-term ARS was an increase in the estimated required rates of return used to discount the estimated future cash flows over the life of each security.

We review our impairments on a quarterly basis in accordance with Statement of Financial Accounting Standards (SFAS) No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and related guidance issued by the Financial Accounting Standards Board (FASB), and the SEC in order to determine the classification of the impairment as temporary or other-than-temporary. A temporary impairment charge results in an unrealized loss being recorded in the other comprehensive loss component of stockholders' equity. Such an unrealized loss does not affect net loss for the applicable accounting period. An other-than-temporary impairment charge is



---

## **Table of Contents**

recorded as an unrealized loss in the Consolidated Statement of Operations and is a component of the net loss for the applicable accounting period. Once an other-than-temporary impairment is recorded, a new cost basis in the investment is established. The primary differentiating factors we considered to classify our impairments between temporary and other-than-temporary impairments are the 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 issuers and our intent and ability to retain our investment in the issuer to maturity to allow for any anticipated recovery in market value.

The valuation of our investment portfolio is subject to uncertainties that are difficult to predict factors that may impact its valuation include duration of time that the ARS remain illiquid, changes to credit ratings of the securities, rates of default of the underlying assets, changes in the underlying collateral value, market discount rates for similar illiquid investments, and ongoing strength and quality of credit markets. If the current market conditions deteriorate further, or the recovery in market values does not occur, we may be required to record additional other-than-temporary impairment charges in future quarters.

Factors that may impact its valuation include changes to credit ratings of the securities as well as to the underlying assets supporting those securities, rates of default of the underlying assets, underlying collateral value, discount rates, liquidity and ongoing strength and quality of credit markets. If the current market conditions deteriorate further, or the recovery in market values does not occur, we may be required to record additional other-than-temporary impairment charges in future quarters.

### ***Fair Value Measurements***

On January 1, 2008, we adopted fair value measurement provisions of Statement SFAS, No. 157 *Fair Value Measurements*, which established a framework for measuring fair value under GAAP and clarified the definition of fair value within that framework. SFAS 157 does not require assets and liabilities that were previously recorded at cost to be recorded at fair value. For assets and liabilities that are already required to be disclosed at fair value, SFAS 157 introduced, or reiterated, a number of key concepts that form the foundation of the fair value measurement approach to be used for financial reporting purposes. The fair values of our financial instruments reflect the amounts that we estimate we would receive in connection with the sale of an asset or that we would pay in connection with the transfer of a liability in an orderly transaction between market participants at the measurement date (exit price). SFAS 157 also established a fair value hierarchy that prioritizes the inputs used in valuation techniques into the following three levels:

Level 1 Prices in active markets for identical assets and liabilities

Level 2 Observable inputs other than quoted prices in active markets for identical assets and liabilities

Level 3 Unobservable inputs

The adoption of SFAS 157 did not have an effect on our financial condition or results of operations, but SFAS 157 introduced new disclosures about how we value certain assets and liabilities. Much of the disclosure focuses on the inputs used to measure fair value, particularly in instances in which the measurement uses significant unobservable (Level 3) inputs. A substantial majority of our financial instruments are Level 1 and Level 2 assets.

At December 31, 2008, total financial assets measured and recognized at fair value were \$105.0 million and of these assets, \$9.6 million, or 9%, were ARS that were measured and recognized using significant unobservable inputs (Level 3). There were no non-financial assets or liabilities measured at fair value as of December 31, 2008.

While our ARS valuation model was based on both Level 2 (credit quality and interest rates) and Level 3 inputs, we determined that the Level 3 inputs were the most significant to the overall fair value measurement, particularly the estimates of risk adjusted discount rates. See Note 2 Investment Securities, in the Notes to Consolidated Financial Statement in Part II, Item 8 of this Form 10-K for more information.

---

**Table of Contents*****Stock-based Compensation Expense***

Under the provisions of FAS No. 123(R), Share-Based Payment (FAS 123R), employee stock-based compensation is estimated at the date of grant based on the employee stock award's fair value using the Black-Scholes option-pricing model and is recognized as expense ratably over the requisite service period in a manner similar to other forms of compensation paid to employees. The Black-Scholes option-pricing model requires the use of certain subjective assumptions. The most significant of these assumptions are our estimates of the expected volatility of the market price of our stock and the expected term of the award. The expected volatility is a 50%/50% blend of implied and historical volatility. We have determined that this is a more reflective measure of market conditions and a better indicator of expected volatility, than its limited historical volatility since the initial public offering of our common stock. When establishing an estimate of the expected term of an award, we consider historical experience of similar awards, giving consideration to the contractual terms of the awards, vesting requirements, and expectation of future employee behavior, including post-vesting terminations. As required under GAAP, we review our valuation assumptions at each grant date, and, as a result, our valuation assumptions used to value employee stock-based awards granted in future periods may change.

As of December 31, 2008, the unrecognized compensation cost, net of expected forfeitures, related to stock options, restricted stock unit awards and employee stock purchase plan awards was \$6.9 million, \$108,000 and \$57,000, which will be recognized using the straight-line attribution method over an estimated weighted-average amortization period of 2.50 years, 0.42 years and 0.33 years, respectively. See Note 5 Stockholders equity, Stock Plans and Stock-Based Compensation Expense, in the Notes to Consolidated Financial Statement in Part II, Item 8 of this Form 10-K for more information.

***Valuation of 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.

---

## Table of Contents

### *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* (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 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 22% in 2008, 24% in 2007 and (126)% in 2006. 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, 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.

Our deferred tax assets are recognized for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities, and for operating losses and tax credit carryforwards. A valuation allowance reduces deferred tax assets to estimated realizable value, which assumes that it is more likely than not that we will be able to generate sufficient future taxable income in certain tax jurisdictions to realize the net carrying value. The four sources of taxable income to be considered in determining whether a valuation allowance is required include:

Future reversals of existing taxable temporary differences (i.e., offset gross deferred tax assets against gross deferred tax liabilities);

Future taxable income exclusive of reversing temporary differences and carryforwards;

Taxable income in prior carryback years; and

Tax planning strategies.

Determining whether a valuation allowance for deferred tax assets is necessary requires an analysis of both positive and negative evidence regarding realization of the deferred tax assets. In general, positive evidence may include:

A strong earnings history exclusive of the loss that created the deductible temporary differences, coupled with evidence indicating that the loss is the result of an aberration rather than a continuing condition;

---

**Table of Contents**

An excess of appreciated asset value over the tax basis of our net assets in an amount sufficient to realize the deferred tax asset; and  
In general, negative evidence may include:

A history of operating loss or tax credit carryforwards expiring unused;

An expectation of being in a cumulative loss position in a future reporting period;

The existence of cumulative losses in recent years; and

A carryback or carryforward period that is so brief that it would limit the realization of tax benefits.  
The weight given to the potential effect of negative and positive evidence should be commensurate with the extent to which it can be objectively verified and judgment must be used in considering the relative impact of positive and negative evidence.

In 2008, our loss before income taxes included unrealized capital losses resulting from other-than-temporary impairment charges for our ARS investments. After considering both the positive and negative evidence as of December 31, 2008, we determined that it was not more-likely-than-not that we would realize the full value of our capital loss related deferred tax assets. As a result, we established a valuation allowance against this deferred tax asset. At December 31, 2008, we had recognized deferred tax assets of \$10.8 million relating to other temporary differences between the financial reporting and tax bases of assets and liabilities, and tax credit carryforwards. We believe that it is more likely than not that we will be able to generate sufficient future taxable income to realize the carrying value of these deferred tax assets. We review the deferred tax asset and valuation allowance on a quarterly basis and consider whether positive and negative evidence exists to effect the realization of deferred tax assets.

***Long-Lived Asset Impairment***

Long-lived assets, such as property and equipment and intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not ultimately be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its ultimate disposition. If the sum of the expected future cash flows is less than the carrying amount of those assets, we recognize an impairment loss based on the excess of the carrying amount over the fair value of the assets.

***Litigation***

We have been, and may in the future become, subject to legal proceedings related to securities litigation, intellectual property and other matters such as the TCPA litigation and the securities class Action Lawsuit described in Item 3 Legal Proceedings. Based on all available information at the balance sheet dates, 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 record a reserve in accordance with Statement of Financial Accounting Standards No. 5, *Accounting for Contingencies*. Currently we have no such reserves recorded for any of the litigations mentioned in Item 3 Legal Proceedings.

**Recent Accounting Pronouncements**

For a full description of recent accounting pronouncements, including the respective expected dates of adoption and effects on results of operations and financial condition see Note 1 Summary of Significant Accounting Policies Recent Accounting Pronouncement in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Form 10-K.





**Table of Contents****Results of Operations**

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

	Year Ended December 31,		
	2008	2007	2006
<b>Operating Ratios:</b>			
Net revenue	100%	100%	100%
Cost of revenue	39%	34%	30%
Gross profit	61%	66%	70%
<b>Operating expenses:</b>			
Sales and marketing	42%	38%	33%
Research and development	9%	7%	6%
General and administrative	14%	12%	15%
Litigation settlement	%	%	19%
Total operating expenses	65%	57%	73%
Income (loss) from operations	(4)%	9%	(3)%
Interest and other income, net	4%	4%	4%
Other-than-temporary impairment of long-term investments	(4)%	%	%
<b>Income (loss) before income taxes</b>	(4)%	13%	1%
Provision (benefit) for income taxes	(1)%	3%	(1)%
Net income (loss)	(3)%	10%	2%

**Total Revenue**

(Dollars in thousands)	Year Ended December 31,				
	2008	% Change	2007	% Change	2006
<b>Revenue mix by geography:</b>					
United States	\$ 41,683	(35)%	\$ 64,084	(8)%	\$ 69,895
Asia	21,297	19%	17,898	13%	15,781
Europe	10,522	14%	9,258	28%	7,239
Rest of the world	9,877	(6)%	10,486	35%	7,777
Total international revenue	41,696	11%	37,642	22%	30,797
Consolidated total revenue	\$ 83,379	(18)%	\$ 101,726	1%	\$ 100,692
United States as a percentage of total revenue	50%		63%		69%
International as a percentage of total revenue	50%		37%		31%
<b>Revenue mix by product category:</b>					
Products	\$ 57,998	(22)%	\$ 74,502	(12)%	\$ 84,695
Product upgrades	8,361	(37)%	13,342	122%	6,006
Service	11,358	24%	9,128	55%	5,890

## Edgar Filing: CUTERA INC - Form 10-K

Titan hand piece refills	5,662	19%	4,754	16%	4,101
Consolidated total revenue	\$ 83,379	(18)%	\$ 101,726	1%	\$ 100,692

U.S. sales decreased 35% in 2008, compared to 2007, and 8% in 2007, compared to 2006. We believe the decrease in U.S. revenue in 2008 was primarily attributable to a U.S. recession that is causing our prospective customers to delay their purchase decisions. We also believe that a segment of our business those aesthetic

**Table of Contents**

practices that operate in settings that are not medical offices are being particularly affected by the economic environment and may be finding it more difficult to obtain credit financing. Also, FDA clearance for our Pearl product was received in early 2007, which allowed us to begin shipping our Pearl product in June 2007 and provided significant Upgrade revenue for the second half of 2007. In contrast, our Pearl Fractional product started shipping in September 2008, which resulted in lower Upgrade revenue in the second half of 2008, compared to the second half of 2007.

International sales increased 11% in 2008, compared to 2007, and increased 22% in 2007, compared to 2006. The weaker international revenue growth in 2008, compared to international revenue growth in 2007, was primarily attributable to the global recession, which adversely affected our international revenue in the second half of 2008. We experienced revenue growth in many of our international markets in 2008, compared with 2007, with particular strength in Australia and Japan. As a result of this continuing international revenue growth, international revenue as a percentage of total revenue increased to 50% in 2008, compared with 37% in 2007. The increase in 2007 was primarily attributable to continuing investments in building our international sales distribution channels. As a result of this continuing international revenue growth, international revenue as a percentage of total revenue increased to 50% in 2008, compared with 37% in 2007, and 31% in 2006.

Product revenue decreased 22% in 2008, compared to 2007, and 12% in 2007, compared to 2006. We believe the decrease in product revenue in 2008 was primarily driven by prospective customers deferring their purchase decisions due to the current global recession, partially offset by higher international product revenue. Upgrade revenue decreased 37% in 2008, compared to 2007, and increased 122% in 2007, compared to 2006. We believe the decrease in Upgrade revenue in 2008 and the increase in Upgrade revenue in 2007 are primarily due to our launch of Pearl Fractional in 2008 and Pearl in 2007. We received FDA clearance for our Pearl product in early 2007, which allowed us to begin shipping it in June 2007, which provided significant Upgrade revenue for the second half of that year. In contrast, our Pearl Fractional product started shipping in September 2008. We believe that late timing, and the global recession, caused us to achieve lower Upgrade revenue in the second half of 2008, compared to the second half of 2007.

Service revenue increased 24% in 2008, compared to 2007, and increased 55% in 2007, compared to 2006. We believe that these increases were due primarily to a larger installed base of customers who are eligible to purchase extended service contracts. However, our sequential service revenue growth rates are declining as a result of fewer customers electing to purchase post-warranty service contracts. We believe this reduced customer demand for service contracts is due to the challenging economic environment and the strong reliability of our products.

Our Titan hand piece refill revenue increased 19% in 2008, compared to 2007, and increased 16% in 2007, compared to 2006. We believe that these increases were due primarily to an increase in the installed base and as a result of greater utilization of this application. Although we experienced modest growth in 2008, when compared to 2007, we have experienced flat sequential revenue in this category during the past four quarters. This revenue trend indicates a declining utilization level which we believe is caused by a softening economy.

**Gross Profit**

(Dollars in thousands)	Year Ended December 31,				
	2008	% Change	2007	% Change	2006
Gross Profit	\$ 51,021	(24)%	\$ 66,724	(6)%	\$ 70,833
<i>As a percentage of total revenue</i>	<i>61%</i>		<i>66%</i>		<i>70%</i>

**Table of Contents**

Our cost of revenue consists primarily of material, labor, stock-based compensation, royalty expense, warranty and manufacturing overhead expenses. Gross margin as a percentage of net revenue was 61% in 2008, 66% in 2007 and 70% in 2006. We believe this decrease in gross margin in 2008, compared to 2007 was primarily attributable to:

Lower overall revenue, which reduced the leverage of our manufacturing and service department expenses and was dilutive to our gross margin percentage;

Higher Service and Titan refill revenue, as a percentage of total revenue, which have a lower gross margin than our Product and Upgrade revenue categories; and

Increased level of international distributor business, which has slightly lower gross margins than our direct business. The decrease in gross margin in 2007, compared to 2006, 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.

**Sales and Marketing**

(Dollars in thousands)	Year Ended December 31,				
	2008	% Change	2007	% Change	2006
Sales and marketing	\$ 35,354	(8)%	\$ 38,277	16%	\$ 32,890
<i>As a percentage of total revenue</i>	<i>42%</i>		<i>38%</i>		<i>33%</i>

Sales and marketing expenses consist primarily of labor, stock-based compensation, expenses associated with customer-attended workshops and trade shows, and advertising. Sales and marketing expenses decreased \$2.9 million in 2008, compared to 2007. This decrease was primarily attributable to lower personnel expenses for North America of \$3.3 million, resulting from lower sales commission expenses (resulting from lower sales) and a reduction in head count. Sales and marketing expenses as a percentage of total revenue, increased to 42% in 2008, compared with 38% in 2007, due primarily to lower U.S. revenue in 2008.

Sales and marketing expenses increased \$5.4 million, or 16%, in 2007, compared to 2006. The 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.

**Research and Development (R&D)**

(Dollars in thousands)	Year Ended December 31,				
	2008	% Change	2007	% Change	2006
Research and development	\$ 7,550	5%	\$ 7,169	11%	\$ 6,473

## Edgar Filing: CUTERA INC - Form 10-K

*As a percentage of total revenue*

9%

7%

6%

Research and development expenses consist primarily of labor, stock-based compensation, clinical, regulatory and material costs. R&D expenses increased by \$381,000 in 2008, compared to 2007. This increase was primarily attributable to higher materials and consultant fees of \$362,000, relating primarily to the research and

**Table of Contents**

development activities of our Pearl Fractional product and other projects in development. R&D expenses as a percentage of total revenue, increased to 9% in 2008, compared with 7% in 2007, due primarily to lower U.S. revenue in 2008.

R&D expenses increased by \$696,000, or 11%, in 2007, compared to 2006. The increase was 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 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.

**General and Administrative (G&A)**

(Dollars in thousands)	Year Ended December 31,				
	2008	% Change	2007	% Change	2006
General and administrative	\$ 11,270	(4)%	\$ 11,721	(23)%	\$ 15,192
<i>As a percentage of total revenue</i>	<i>14%</i>		<i>12%</i>		<i>15%</i>

General and administrative expenses consist primarily of labor, stock-based compensation, legal fees, accounting, audit and tax consulting fees, and other general and administrative expenses. G&A expenses decreased \$451,000 in 2008, compared to 2007. This slight decrease was primarily attributable to lower personnel expenses for North America of \$998,000, partially offset by higher North America professional consulting fees related to legal, accounting and tax related matters of \$508,000. G&A expenses as a percentage of total revenue increased, to 14% in 2008, compared with 12% in 2007, due primarily to lower U.S. revenue in 2008.

G&A expenses decreased by \$3.5 million, or 23%, to \$11.7 million in 2007, compared to 2006. 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. As a result of the lower expenses, G&A expenses as a percentage of total revenue decreased to 12% in 2007, compared to 15% 2006.

**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 an intangible asset representing the value of the ongoing sublicense obtained as part of the settlement agreement.

**Interest and Other Income, Net**

The components of Interest and Other Income, Net are as follows:

(Dollars in thousands)	Year Ended December 31,				
	2008	% Change	2007	% Change	2006
Interest income	\$ 3,170	(22)%	\$ 4,083	29%	\$ 3,161
Other income (expense), net	(124)	NA	124	(71)%	435
<b>Total Interest and other income, net</b>	<b>\$ 3,046</b>	<b>(28)%</b>	<b>\$ 4,207</b>	<b>17%</b>	<b>\$ 3,596</b>

Interest income decreased 22% in 2008, compared to 2007, and increased 29% in 2007, compared to 2006. The decrease in 2008 was due primarily to reduced tax-exempt interest yields resulting primarily from the Federal



**Table of Contents**

Reserve cutting interest rates. The increase of \$922,000, or 29%, in interest income in 2007, compared to 2006, was primarily attributable to improved tax-exempt interest yields on investments in government bonds and an increased average amount invested. Our cash, cash equivalents, marketable investments and long-term investments measured and recognized at fair value were \$106.8 million at December 31, 2008, \$107.0 million at December 31, 2007 and \$108.1 million December 31, 2006.

**Other-Than-Temporary Impairments of Long-Term Investments**

(Dollars in thousands)	Year Ended December 31,				
	2008	% Change	2007	% Change	2006
Other-than-temporary impairment of long-term investments	\$ 3,554	NA	\$	%	\$

For the year ended December 31, 2008, we determined there was a decline in the fair value of our ARS investments for which we recorded a \$3.6 million other-than-temporary impairment charge. See the Critical Accounting Estimates section above, for additional details relating to the charge.

**Provision (Benefit) for Income Taxes**

(Dollars in thousands)	Year Ended December 31,				
	2008	\$ Change	2007	\$ Change	2006
Income (loss) before income taxes	\$ (3,661)	\$ (17,425)	\$ 13,764	\$ 12,825	\$ 939
Provision (benefit) for income taxes	(792)	(4,052)	3,260	4,444	(1,184)
Effective tax rate	22%		24%		(126)%

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 22% in 2008, 24% in 2007 and (126)% in 2006. The change in the effective tax rate for 2008, compared to 2007, was primarily attributable to tax exempt interest income being a larger percentage of the pre-tax loss for fiscal year 2008. The change in the effective tax rate for 2007, compared to 2006, was primarily attributable to the litigation settlement expense of \$18.9 million that 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 in 2006.

With respect to the \$3.6 million other-than-temporary impairment charge for ARS investments recognized in 2008, we recorded a deferred tax asset. However, because we did not believe it is more likely than not realizable, given this is a capital loss, we recorded a valuation allowance against the deferred tax asset. As a result, there was no effect on our total tax provision in 2008 for this charge.

**Net Income and Net Income Per Diluted Share**

(Dollars in thousands, except per share data)	Year Ended December 31,				
	2008	% Change	2007	% Change	2006
Net income (loss)	\$ (2,869)	NA	\$ 10,504	395%	\$ 2,123
Net income (loss) per diluted share	\$ (0.22)	NA	\$ 0.74	393%	\$ 0.15

The \$13.4 million decrease in net income (loss), and \$0.96 decrease in net income (loss) per diluted share, in 2008, compared with 2007, was primarily attributable to \$22.4 million in lower U.S. sales and \$3.6 million in an other-than-temporary impairment of long-term investments.

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





**Table of Contents**

marginal tax impact of \$7.2 million being incurred in 2006 but not in 2007. The \$11.7 million patent litigation expense was offset in part by lower gross margins, higher operating expenses and a higher effective income tax rate.

**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. The majority of our cash and investments are held in U.S. banks and our foreign subsidiaries maintain a limited amount of cash in their local banks to cover their short term operating expenses.

The following table summarizes our cash and cash equivalents, marketable investments and long-term investments (in thousands):

(Dollars in thousands)	As of December 31,		
	2008	2007	Change
Cash, cash equivalents and marketable securities:			
Cash and cash equivalents	\$ 36,540	\$ 11,054	\$ 25,486
Marketable investments	60,653	88,510	(27,857)
Long-term investments	9,627	7,429	2,198
<b>Total</b>	<b>\$ 106,820</b>	<b>\$ 106,993</b>	<b>\$ (173)</b>

**Cash Flows**

In summary, our cash flows were as flows:

(Dollars in thousands)	Year ended December 31,		
	2008	2007	2006
Cash flows provided by (used in):			
Operating activities	\$ 4,340	\$ 16,890	\$ 12,466
Investing activities	20,644	(426)	(11,355)
Financing activities	502	(17,210)	5,429
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>\$ 25,486</b>	<b>\$ (746)</b>	<b>\$ 6,540</b>

**Cash Flows From Operating Activities**

We generated net cash from operating activities of \$4.3 million in 2008, which was primarily attributable to:

\$5.1 million generated from net loss of \$2.9 million after adjusting for non-cash related items of \$8.0 million, primarily consisting of \$5.2 million of stock-based compensation and \$3.6 million of other-than-temporary impairment of long-term investments, partially offset by \$1.9 million increase in deferred tax assets resulting from unutilized deductions for stock-based compensation expenses;

\$4.9 million of cash generated from the collection of the higher accounts receivable balance as of December 31, 2007; offset by

## Edgar Filing: CUTERA INC - Form 10-K

\$4.7 million used to pay down the higher 2007 year-end accrued liabilities relating primarily to personnel expenses of \$2.0 million, reduction of the income taxes payable balance by \$849,000, reduction of accrued warranty expenses by \$809,000 due primarily to fewer units remaining under

**Table of Contents**

warranty, and net reduction of \$424,000 of accrued royalties due to the reduced revenue in the fourth quarter of 2008, compared with the fourth quarter of 2007.

\$2.8 million cash used as a result of the increase in inventories following the lower than expected revenue in the fourth quarter of 2008.

We generated net cash from operating activities of \$16.9 million in 2007, which was primarily attributable to:

\$15.2 million generated from net income of \$10.5 million after adjusting for non-cash related items of \$4.7 million, primarily consisting of \$5.6 million of stock-based compensation and \$4.2 million of tax benefit from employee stock option exercises, 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 a \$2.7 million increase in deferred tax assets resulting from an increase in accrued liabilities and unutilized deductions for stock-based compensation expenses; and

\$3.8 million in deferred revenue due to the growth in service contracts sold to our expanding customer installed base; offset by

\$2.6 million increase in inventories to support a broader product offering and due to lower than expected revenue in the fourth quarter 2007; and

\$1.1 million cash generated resulting from a higher uncollected balance relating to fourth quarter 2007 revenue.

***Cash Flows From Investing Activities***

We generated net cash of \$20.6 million from investing activities in 2008, which was primarily attributable to:

\$85.2 million in net proceeds from the sales and maturities of marketable investments due to an attempt to reduce our exposure to the auction rate and variable rate demand note markets during 2008; partially offset by

\$63.8 million of cash used to purchase marketable and long-term investments; and

\$703,000 of cash used to purchase property and equipment primarily for the research and development function.

We used cash of \$426,000 in investing activities in 2007, which was primarily attributable to:

\$1.0 million used to purchase capital equipment for R&D and manufacturing operations as well as a trade show booth for marketing, and \$20,000 used to purchase an intangible asset; partially offset by

\$594,000, net from cash proceeds from the sales and maturities of marketable investments and cash used to used to purchase marketable and long-term investments the cash generated from operations in marketable securities of cash used to purchase marketable and long-term investments.

***Cash Flows From Financing Activities***

## Edgar Filing: CUTERA INC - Form 10-K

Net cash provided by financing activities in 2008 was \$502,000, which resulted from \$458,000 of cash generated by the issuance of stock through our stock option and employee stock purchase plans and \$44,000 of excess tax benefits related to stock-based compensation expenses reclassified from operating activities to financing activities in accordance with FAS 123(R).

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

**Table of Contents**

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).

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

We had cash, cash equivalents, marketable and long-term investments of \$106.8 million as of December 31, 2008. Of this amount, we had \$9.6 million invested in long-term ARS investments (see *Critical Accounting Estimates* section above, for a full description of our long-term investments in ARS). We believe that our existing cash resources are sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months.

***Off-Balance Sheet Arrangements***

We do not participate in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance, variable interest or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As of December 31, 2008, we were not involved in any unconsolidated transactions.

***Commitments***

See Note 11, *Commitments and Contingencies*, in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Form 10-K.

***Contractual Obligations***

The following are our obligations for future minimum lease commitments related to facility leases as of December 31, 2008:

	Total	Payments Due by Period (\$ 000 s)			
		Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
<b>Contractual Obligations</b>					
Operating leases	\$ 7,147	\$ 1,513	\$ 2,660	\$ 2,974	\$
<b><i>Income Tax Liability</i></b>					

We adopted the provisions of FIN 48 on January 1, 2007. Implementation of FIN 48 did not result in any adjustment to our Consolidated Statements of Income or a cumulative adjustment to retained earnings. As a result of the adoption of FIN 48, as of December 31, 2008, we have included in our Consolidated Balance Sheet \$1.5 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.

***Purchase Commitments***

We maintain certain open inventory purchase commitments with our suppliers to ensure a smooth and continuous supply for key components. Our 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. Our open inventory purchase commitments were not material at December 31, 2008. 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



---

**Table of Contents**

directors and executive officers. In 2007, two of our officers were named as defendants in securities class action litigation see Part I, Item 3 Legal Proceedings. Our exposure under the various indemnification obligations, including those under the indemnification agreements with our directors and 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****Interest Rate Sensitivity**

Our exposure to interest rate risk relates primarily to our investment portfolio. Fixed rate securities may have their fair market value adversely impacted due to fluctuations in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectation due to changes in interest rates or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates. The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in debt instruments of the U.S. Government and its agencies and municipal bonds, and, by policy, restrict our exposure to any single type of investment or 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 ARS) of generally less than eighteen months. Assuming a hypothetical increase in interest rates of one percentage point, the fair value of our total investment portfolio would have potentially declined by approximately \$858,000 as of December 31, 2008.

We hold interest bearing ARS that represent investments in pools of student loans issued by either the Federal Family Education Loan Program or the Maine Education Loan Authority. At the time of acquisition, these ARS investments were intended to provide liquidity via an auction process that resets the applicable interest rate at predetermined calendar intervals, allowing investors to either roll over their holdings or gain immediate liquidity by selling such interests at par. Since February 2008, uncertainties in the credit markets affected all of our holdings in ARS investments and auctions for our investments in these securities have continued to fail. Consequently, the investments are not currently liquid and we will not be able to access these funds until a future auction of these investments is successful, a buyer is found outside of the auction process or the ARS is refinanced by the issuer into another type of debt instrument. Maturity dates for these ARS investments range from 2028 to 2043. We currently classify all of these investments as long-term investments in our Consolidated Balance Sheet because of our continuing inability to determine when these investments will settle. We have also modified our current investment strategy and increased our investments in more liquid money market investments, United States Treasury securities, municipal bonds, and eliminated investments in corporate debt. The valuation of our ARS investment portfolio is subject to uncertainties that are difficult to predict. Factors that may impact its valuation include, duration of time that the ARS remain illiquid, changes to credit ratings of the securities, rates of default of the underlying assets, changes in the underlying collateral value, market discount rates for similar illiquid investments, ongoing strength and quality of credit markets. If the current market conditions deteriorate further, or the recovery in market values does not occur, we may be required to record additional other-than-temporary impairment charges in future quarters.

**Foreign Currency Exchange Risk**

We have international subsidiaries and operations and are, therefore, subject to foreign currency rate exposure. Although the majority of our revenue and purchases are denominated in U.S. dollars, we have revenue to certain international customers and expenses denominated in the Japanese Yen, Euro, Pounds Sterling, Australian Dollars, Swiss Francs and Canadian Dollars. The net gains and losses from the revaluation of foreign



**Table of Contents**

denominated assets and liabilities was a loss of \$132,000 for the year ended December 31, 2008 and is included in operating loss in our Consolidated Statements of Operations. Movements in currency exchange rates could cause variability in our revenues, expenses or interest and other income (expense). Though to date our exposure to exchange rate volatility has not been significant, we cannot assure that there will not be a material impact in the future. Future fluctuations in the value of the U.S. dollar may affect the price competitiveness of our products. We do not believe, however, that we currently have significant direct foreign currency exchange rate risk and have not hedged exposures denominated in foreign currencies.

We do not utilize derivative financial instruments, derivative commodity instruments or other market risk sensitive instruments.

---

**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:

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	56
<u>Consolidated Balance Sheets</u>	57
<u>Consolidated Statements of Operations</u>	58
<u>Consolidated Statements of Stockholders' Equity</u>	59
<u>Consolidated Statements of Cash Flows</u>	60
<u>Notes to Consolidated Financial Statements</u>	61

The following Consolidated Financial Statement Schedule of the Registrant and its subsidiaries for the years ended December 31, 2008, 2007 and 2006 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:

<b>Schedule</b>	<b>Page</b>
II <u>Valuation and Qualifying Accounts</u>	85

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, 2008 and 2007, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2008 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, 2008, 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 the 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 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 13, 2009

**Table of Contents****CUTERA, INC.****CONSOLIDATED BALANCE SHEETS**

(in thousands, except share and per share data)

	December 31,	
	2008	2007
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 36,540	\$ 11,054
Marketable investments	60,653	88,510
Accounts receivable, net of allowance for doubtful accounts in 2008 and 2007 of \$61 and \$9, respectively	5,792	10,692
Inventories	9,927	7,533
Deferred tax asset	4,257	8,058
Other current assets	1,771	1,955
<b>Total current assets</b>	<b>118,940</b>	<b>127,802</b>
Property and equipment, net	1,357	1,361
Long-term investments	9,627	7,429
Intangibles, net	1,025	1,227
Deferred tax asset, net of current portion	6,527	834
<b>Total assets</b>	<b>\$ 137,476</b>	<b>\$ 138,653</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,690	\$ 2,350
Accrued liabilities	8,848	13,587
Deferred revenue	6,758	4,971
<b>Total current liabilities</b>	<b>17,296</b>	<b>20,908</b>
Deferred rent	1,713	1,639
Deferred revenue, net of current portion	4,907	5,593
Income tax liability	1,452	1,160
<b>Total liabilities</b>	<b>25,368</b>	<b>29,300</b>
Commitments and contingencies (Note 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;		
Issued and outstanding: 12,806,035 and 12,738,449 shares in 2008 and 2007, respectively	13	13
Additional paid-in capital	80,318	74,871
Retained earnings	31,410	34,279
Accumulated other comprehensive income	367	190
<b>Total stockholders' equity</b>	<b>112,108</b>	<b>109,353</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 137,476</b>	<b>\$ 138,653</b>

Edgar Filing: CUTERA INC - Form 10-K

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

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

	Year Ended December 31,		
	2008	2007	2006
Net revenue	\$ 83,379	\$ 101,726	\$ 100,692
Cost of revenue	32,358	35,002	29,859
Gross profit	51,021	66,724	70,833
Operating expenses:			
Sales and marketing	35,354	38,277	32,890
Research and development	7,550	7,169	6,473
General and administrative	11,270	11,721	15,192
Litigation settlement			18,935
Total operating expenses	54,174	57,167	73,490
Income (loss) from operations	(3,153)	9,557	(2,657)
Interest and other income, net	3,046	4,207	3,596
Other-than-temporary impairments of long-term investments	(3,554)		
Income (loss) before income taxes	(3,661)	13,764	939
Provision (benefit) for income taxes	(792)	3,260	(1,184)
Net income (loss)	\$ (2,869)	\$ 10,504	\$ 2,123
Net income (loss) per share:			
Basic	\$ (0.22)	\$ 0.80	\$ 0.17
Diluted	\$ (0.22)	\$ 0.74	\$ 0.15
Weighted-average number of shares used in per share calculations:			
Basic	12,770	13,153	12,558
Diluted	12,770	14,228	14,278

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, 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
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
Issuance of common stock for employee purchase plan	50,693		464				464
Exercise of stock options	8,449		45				45
Issuance of common stock in settlement of restricted stock units, net of shares withheld for employee taxes	8,444		(51)				(51)
Share-based compensation expense			5,220				5,220
Tax deficit from exercises of stock-based payment awards			(231)				(231)

## Edgar Filing: CUTERA INC - Form 10-K

Components of other comprehensive loss:											
Net loss							(2,869)		(2,869)		
Other comprehensive income, net of tax of \$230								177	177		
Comprehensive loss											
									(2,692)		
Balance at December 31, 2008	12,806,035	\$	13	\$	80,318	\$	31,410	\$	367	\$	112,108

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,		
	2008	2007	2006
<b>Cash flows from operating activities:</b>			
Net income (loss)	\$ (2,869)	\$ 10,504	\$ 2,123
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Stock-based compensation	5,220	5,627	4,542
Tax benefit (deficit) from stock-based compensation	(231)	4,195	1,808
Excess tax benefit related to stock-based compensation	(44)	(3,652)	(1,032)
Depreciation and amortization	904	913	869
Other-than-temporary impairments of long-term investments	3,554		
Change in deferred tax asset	(1,892)	(2,662)	(2,765)
Other	467	248	(53)
Changes in assets and liabilities:			
Accounts receivable	4,848	(1,066)	(2,980)
Inventories	(2,803)	(2,592)	(65)
Other current assets	1,348	747	1,026
Accounts payable	(660)	138	860
Accrued liabilities	(4,739)	367	4,175
Deferred rent	74	215	328
Deferred revenue	1,101	3,792	3,630
Income tax liability	62	116	
Net cash provided by operating activities	4,340	16,890	12,466
<b>Cash flows from investing activities:</b>			
Acquisition of property and equipment	(703)	(1,000)	(642)
Purchase of intangibles		(20)	(1,218)
Proceeds from sales of marketable investments	55,104	69,103	23,522
Proceeds from maturities of marketable investments	30,065	31,508	99,439
Purchase of marketable and long-term investments	(63,822)	(100,017)	(132,456)
Net cash provided by (used in) investing activities	20,644	(426)	(11,355)
<b>Cash flows from financing activities:</b>			
Proceeds from exercise of stock options and employee stock purchase plan	458	4,138	4,397
Repurchase of common stock		(25,000)	
Excess tax benefit related to stock-based compensation	44	3,652	1,032
Net cash provided by (used in) financing activities	502	(17,210)	5,429
Net increase (decrease) in cash and cash equivalents	25,486	(746)	6,540
Cash and cash equivalents at beginning of year	11,054	11,800	5,260
Cash and cash equivalents at end of year	\$ 36,540	\$ 11,054	\$ 11,800
<b>Supplemental and non-cash disclosure of cash flow information:</b>			
Change in deferred stock-based compensation, net of terminations	\$	\$ (9)	\$ (1,271)

Edgar Filing: CUTERA INC - Form 10-K

Cash paid (received) for income taxes	\$ 2,098	\$ (808)	\$ (1,990)
---------------------------------------	----------	----------	------------

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 physicians and other qualified practitioners to allow its customers 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.

***Use of Estimates.***

The preparation of Consolidated Financial Statements in conformity with generally accepted accounting principles in the United States of America (GAAP) requires the Company's management to make estimates and assumptions that affect the amounts reported and disclosed in the financial statements and the accompanying notes. Actual results could differ materially from those estimates. On an ongoing basis, the Company evaluates their estimates, including those related to the, warranty obligation, sales commission, accounts receivable and sales allowances, fair values of long-term investments, fair values of acquired intangible assets, useful lives of intangible assets and property and equipment, fair values of options to purchase the Company's common stock, recoverability of deferred tax assets, and effective income tax rates, among others. Management bases their estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities.

***Cash, Cash Equivalents, Marketable Investments, and Long-Term Investments.***

The Company invests its cash primarily in money market funds and in highly liquid debt instruments of U.S. federal and municipal governments and their agencies. 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 majority of the Company's cash and investments are held in U.S. banks and its foreign subsidiaries maintain a limited amount of cash in their local banks to cover their short term operating expenses.

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 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 reported as a component of stockholders' equity. 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.

---

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

The Company holds a variety of interest bearing auction rate securities (ARS) that represent investments in pools of student loan assets. The ARS held by the Company have been issued either by the Federal Family Education Loan Program (FELP), or the Maine Education Loan Authority (MELA). At the time of acquisition, these ARS investments were intended to provide liquidity via an auction process that resets the applicable interest rate at predetermined calendar intervals, allowing investors to either roll over their holdings or gain immediate liquidity by selling such interests at par. Since February 2008, uncertainties in the credit markets affected these ARS investments and auctions for the Company's investments in these securities have failed to settle on their respective settlement dates. Consequently, the investments are not currently liquid and the Company will not be able to access these funds until a future auction of these investments is successful, a buyer is found outside of the auction process or the issuer refinances their debt. Maturity dates for these ARS investments range from 2028 to 2043.

As of December 31, 2008, the Company had \$9.6 million of ARS classified as long-term investments and \$250,000 included in marketable investments representing the ARS that were refinanced by the issuers at par in January 2009. The Company has classified its non-refinanced ARS investment balance as long-term investments in the accompanying Consolidated Balance Sheet because of the Company's belief that it could take more than one year before they are readily marketable. The Company's ARS have been classified and accounted for as available-for-sale. These securities are carried at fair value with the unrealized gains and losses reported as a component of stockholders' equity. The estimated fair value of the Company's ARS investments was \$9.9 million at December 31, 2008 and \$21.5 million at December 31, 2007.

The Company reviews the impairment of its investments on a quarterly basis in accordance with Statement of Financial Accounting Standards (SFAS), No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and related guidance issued by the Financial Accounting Standards Board (FASB), and the Securities and Exchange Commission (SEC), in order to determine the classification of the impairment as temporary or other-than-temporary. A temporary impairment charge results in an unrealized loss being recorded in the other comprehensive loss component of stockholders' equity. An other-than-temporary impairment charge is recorded as an unrealized loss in the Consolidated Statement of Operations and is a component of the net loss for the applicable accounting period. Once an other-than-temporary impairment is recorded, a new cost basis in the investment is established. The primary differentiating factors considered by the Company to classify their impairments between temporary, and other-than-temporary, are the 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 issuers and the Company's intent and ability to retain the investment in the issuer to maturity to allow for any anticipated recovery in market value. Using this assessment, the Company determined that there was an other-than-temporary decline in the fair value of its ARS investments of approximately \$3.6 million, which was recognized as an other-than-temporary impairment charge in the Consolidated Statement of Operations for the year ended December 31, 2008. In 2007 and 2006, the Company had not incurred any losses that were other-than-temporary.

***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

---

**Table of Contents**

**CUTERA, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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 worldwide customers. The Company performs credit evaluations of its customers and maintains reserves for potential credit losses. Concentrations of accounts receivable balances are presented in Note 3 and segment, geographic and major customer information is presented in Note 10.

The Company invests in debt instruments including bonds and ARS 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.

***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.

---

**Table of Contents**

**CUTERA, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***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 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, 2008, 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. To determine the estimated warranty reserve, the Company utilizes actual service records to calculate the average service expense per system and applies this to the equivalent number of units exposed under warranty. The Company updates these estimated charges every quarter.

***Revenue Recognition.***

The Company recognizes distributor and non-distributor revenue in accordance with the SEC's Staff Accounting Bulletin, No. 104, *Revenue Recognition* (SAB 104). 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.

## Edgar Filing: CUTERA INC - Form 10-K

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, 2008, 2007 and 2006 was \$11.4 million, \$9.1 million and \$5.9 million, respectively

---

**Table of Contents**

**CUTERA, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Research and Development Expenditures.***

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

***Advertising Costs.***

Advertising costs are included as part of sales and marketing expense and are expensed as incurred. Advertising expense for the years ended December 31, 2008, 2007 and 2006 were \$1.9 million, \$2.1 million and \$1.5 million, respectively.

***Stock-based Compensation.***

The Company accounts for stock-based payments under SFAS 123(R), *Share-Based Payment (revised 2004)*, (SFAS 132(R)), which requires the 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 unit awards (RSUs). SFAS 123(R) requires that compensation cost relating to share-based payment transactions be measured based on the fair value for all awards. The Company uses the Black-Scholes method of valuation to determine the fair value of share-based payments. The Company applied the modified prospective application method under which the provisions of SFAS 123(R) apply to new awards and to awards modified, repurchased or cancelled after the adoption date. Changes in the estimated forfeiture rates are reflected prospectively.

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 vested during the years ended December 31, 2008, 2007 and 2006. During the year ended December 31, 2008, 2007 and 2006, the amount of cash received from the grant of ESPP shares and exercise of stock options was \$458,000, \$4.1 million and \$4.4 million, respectively, and the total direct tax benefit (deficit) realized, including the excess tax benefit (deficit), from stock based award activity was (\$231,000), \$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.

***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 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.



---

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

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*, (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 (loss).***

Comprehensive income (loss) 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 represent the only component of other comprehensive income that is excluded from net income (loss).

***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 (loss) and are insignificant for each of the three years ended December 31, 2008. 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, 2008.

***Recent Accounting Pronouncements.***

In April 2008, the FASB issued FASB Staff Position (FSP), FAS 142-3, *Determination of the Useful Life of Intangible Assets* (FSP FAS 142-3). FSP FAS 142-3 removes the requirement of SFAS 142, *Goodwill and Other Intangible Assets* for an entity to consider, when determining the useful life of an acquired intangible asset, whether the intangible asset can be renewed without substantial cost or material modifications to the existing terms and conditions associated with the intangible asset. FSP FAS 142-3 replaces the previous useful-life assessment criteria with a requirement that an entity considers its own experience in renewing similar arrangements. If the entity has no relevant experience, it would consider market participant assumptions regarding renewal. FSP FAS 142-3 is effective for fiscal years beginning after December 15, 2008. The Company does not expect the adoption of FSP FAS 142-3 to have a material effect on its Consolidated Financial Statements for 2009.

In February 2008, the FASB issued FSP No. FAS 157-2, *Effective Date of FASB Statement No. 157* (FSP 157-2), to partially defer SFAS 157. FSP 157-2 defers the effective date of SFAS 157 for nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), to fiscal years, and interim periods within those fiscal years, beginning after November 15, 2008. The Company does not expect the adoption of the provisions of FSP 157-2 for non-financial assets and non-financial liabilities to have a material effect on its Consolidated Financial Statements for 2009.

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

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations* (SFAS 141R), and SFAS No. 160, *Accounting and Reporting of Non-controlling Interest in Consolidated Financial Statements, an amendment of ARB 51* (SFAS 160), which will change the accounting for and reporting of business combination transactions and noncontrolling interests in consolidated financial statements. The provisions of SFAS 141R and SFAS 160 were effective for the Company on January 1, 2009. SFAS 160 requires changes in classification and presentation of minority interests in the consolidated balance sheets, statements of income, and statements of stockholders' equity. The adoption of the provisions of SFAS 141R is not expected to have any impact on the Company's Consolidated Financial Statements for 2009.

**NOTE 2 INVESTMENT SECURITIES:**

Cash and cash equivalents, marketable investments and long-term investments at December 31, 2008 and 2007 consist of the following (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
<b>December 31, 2008</b>				
Cash and cash equivalents	\$ 36,540	\$	\$	\$ 36,540
Marketable investments:				
Municipal securities	59,837	566		60,403
ARS	219	31		250
<b>Total marketable investments</b>	<b>60,056</b>	<b>597</b>		<b>60,653</b>
Long-term investments in ARS	9,627			9,627
	<b>\$ 106,223</b>	<b>\$ 597</b>	<b>\$</b>	<b>\$ 106,820</b>

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
<b>December 31, 2007</b>				
Cash and cash equivalents:				
Cash and money market funds	\$ 6,405	\$	\$	\$ 6,405
Marketable securities - municipal bonds	4,649			4,649
<b>Total cash and cash equivalents</b>	<b>11,054</b>			<b>11,054</b>
Marketable investments:				
Municipal securities	74,229	190		74,749
ARS	14,091			14,091
<b>Total marketable investments</b>	<b>88,320</b>	<b>190</b>		<b>88,510</b>
Long-term investments in ARS	7,429			7,429
	<b>\$ 106,803</b>	<b>\$ 190</b>	<b>\$</b>	<b>\$ 106,993</b>

The contractual maturities of marketable investment in municipal securities and ARS classified as available for sale as of December 31, 2008, are as follows (in thousands):

Edgar Filing: CUTERA INC - Form 10-K

<b>December 31, 2008</b>	<b>Amount</b>
Due in less than one year (fiscal year 2009)	\$ 21,074
Due in 1 to 3 years (fiscal year 2010- 2011)	33,087
Due in 3 to 5 years (fiscal year 2012-2013)	
Due in 5 to 10 years (fiscal year 2014-2018)	
Due in greater than 10 years (fiscal year 2019 and beyond)	16,119
	\$ 70,280

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

On January 1, 2008, the Company adopted SFAS No. 157, *Fair Value Measurements* (SFAS 157), as it relates to financial assets and financial liabilities. In February 2008, the Financial Accounting Standards Board (FASB) issued FASB Staff Position (FSP) No. FAS 157-2, *Effective Date of FASB Statement No. 157*, which delayed the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on at least an annual basis, until January 1, 2009 for calendar year-end entities. SFAS 157 defines fair value, establishes a framework for measuring fair value in GAAP and expands disclosures about fair value measurements.

SFAS 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. This standard is now the single source in GAAP for the definition of fair value, except for the fair value of leased property as defined in SFAS No. 13, *Accounting for Leases*. SFAS 157 establishes a fair value hierarchy that distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy under SFAS 157 are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Directly or indirectly observable inputs as of the reporting date through correlation with market data, including quoted prices for similar assets and liabilities in active markets and quoted prices in markets that are not active. Level 2 also includes assets and liabilities that are valued using models or other pricing methodologies that do not require significant judgment since the input assumptions used in the models, such as interest rates and volatility factors, are corroborated by readily observable data from actively quoted markets for substantially the full term of the financial instrument.

Level 3: Unobservable inputs that are supported by little or no market activity and reflect the use of significant management judgment. These values are generally determined using pricing models for which the assumptions utilize management's estimates of market participant assumptions.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

As of December 31, 2008, financial assets measured and recognized at fair value on a recurring basis and classified under the appropriate level of the fair value hierarchy as described above was as follows (in thousands):

	Level 1	Level 2	Level 3	Total
Cash equivalents	\$ 34,702	\$	\$	\$ 34,702
Short term marketable investments:				
Available-for-sale securities		60,653		60,653
Long-term investments:				
Available-for-sale ARS			9,627	9,627

Edgar Filing: CUTERA INC - Form 10-K

Total assets at fair value	\$ 34,702	\$ 60,653	\$ 9,627	\$ 104,982
----------------------------	-----------	-----------	----------	------------

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

The Company's Level 1 financial assets are money market funds and highly liquid debt instruments of U.S. federal and municipal governments and their agencies with stated maturities of three months or less from the date of purchase, whose fair values are based on quoted market prices. The Company's Level 2 financial assets are highly liquid debt instruments of U.S. federal and municipal governments and their agencies with stated maturities of greater than three months, whose fair values are obtained from readily-available pricing sources for the identical underlying security that may, or may not, be actively traded.

At December 31, 2008, observable market information was not available to determine the fair value of the Company's ARS investments. Therefore, the fair value is based on broker-provided valuation models that relied on Level 3 inputs including those that are based on expected cash flow streams and collateral values, assessments of counterparty credit quality, default risk underlying the security, market discount rates and overall capital market liquidity. The valuation of the Company's ARS investment portfolio is subject to uncertainties that are difficult to predict. Factors that may impact the valuations in the future include changes to credit ratings of the securities, as well as to the underlying assets supporting those securities, rates of default of the underlying assets, underlying collateral value, discount rates, counterparty risk and ongoing strength and quality of market credit and liquidity. These financial instruments are classified within Level 3 of the fair value hierarchy.

The table presented below summarizes the change in carrying value associated with Level 3 financial assets, which represents the Company's investment in ARS and classified as long-term investments, for the year ended December 31, 2008 (in thousands):

	<b>December 31, 2008</b>
Balance at December 31, 2007	\$
Transfers into Level 3	13,400
Transfers from Level 3 to Level 2	(250)
Total gains or losses (realized or unrealized)	
Included in earnings (other-than-temporary impairment of non-current ARS investments)	(3,554)
Included in other comprehensive income	31
Balance at December 31, 2008	\$ 9,627

**NOTE 3 BALANCE SHEET DETAIL:*****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, 2008 and 2007, one customer accounted for 25% and 35% of the Company's total accounts receivable balance, respectively.

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

Inventories consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Raw materials	\$ 5,071	\$ 3,313
Finished goods	4,856	4,220
	<b>\$ 9,927</b>	<b>\$ 7,533</b>

**Property and Equipment, net:**

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

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Leasehold improvements	\$ 347	\$ 152
Office equipment and furniture	2,572	2,541
Machinery and equipment	2,403	1,987
	5,322	4,680
Less: Accumulated depreciation	(3,965)	(3,319)
Property and equipment, net	\$ 1,357	\$ 1,361

Depreciation expense related to property and equipment was \$702,000, \$674,000 and \$628,000 for the years ended December 31, 2008, 2007 and 2006, respectively.

**Intangible Assets:**

Intangible assets were principally comprised of a patent sublicense acquired from Palomar in 2006, a technology sublicense acquired in 2002 and other intangible assets acquired in 2007. The components of intangible assets at December 31, 2008 and 2007 were as follows (in thousands):

	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization Amount</b>	<b>Net Amount</b>
<b>December 31, 2008 (in thousands)</b>			
Patent sublicense	\$ 1,218	\$ 379	\$ 839
Technology sublicense	538	356	182
Other intangibles	20	16	4

Edgar Filing: CUTERA INC - Form 10-K

Total	\$ 1,776	\$ 751	\$ 1,025
<b>December 31, 2007 (in thousands)</b>			
Patent sublicense	\$ 1,218	\$ 241	\$ 977
Technology sublicense	538	302	236
Other intangibles	185	171	14
Total	\$ 1,941	\$ 714	\$ 1,227



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

For the year ended December 31, 2008, 2007 and 2006, amortization expense for intangible assets was \$202,000, \$239,000 and \$241,000, respectively.

Based on intangible assets recorded at December 31, 2008, 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):

<b>Year ending December 31,</b>	<b>Amount</b>
2009	\$ 196
2010	192
2011	192
2012	158
2013	138
2014 and thereafter	149
<b>Total</b>	<b>\$ 1,025</b>

**Accrued Liabilities:**

Accrued liabilities consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Payroll and related expenses	\$ 3,523	\$ 5,547
Warranty	1,916	2,725
Royalty	623	1,047
Professional fees	432	328
Income tax payable	285	1,134
Sales and marketing accruals	200	588
Sales tax	806	809
Customer deposits	225	208
Other	838	1,201
	<b>\$ 8,848</b>	<b>\$ 13,587</b>

**NOTE 4 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, Spain 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):***

	<b>Year Ended December 31,</b>	
	<b>2008</b>	<b>2007</b>
Balance at beginning of year	\$ 2,725	\$ 3,055
Add: Accruals for warranties issued during the year	4,560	5,087
Less: Settlements made during the year	(5,369)	(5,417)
Balance at end of year	\$ 1,916	\$ 2,725

***Deferred Service Contract Revenue (in thousands):***

	<b>Year Ended December 31,</b>	
	<b>2008</b>	<b>2007</b>
Balance at beginning of year	\$ 10,564	\$ 6,652
Add: Payments received	9,915	10,498
Less: Revenue recognized	(8,814)	(6,586)
Balance at end of year	\$ 11,665	\$ 10,564

Costs incurred under service contracts during the years ended December 31, 2008, 2007 and 2006 amounted to \$4.4 million, \$2.4 million and \$1.6 million, respectively, and are recognized as incurred.

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

As of December 31, 2008, 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 254,769 and 258,788 reserved shares to the 2004 ESPP on January 1, 2008 and January 1, 2007, respectively. 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 50,693 and 42,868 shares of common stock under the 2004 ESPP in fiscal years 2008 and 2007, respectively. At December 31, 2008, 949,200 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 was 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. The Company added 636,922 and 646,969 shares to the 2004 Equity Incentive Plan on January 1, 2008 and January 1, 2007, respectively. During 2008, the 2004 Equity Incentive Plan was amended to remove this feature beginning in 2009.

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 2004 Equity Incentive 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 1/48<sup>th</sup> 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 2008 and 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, 2006, 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.

The Company issues new shares upon the exercise of options, restricted stock units and ESPP shares.

**Table of Contents**

## CUTERA, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**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)*
<b>Balances as of December 31, 2007</b>	2,047,649	2,417,575	\$ 14.22		
Additional shares reserved	636,922				
Options granted	(888,150)	888,150	\$ 10.77		
Options exercised		(8,449)	\$ 5.39		
Options cancelled or forfeited	215,543	(215,543)	\$ 18.69		
Restricted stock units cancelled or forfeited	1,125				
<b>Balances as of December 31, 2008</b>	2,013,089	3,081,733	\$ 12.94	4.58	\$ 6.0
<b>Exercisable as of December 31, 2008</b>		1,842,485	\$ 11.44	3.77	\$ 6.0

\* Based on the closing stock price of \$8.87 for the Company's common stock on December 31, 2008, the last day of trading for the 2008 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 2008 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, 2008. 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, 2008, 2007 and 2006 was \$57,000, \$23.9 million and \$13.5 million, respectively.

The options outstanding and exercisable at December 31, 2008 were in the following exercise price ranges:

Range of Exercise Prices	Options Outstanding Number Outstanding	Options Outstanding Weighted-Average Remaining Contractual Life (in years)	Options Exercisable Number Outstanding	Options Exercisable Weighted-Average Exercise Price
\$ 0.10 \$ 0.10	433,333	0.70	433,333	\$ 0.10
\$ 0.50 \$ 4.25	337,658	3.12	337,658	2.90
\$ 5.50 \$10.00	143,819	5.22	76,132	7.32
\$10.43 \$10.43	610,250	6.38		
\$12.14 \$13.80	340,547	5.45	203,985	13.49
\$14.00 \$20.25	396,839	6.15	370,281	17.14

Edgar Filing: CUTERA INC - Form 10-K

\$21.84	\$23.75	357,953	4.86	186,358	23.70
\$24.46	\$25.39	315,896	3.72	135,425	24.66
\$25.73	\$27.36	137,125	6.33	94,646	26.26
\$34.45	\$34.45	8,313	3.57	4,667	34.45
\$ 0.10	\$34.45	3,081,733	4.58	1,842,485	\$ 11.44

As of December 31, 2007 there were 1,494,100 options that were exercisable at a weighted average exercise price of \$8.99.

**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 <sup>(1)</sup> (in thousands)
<b>Outstanding at December 31, 2007</b>	27,372	\$ 20.25	
Granted		\$	
Vested <sup>(2)</sup>	(13,436)	\$ 20.25	\$ 138 <sup>(3)</sup>
Forfeited	(1,125)	\$ 20.25	
<b>Outstanding at December 31, 2008</b>	12,811	\$ 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 \$272,000.

**Stock-Based Compensation.**

Stock-based compensation expense for stock options, restricted stock units and ESPP shares for the year ended December 31, 2008 and 2007 was as follows (in thousands):

	Year Ended December 31,	
	2008	2007
Stock Options	\$ 4,783	\$ 4,982
RSUs	257	294
ESPP	180	351
Total share-based compensation expense	5,220	5,627
Tax effect on share-based compensation at the marginal tax rates	(1,788)	(1,963)
Net share-based compensation expense	\$ 3,432	\$ 3,664

Total pre-tax stock-based compensation expense by department recognized during the year ended December 31, 2008 and 2007 was as follows (in thousands):



Edgar Filing: CUTERA INC - Form 10-K

	Year Ended December 31,	
	2008	2007
Cost of revenue	\$ 846	\$ 891
Sales and marketing	1,657	1,678
Research and development	628	752
General and administrative	2,089	2,306
<b>Total share-based compensation expense</b>	<b>\$ 5,220</b>	<b>\$ 5,627</b>

As of December 31, 2008, the unrecognized compensation cost, net of expected forfeitures, related to stock options, RSUs and ESPP was \$6.9 million, \$108,000 and \$57,000, which will be recognized using the straight- line attribution method over an estimated weighted-average amortization period of 2.50 years, 0.42 years and 0.33 years, respectively.

**Table of Contents****CUTERA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)*****Valuation Assumptions and Fair Value of Stock Option and ESPP Grants.***

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		
	2008	2007	2006	2008	2007	2006
Estimated fair value of grants during the year	\$ 5.29	\$ 11.42	\$ 14.16	\$ 4.52	\$ 9.20	\$ 8.97
Expected term (in years) <sup>(1)</sup>	4.68	3.76	5.05	0.50	0.62	0.75
Risk-free interest rate <sup>(2)</sup>	3.2%	4.9%	4.9%	1.90%	4.7%	4.4%
Volatility <sup>(3)</sup>	55%	56%	64%	51%	59%	58%
Dividend yield <sup>(4)</sup>	%	%	%	%	%	%

- (1) The expected term represents the period during which the Company's stock-based awards are expected to be outstanding. The estimated term is based on historical experience of similar awards, giving consideration to the contractual terms of the awards, vesting requirements, and expectation of future employee behavior, including post-vesting terminations. Prior to 2008, the Company used the simplified method of calculating expected life described in SAB 107, *Share Based Payment*, 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 Initial Public Offering (IPO) of its common stock.
- (2) The risk-free interest rate is based on U.S. Treasury debt securities with maturities close to the expected term of the option as of the date of grant.
- (3) Expected volatility is a 50%/50% blend of implied and historical volatility. The Company has determined that this is a more reflective measure of market conditions and a better indicator of expected volatility, than its limited historical volatility since the IPO, of its common stock.
- (4) The Company has not historically issued any dividends and does not expect to do so in the foreseeable future.

The Company periodically estimates forfeiture rates based on its historical experience within separate groups of employees and adjusts the share-based payment expense accordingly.

**NOTE 6: COMMON STOCK REPURCHASES*****Common Stock Repurchase Program***

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 Rule 10b5-1 trading 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 5 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. The Company withheld 4,992 and 5,288 shares of common stock to satisfy approximately \$51,000 and \$139,000 of its employees' tax obligations, during 2008 and 2007, respectively. The Company paid this amount in cash to the appropriate taxing authorities.



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

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 7 INCOME TAXES:**

The Company files income tax returns in the U.S. federal and various state and local jurisdictions and foreign jurisdictions. The components of the provision for income taxes are as follows (in thousands):

	2008	December 31, 2007	2006
Current:			
Federal	\$ 1,009	\$ 4,904	\$ 1,024
State	305	626	176
Foreign	382	260	382
	1,696	5,790	1,582
Deferred:			
Federal	(2,313)	(2,052)	(2,457)
State	(78)	(416)	(309)
Foreign	(97)	(62)	
	(2,488)	(2,530)	(2,766)
Provision (benefit) for income taxes	\$ (792)	\$ 3,260	\$ (1,184)

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

	December 31, 2008	2007
Credits	\$ 922	\$ 857
Accrued warranty	737	1,075
Other accruals and reserves	4,458	3,450
Stock-based compensation	4,056	2,780
Other	514	419
Foreign	226	130
Capital loss	1,133	
Deferred tax asset	12,046	8,711
Depreciation and amortization	105	181
Net deferred tax asset before valuation allowance	12,151	8,892
Valuation allowance against capital loss related deferred tax asset	(1,367)	
Net deferred tax asset after valuation allowance	\$ 10,784	\$ 8,892



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

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

	Year Ended December 31,		
	2008	2007	2006
U.S. federal statutory income tax rate	35.00%	35.00%	35.00%
State tax rate, net of federal benefit	(2.38)	4.58	4.98
Meals and entertainment	(3.45)	0.92	11.80
Benefit for research and development credit	11.07	(10.62)	(109.81)
Stock-based compensation	(5.65)	1.90	19.89
Tax-exempt interest	27.85	(9.61)	(112.08)
Valuation allowance	(37.34)		
Other	(3.47)	1.51	24.07
<b>Effective tax rate</b>	<b>21.63%</b>	<b>23.68%</b>	<b>(126.15)%</b>

The Company recognizes deferred tax assets for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities, and for operating losses and tax credit carryforwards. The Company records a valuation allowance to reduce the deferred tax assets to their estimated realizable value, when it is more likely than not that it will not be able to generate sufficient future taxable income to realize the net carrying value.

In 2008, the Company loss before income taxes included an unrealized capital loss resulting from an other-than-temporary impairment charge relating to ARS investments. After considering both the positive and negative evidence as of December 31, 2008, the Company determined that it was not more-likely-than-not that it would realize the full value of its capital loss related deferred tax assets. As a result, the Company established a valuation allowance against this deferred tax asset. The Company believes that it is more likely than not that it will be able to generate sufficient future taxable income to realize the carrying value of the remaining deferred tax assets. The Company reviews the deferred tax asset and valuation allowance on a quarterly basis, and considers whether positive and negative evidence exists to effect the realization of deferred tax assets.

Undistributed earnings of the Company's foreign subsidiaries of approximately \$2.1 million at December 31, 2008, 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, 2008, the Company had cumulative carry-forwards for research and development credits for federal and state income tax purposes of approximately \$2.8 million and \$2.7 million, respectively. These federal research and development tax credits expire through the year 2028. The state research and development credits can be carried forward indefinitely, except for \$284,000, which will expire at various dates through the year 2020. Furthermore, the Company has federal alternative minimum tax credits of approximately \$1.1 million 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 \$4.5 million as a credit to additional paid in capital as and when such excess tax benefits are ultimately realized.

As of December 31, 2008, the Company did not have any cumulative net operating loss carry-forwards for federal and state income tax purposes.



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

During 2008, the IRS completed its examination of the Company's U.S. income tax returns for 2005 and 2006. The net adjustment resulting from the examination did not have a material effect on the Company's net loss or financial position and has been reflected in the 2008 tax provision.

***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. 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 December 31, 2007 to December 31, 2008 (in thousands):

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Balance at beginning of year	\$ 1,500	\$ 1,067
Increases related to prior year tax positions		588
Decreases related to prior year tax positions	(98)	(59)
Increases related to current year tax positions	258	
Decreases related to settlements with taxing authorities		
Decreases related to lapsing of statute of limitations	(20)	(96)
Balance at end of year	\$ 1,640	\$ 1,500

The Company's total unrecognized tax benefits that, if recognized, would affect its effective tax rate were approximately \$810,000 and \$664,000 as of December 31, 2008 and 2007, respectively. The Company had accrued approximately \$104,000 and \$109,000 for payment of interest as of December 31, 2008 and 2007, respectively. 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 not change within the next 12 months.

**NOTE 8 NET INCOME (LOSS) PER SHARE:**

Basic net income (loss) per share is calculated by dividing net income (loss) by the weighted-average number of common shares outstanding during the year. Diluted net income per share is calculated by using the weighted-average number of common shares outstanding during the year 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, Employee Stock Purchase Plan shares and restricted stock units is reflected in diluted net income 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*.

For years presented with a net diluted net loss per common share is the same as basic net loss per common share, as the effect of the potential common stock equivalents is anti-dilutive and as such is excluded from the calculations of the diluted net loss per share.



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

The following table sets forth the computation of basic and diluted net income (loss) and the weighted average number of shares used in computing basic and diluted net income (loss) per share (in thousands):

	Year Ended December 31,		
	2008	2007	2006
<b>Numerator:</b>			
Net income (loss) Basic and Diluted	\$ (2,869)	\$ 10,504	\$ 2,123
<b>Denominator:</b>			
Weighted-average number of common shares outstanding used in computing basic net income (loss) per share	12,770	13,153	12,558
Dilutive potential common shares used in computing diluted net income (loss) per share		1,075	1,720
Total weighted-average number of shares used in computing diluted net income (loss) per share	12,770	14,228	14,278

**Anti-dilutive Securities**

The following number of weighted shares outstanding, prior to the application of the treasury stock method, were excluded from the computation of diluted net income (loss) per common share for the years presented because including them would have had an anti-dilutive effect (in thousands):

	Year Ended December 31,		
	2008	2007	2006
Options to purchase common stock	2,882		
Restricted stock units	19		
Employee stock purchase plan shares	94	829	621
	2,995	829	621

**NOTE 9 DEFINED CONTRIBUTION PLAN:**

In the United States, the Company has an employee savings plan (401(k) 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 401(k) 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 401(k) Plan year. During the years ended December 31, 2008, 2007 and 2006, the Company made discretionary contributions of \$572,000, \$597,000 and \$557,000, respectively, under the 401(k) Plan.

For the Company's Japanese subsidiary, it has established an employee retirement plan at its discretion. In addition, for some of the Company's other foreign subsidiaries, the Company deposits funds with insurance companies, third-party trustees, or into government-managed accounts consistent with the requirements of local laws. The Company has fully funded or accrued for its obligations as of December 31, 2008, and the related expense was not material in each of the years ended December 31, 2008, 2007 and 2006.



**Table of Contents****CUTERA, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****NOTE 10 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.

The Company had one customer that represented net revenue of 14% in 2008 and 2007, and 15% in 2006 and accounted for 25% and 35% of the Company's total accounts receivable balance, as of December 31, 2008 and 2007, respectively.

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

	Year Ended December 31,		
	2008	2007	2006
<b>Revenue mix by geography:</b>			
United States	\$ 41,683	\$ 64,084	\$ 69,895
Japan	10,929	8,453	7,396
Asia, excluding Japan	10,368	9,445	8,385
Europe	10,522	9,258	7,239
Rest of the world	9,877	10,486	7,777
<b>Consolidated total</b>	<b>\$ 83,379</b>	<b>\$ 101,726</b>	<b>\$ 100,692</b>
<b>Revenue mix by product category:</b>			
Products	\$ 57,998	\$ 74,502	\$ 84,695
Product upgrades	8,361	13,342	6,006
Service	11,358	9,128	5,890
Titan hand piece refills	5,662	4,754	4,101
<b>Consolidated total</b>	<b>\$ 83,379</b>	<b>\$ 101,726</b>	<b>\$ 100,692</b>

**NOTE 11 COMMITMENTS AND CONTINGENCIES:****Facility Leases.**

The Company leases its Brisbane, California, office and manufacturing facility under a non-cancelable operating lease which expires in 2013. In addition, the Company has leased office facilities in certain international countries as follows:

Country	Square Footage	Lease termination or Expiration
Japan	Approximately 5,790	Three leases which expire in May 2009, May 2010 and July 2010
Switzerland	Approximately 2,884	

## Edgar Filing: CUTERA INC - Form 10-K

France	Approximately 1,240	Lease can be terminated by either party at the end of any calendar quarter upon six months' written notice
Spain	Approximately 175	Lease expires in December 2009
		Lease automatically renews at the end of each six-month period

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

As of December 31, 2008, the Company was committed to minimum lease payments for facilities and other leased assets under long-term non-cancelable operating leases as follows (in thousands):

<b>Year Ending December 31,</b>	<b>Amount</b>
2009	\$ 1,513
2010	1,341
2011	1,319
2012	1,430
2013	1,544
2014 and thereafter	
<b>Future minimum rental payments</b>	<b>\$ 7,147</b>

For the years ended December 31, 2008, 2007 and 2006, gross rent expense was \$1.7 million, \$1.5 million and \$1.3 million, respectively.

***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, 2008.

***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 *Litigation* and *Litigation Settlement* below. 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.

***Litigation***

Two securities class action lawsuits were filed against the Company and two of the Company's 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. On September 30, 2008, in response to the Company's motion, the Court issued an order dismissing the plaintiffs' amended complaint without prejudice. On October 28, 2008, the plaintiffs filed a



---

**Table of Contents**

**CUTERA, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Notice Of Intention Not to File A Second Amended Consolidated Complaint. On November 25, 2008, the Court closed the case on its own initiative. On November 26, 2008, the plaintiffs filed a Notice of Appeal to the U.S. Court of Appeals for the Ninth Circuit. The Company intends to continue to defend this case vigorously, regardless of the stage of litigation. Although the Company retains director and officer liability insurance, 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. Since the Company does not believe that a significant adverse result in this litigation is probable and since the amount of potential damages in the event of an adverse result is not reasonably estimable, 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 nationwide during the four-year period preceding the lawsuit without the prior express invitation or permission of the recipients. Two state law claims, limited to Illinois recipients, allege a class period of three and five years, respectively. 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 it is unclear how many facsimiles were transmitted during the period for which the plaintiff seeks class certification and unclear how many of these facsimiles were unsolicited within the meaning of the TCPA, the Company expects that the number of unsolicited facsimiles could be large and potential liability may be substantial as a result. The Company retained general liability insurance, with one insurer covering the first two years of the four-year period preceding the lawsuit, and a second insurer covering the latter two years of that four-year period. The first carrier has agreed to defend the Company subject to a reservation of rights. The second carrier has declined coverage. The Company intends to defend this case vigorously, including the plaintiff's allegations seeking class certification, regardless of the stage of litigation. Since the Company does not believe that a significant adverse result in this litigation is probable and since the amount of potential damages in the event of an adverse result is not reasonably estimable, no expense has been recorded with respect to the contingent liability associated with this matter.

***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, 2008, the Company was not a party to any material pending litigation other than those described above in the *Litigation* section.

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

<b>Quarter ended:</b>	<b>Dec. 31, 2008</b>	<b>Sept. 30, 2008</b>	<b>June 30, 2008</b>	<b>March 31, 2008</b>	<b>Dec. 31, 2007</b>	<b>Sept. 30, 2007</b>	<b>June 30, 2007</b>	<b>March 31, 2007</b>
Net revenue	\$ 17,897	\$ 19,110	\$ 24,754	\$ 21,618	\$ 26,453	\$ 28,143	\$ 23,873	\$ 23,257
Cost of revenue	7,045	7,823	9,271	8,219	9,704	9,607	7,910	7,781
Gross profit	10,852	11,287	15,483	13,399	16,749	18,536	15,963	15,476
Operating expenses:								
Sales and marketing	6,568	8,076	10,361	10,349	9,438	10,586	9,190	9,063
Research and development	1,933	1,828	2,004	1,785	1,735	1,764	1,923	1,747
General and administrative	2,723	2,583	3,023	2,941	2,725	3,078	2,900	3,018
Total operating expense	11,224	12,487	15,388	15,075	13,898	15,428	14,013	13,828
Income (loss) from operations	(372)	(1,200)	95	(1,676)	2,851	3,108	1,950	1,648
Interest and other income, net	555	733	857	901	1,001	1,096	1,108	1,002
Other-than-temporary impairment of long-term investments	(1,182)	(2,372)						
Income (loss) before income taxes	(999)	(2,839)	952	(775)	3,852	4,204	3,058	2,650
Provision (benefit) for income taxes	(764)	(86)	291	(233)	229	1,112	1,024	895
Net income (loss)	\$ (235)	\$ (2,735)	\$ 661	\$ (542)	\$ 3,623	\$ 3,092	\$ 2,034	\$ 1,755
Net income (loss) per share basic	\$ (0.02)	\$ (0.22)	\$ 0.05	\$ (0.04)	\$ 0.28	\$ 0.24	\$ 0.15	\$ 0.13
Net income (loss) per share diluted	\$ (0.02)	\$ (0.22)	\$ 0.05	\$ (0.04)	\$ 0.27	\$ 0.22	\$ 0.14	\$ 0.12
Weight-average number of shares used in per share calculations:								
Basic	12,797	12,780	12,764	12,740	12,714	13,026	13,610	13,216
Diluted	12,797	12,780	13,465	12,740	13,561	13,970	14,666	14,629
Cash and cash equivalents, marketable investments and long-term investments	\$ 106,820	\$ 109,373	\$ 107,814	\$ 104,490	\$ 106,993	\$ 99,536	\$ 115,415	\$ 111,239



Table of Contents

## SCHEDULE II

## CUTERA, INC.

## VALUATION AND QUALIFYING ACCOUNTS

(in thousands)

For the Year Ended December 31, 2008, 2007 and 2006

	Balance at Beginning of Year	Additions	Deductions	Balance at End of Year
Allowance for doubtful accounts receivable				
Year ended December 31, 2008	\$ 9	\$ 191	\$ 139	\$ 61
Year ended December 31, 2007	\$ 34	\$ 222	\$ 247	\$ 9
Year ended December 31, 2006	\$ 177	\$ 221	\$ 364	\$ 34
Reserve for excess and obsolete inventories				
Year ended December 31, 2008	\$ 1,051	\$ 409	\$ 593	\$ 867
Year ended December 31, 2007	\$ 851	\$ 279	\$ 79	\$ 1,051
Year ended December 31, 2006	\$ 992	\$ 90	\$ 231	\$ 851
Valuation allowance for deferred tax assets				
Year ended December 31, 2008	\$	\$ 1,367	\$	\$ 1,367

---

**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, 2008. The effectiveness of our internal control over financial reporting as of December 31, 2008 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 2009 Annual Meeting of Stockholders will be held at their principal executive offices located at 3240 Bayshore Blvd., Brisbane, CA 94005-1021 on May 5, 2009 at 10:00 a.m. and the record date for the purposes of voting in that meeting shall be March 9, 2009.

**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 2009 Annual Meeting of Stockholders with the Securities and Exchange Commission within 120 days after the end of our fiscal year ended December 31, 2008.

**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 schedule required by Item 15(a) filed as Item 8 of this annual report.
- (3) Exhibits.

<b>Exhibit No.</b>	<b>Description</b>
3.2 <sup>(1)</sup>	Amended and Restated Certificate of Incorporation of the Registrant (Delaware).
3.4 <sup>(1)</sup>	Bylaws of the Registrant.
4.1 <sup>(4)</sup>	Specimen Common Stock certificate of the Registrant.
10.1 <sup>(1)</sup>	Form of Indemnification Agreement for directors and executive officers.
10.2 <sup>(1)</sup>	1998 Stock Plan.
10.3 <sup>(1)</sup>	2004 Equity Incentive Plan.
10.4 <sup>(5)</sup>	2004 Employee Stock Purchase Plan.
10.6 <sup>(1)</sup>	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 <sup>(2)</sup>	Settlement Agreement and Non-Exclusive Patent License, each between the Registrant and Palomar Medical Technologies, Inc. dated June 2, 2006.
10.11 <sup>(3)</sup>	Form of Performance Unit Award Agreement.
10.13 <sup>(4)</sup>	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 90).
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

- (1) Incorporated by reference from our Registration Statement on Form S-1 (Registration No. 333-111928) which was declared effective on March 30, 2004.
- (2) Incorporated by reference from our Current Report on Form 8-K filed on June 2, 2006.
- (3) Incorporated by reference from our Quarterly Report on Form 10-Q filed on November 14, 2005.
- (4) Incorporated by reference from our Quarterly Report on Form 10-Q filed on November 8, 2006.
- (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 16th day of March, 2009.

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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<i>/s/</i> KEVIN P. CONNORS <b>Kevin P. Connors</b>	President, Chief Executive Officer and Director (Principal Executive Officer)	March 16, 2009
<i>/s/</i> RONALD J. SANTILLI <b>Ronald J. Santilli</b>	Chief Financial Officer and Executive Vice President (Principal Financial and Accounting Officer)	March 16, 2009
<i>/s/</i> DAVID A. GOLLNICK <b>David A. Gollnick</b>	Executive Vice President of Research and Development and Director	March 16, 2009
<i>/s/</i> DAVID B. APFELBERG <b>David B. Apfelberg</b>	Director	March 16, 2009
<i>/s/</i> ANNETTE J. CAMPBELL-WHITE <b>Annette J. Campbell-White</b>	Director	March 16, 2009
<i>/s/</i> MARK LORTZ <b>Mark Lortz</b>	Director	March 16, 2009
<i>/s/</i> TIM O SHEA <b>Tim O Shea</b>	Director	March 16, 2009
<i>/s/</i> JERRY P. WIDMAN	Director	March 16, 2009

**Jerry P. Widman**

90