

CUTERA INC
Form 10-K
March 15, 2010

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, 2009

Commission file number: 000-50644

Cutera, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period than the registrant was

Edgar Filing: CUTERA INC - Form 10-K

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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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, 2009 (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 Select Market on that date, was \$56 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 26, 2010 was 13,436,163.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates by reference certain information from the registrant's definitive proxy statement for the 2010 Annual Meeting of Stockholders.

TABLE OF CONTENTS

	Page
PART I	
Item 1. Business	3
Item 1A. Risk Factors	15
Item 1B. Unresolved Staff Comments	26
Item 2. Properties	26
Item 3. Legal Proceedings	26
Item 4. [Reserved]	27
PART II	
Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	27
Item 6. Selected Financial Data	29
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	30
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	43
Item 8. Financial Statements and Supplementary Data	45
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	72
Item 9A. Controls and Procedures	72
Item 9B. Other Information	72
PART III	
Item 10. Directors, Executive Officers and Corporate Governance	73
Item 11. Executive Compensation	73
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	73
Item 13. Certain Relationships and Related Transactions, and Director Independence	73
Item 14. Principal Accounting Fees and Services	73
PART IV	
Item 15. Exhibits and Financial Statement Schedules	74

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 Platform 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. This product platform represents the largest contributor to our Product and Upgrade revenue.
- **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 laser and light based platforms 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.

In addition to systems and upgrades, we generate revenue from the sale of post warranty service and Titan hand piece refills.

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.

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 2008 there were over 10 million minimally-invasive aesthetic procedures performed, a 5% increase over 2007 and a 90% 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 45 to 63 in 2009, 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 nearly 375,000 sclerotherapy procedures were performed in 2008.

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 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 2008, 5.0 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 840,000 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 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.

Strategy

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

- **Continue to Expand our Product Offering-** Though we believe that our current portfolio of products is comprehensive, our research and development group has a pipeline of potential products under development that we expect to commercialize in the future. In the fourth quarter of 2009, we indefinitely postponed the launch of our TruSculpt product for the body contouring market. We plan to continue to refine this product and obtain additional clinical data until we establish that the clinical protocols yield the desired outcome. In addition to products in the laser and light based aesthetic market, we are expanding our product offering into other complementary aesthetic applications, such as dermal fillers and cosmeceuticals. Such products will allow us to leverage our existing customer call points, and provide us with new customer call points, to generate additional revenue, which will enhance the productivity of our distribution channels.
- **Increasing Revenue and Improving Productivity-** We believe that the market for aesthetic systems will continue to offer growth opportunities in the future even though our revenue declined by 36% in 2009, compared with 2008, due to the global recession. We continue to build brand-recognition, add additional products to our international distribution channel and remain focused on enhancing our global distribution network, all of which we expect will increase our revenue. In addition, we plan to grow our U.S. revenue by leveraging our relationship with PSS World Medical Shared Services, Inc., or PSS a wholly-owned subsidiary of PSS World Medical that operates medical supply distribution service centers with over 700 sales consultants serving physician offices throughout the United States. In 2009, we restructured our direct sales force with goals of managing expenses in line with our reduced business, and improving productivity by retaining our key performers and expanding their sales territories.
- **Increasing Focus on Practitioners with Established Medical Offices-** We believe there is growth opportunity in targeting our products to a broad customer base, however, due to the recent global recession, we have shifted our focus to the core practitioners and physicians with established medical offices. We believe that our customer success is largely dependent upon having an existing medical practice, in which our systems provide incremental revenue sources to augment their practice revenue.
- **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 2010, we plan on continuing to market upgrades to our installed base, including our Pearl and Pearl Fractional applications introduced in 2007

and 2008, respectively.

5

- **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 through direct billing for parts and labor. These post-warranty services serve as additional sources of recurring revenue.

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:	Skin Rejuvenation		
System Platforms:	Products:	Year:	Energy Source:		Dyschromia:	Texture, Lines and Wrinkles:	Skin Laxity:
CoolGlide	CV	2000	a	x			
	Excel	2001	a				
	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.

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.

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.

VASER® Lipo System

In January 2010, we announced a strategic alliance with Sound Surgical Technologies, LLC to distribute their VASER Lipo System in Europe and Canada. The VASER System is an ultrasonic liposuction device that allows physicians to perform a wide array of body contouring applications.

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.

Service

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.

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.

Fillers and Cosmeceuticals

In the fourth quarter of 2008, we began to distribute BioForm's Radiesse® dermal filler product to physicians in the Japanese market. In January 2010, we announced a distribution agreement with Obagi Medical Product, Inc. to distribute their prescription-based, topical skin health systems in Japan.

Our Applications and Procedures

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

Hair Removal- Our laser technology allows our customers to treat all skin types and hair thicknesses. Our 1064 nm Nd:YAG laser permits energy to safely penetrate through the epidermis of any skin type and into the dermis where the hair follicle is located. Using the universal graphic user interface on our control console, the practitioner sets parameters to deliver therapeutic energy with a large spot size and variable pulse durations, allowing the practitioner to treat fine or coarse hair. Our 1064nm Nd:YAG hand piece allows our customers to treat all skin types, while our ProWave 770 hand piece, with its pulsed light technology, treats the majority of skin types quickly and effectively.

To remove hair using a 1064nm Nd:YAG hand piece, the treatment site on the skin is first cleaned and shaved. The practitioner then applies a thin layer of gel to glide across the skin, and next applies the hand piece directly to the skin to cool the area to be treated and then delivers a laser pulse to the pre-cooled area. To remove hair using the ProWave 770 hand piece, mineral oil is used instead of gel, and cooling is provided by a sapphire window placed directly on the skin, allowing the pulse of light to be applied while the treatment area is being cooled. In the case of both hand pieces, delivery of the energy destroys the hair follicles and prevents hair re-growth. This procedure is then repeated at the next treatment site on the body, and can be done in a gliding motion to increase treatment speed. Patients receive on average three to six treatments. Each treatment can take between five minutes and one hour depending on the size of the area and the condition being treated. On average, there are six to eight weeks between treatments.

Vascular Lesions- Our laser technology allows our customers to treat the widest range of aesthetic vein conditions, including spider and reticular veins and small facial veins. Our 1064nm Nd:YAG hand piece's adjustable spot size of 3, 5, 7 or 10 millimeters allows the practitioner to control treatment depth to target different sized veins. Selection of the appropriate energy level and pulse duration ensures effective treatment of the intended target. Our AcuTip 500 hand piece, with its 6 millimeter spot size, uses pulsed-light technology and is designed for the treatment of facial vessels.

The vein treatment procedure when using the 1064nm Nd:YAG hand piece is performed in a substantially similar manner to the laser hair removal procedure. The laser hand piece is used to cool the treatment area both before and after the laser pulse has been applied. With the AcuTip 500 hand piece, the pulse of light is delivered while the treatment area is being cooled with the sapphire tip. The delivered energy damages the vein and, over time, it is absorbed by the body. Patients receive on average between one and six treatments, with six weeks or longer between treatments.

Skin Rejuvenation- Our laser and other light-based technologies allow our customers to perform non-invasive and minimally-invasive treatments that reduce redness, pore size, fine lines and laxity, improve skin texture, and treat other aesthetic conditions. Our products are each designed to minimize the risk of damage to the surrounding tissue.

Texture; 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.

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.

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, 2009, we had a U.S. direct sales force of 24 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. Revenue from PSS was \$3.8 million in 2009, \$12.1 million in 2008, and \$14.6 million in 2007.

International sales are generally made through a direct international sales force of 26 employees, as well as a worldwide distributor network in over 30 countries as of December 31, 2009. As of December 31, 2009, we had direct sales offices in Australia, Canada, France, Japan, Spain, Switzerland and the United Kingdom. Our international revenue as a percentage of total revenue represented 61% in 2009, 50% in 2008, and 37% in 2007.

We internally manage our U.S. and Canadian sales organization as one North American sales region with 30 territories as of December 31, 2009.

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, address the specific aesthetic procedures in demand, and are upgradeable on our customers' existing systems. In addition, we provide attractive upgrade pricing to new product families and are responsive to our customers' financing preferences. To increase market penetration, in addition to marketing to the core specialties of plastic surgeons and dermatologists, we 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, ongoing training and support, and distributing (in Japan only) a dermal filler product. We primarily target our marketing efforts to practitioners through office visits, workshops, trade shows, webinars and trade journals. We also market to potential patients through brochures, workshops and our website. In addition, 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 Cynosure, Elen (in Italy), Iridex, Palomar, Solta and Syneron, as well as private companies, including, Alma, 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, 2009, our research and development activities were conducted by a staff of 19 employees with a broad base of experience in lasers and optoelectronics. We have developed relationships with outside contract engineering and design consultants, giving our team additional technical and creative breadth. We work closely with thought leaders and customers, to understand unmet needs and emerging applications in aesthetic medicine. Research and development expenses were \$6.8 million in 2009, \$7.6 million in 2008 and \$7.2 million in 2007.

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, 2009, we had a 35-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.

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, 2009, we had thirteen issued U.S. patents and thirty 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, which is being amortized on a straight-line basis over its expected useful life of 10 years, and a trademark license purchased in 2007, that was amortized over its expected useful lives of two years.

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.

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

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

- for use with the Titan hand piece	October 2004
- for use with our pulsed-light hand pieces	January 2005

Pearl product for the treatment of wrinkles	March 2007
---	------------

Pearl Fractional product for skin resurfacing and coagulation	August 2008
---	-------------

Pre-Market Approval (PMA) Pathway

A PMA must be submitted to the FDA if the device cannot be cleared through the 510(k) process. A PMA must be supported by extensive data, including but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. No device that we have developed to date has required pre-market approval, development of future devices or indications may require pre-market approval.

Product Modifications

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

Clinical Trials

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

In addition, in 2009, we began performing clinical trials for a new body contouring product called TruSculpt. Though the launch of this product was indefinitely postponed in the fourth quarter of 2009, we continue to develop this product and obtain clinical data to prove efficacy. 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 and the CDHS. The FDA and the CDHS 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 and CDHS.

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

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

- Warning letters, fines, injunctions, consent decrees and civil penalties;
- Repair, replacement, recall or seizure of our products;
- 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 and 2009, we passed our ISO 13485 recertification audit.

Employees

As of December 31, 2009, we had 186 employees, compared to 244 employees as of December 31, 2008. This reduction in employees resulted primarily from a company-wide reduction in force in January and April 2009. Of the

Edgar Filing: CUTERA INC - Form 10-K

186 employees at December 31, 2009, 78 were in sales and marketing, 31 in manufacturing operations, 35 in technical service, 19 in research and development and 23 in general and administrative. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel. None of our employees is represented by a labor union, and we believe our employee relations are good.

Available Information

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

In 2009, our revenue decreased by 36%, compared to 2008. The general economic difficulties being experienced by our customers, reduced end consumer demand for procedures, the lack of availability of consumer credit for some of our customers, and the general reluctance of many of our current and prospective customers to spend significant amounts of money on capital equipment during these unstable economic times, are adversely affecting the market in which we operate. In times of economic uncertainty individuals often reduce the amount of money that they spend on discretionary items, including aesthetic procedures. This economic uncertainty may cause potential customers to further 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 the sales professionals, 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 retain, train and manage our sales professionals and improve their productivity may not be successful. Our direct sales professionals earn a material portion of their compensation through commissions. Unless revenue improves, their total compensation may remain low, which could result in higher turnover. In response to reduced commission earnings resulting from the decrease in revenue, some of our sales professionals left the industry entirely or left our company to work for our competitors. We are selectively hiring new sales professionals in key territories to fill vacant positions. The replacement or absence of seasoned sales professionals may adversely affect our revenue. Following the resignation of our Vice President of Sales in June 2009, we promoted our General Manager for our Japan operations to the Vice President of North American Sales position in July 2009. If the North American sales team does not align with our new Vice President of North American Sales, we could experience more turnover in the future. 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 and this could materially harm our business.

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

In 2009, our total revenue decreased 36%, U.S. revenue decreased by 50% and international revenue decreased by 22%, compared to 2008. In an effort to improve our revenue and profitability, we have implemented several strategic initiatives focusing on our worldwide sales and marketing infrastructure, product introductions and expense management. For example, we had company-wide reductions in force in January 2009 and April 2009 resulting in a total net reduction of approximately 22% of our workforce from December 31, 2008, and we reduced or eliminated certain employee benefit programs. Further, following the resignation of our Vice President of Sales in June 2009, we promoted our General Manager for our Japan operations to the position of Vice President of North American Sales in July 2009. These initiatives are intended to improve our revenue and profitability; however, they may instead contribute to employee turnover, instability to our operations, or further reduction in our revenue and 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:

- 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;
- An increase in malpractice lawsuits that result in/or higher insurance costs; and

Our ability to develop and market our products to the core market specialties of dermatologists and plastic surgeons.

If we do not achieve anticipated demand for our products our revenue may be adversely impacted.

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 and access to consumer credit, which as a result of the unstable economy, may have been significantly impacted;
- 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.

We offer credit terms to some qualified customers and also to leasing companies to finance the purchase of our products. In the event that any of these customers default on the amounts payable to us, our earnings may be adversely affected.

While we qualify customers to whom we offer credit terms (generally net 30 to 60 days), we cannot provide any assurance that the financial position of these customers will not change adversely before we receive payment. For example, in early 2009, one leasing company that we provided credit, based on their historical payment history and good credit standing, defaulted on their payment of \$473,000 due to experiencing significant financial difficulties. As a result, our general and administrative expenses, and therefore net loss, for 2009, were negatively impacted by an increase in the allowance for doubtful accounts. In the event that there is a default by any other customers to whom we have provided credit terms, this could further negatively affect our earnings and results of operations in the future.

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 historically experienced steep increases in our product liability insurance premiums as a percentage of revenue. 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.

Healthcare reform legislation and changes occurring at U.S. Food and Drug Administration, or FDA, could adversely affect our revenue and financial condition.

In recent years, there have been numerous initiatives on the federal and state levels for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services in the United States. These initiatives have ranged from proposals to fundamentally change federal and state healthcare reimbursement programs, including providing comprehensive healthcare coverage to the public under governmental funded programs, to minor modifications to existing programs. Recently, the current administration and members of Congress have proposed significant reforms to the U.S. healthcare system. Both the U.S. Senate and House of Representatives have conducted hearings about U.S. healthcare reform. Our products are not reimbursed by insurance companies or federal or state governments and some of this proposed legislation will therefore not affect us. This proposed legislation, however, includes a tax on manufacturers of medical devices and diagnostic products which would be applicable to us and, if passed, would decrease our net income.

In addition, there are several changes occurring at FDA that may lengthen the regulatory approval process for medical devices and require additional clinical data to support regulatory clearance for the sale and marketing of our new products. These changes in the FDA regulatory approval process may delay or prevent the approval of new products and could result in lost market opportunity. Changes in FDA regulations may require additional safety monitoring, labeling changes, restrictions on product distribution or use, or other measures after the introduction of our products to market, which could increase our costs of doing business, adversely affect the future permitted uses of approved products, or otherwise adversely affect the market for our products.

The ultimate content or timing of any future healthcare reform legislation, and its impact on us, is impossible to predict. If significant reforms are made to the healthcare system in the United States, or in other jurisdictions, those reforms may have an adverse effect on our financial condition and results of operations.

We have recently entered into strategic alliances to distribute third party products internationally. To successfully market and sell these products, we must address many issues that are unique to these businesses and could reduce our available cash reserves and negatively impacting our profitability.

Recently, we have entered into distribution arrangements pursuant to which we utilize our sales force and distributors to sell products manufactured by other companies. We entered into an agreement with Obagi Medical Products, Inc. (Obagi), to distribute certain of their proprietary cosmeceuticals, or skin care products, in Japan. This agreement requires us to purchase a minimum dollar amount of Obagi products of \$1.25 million in 2010, and the purchase commitments for 2011 and beyond have yet to be determined. In addition, we entered into an agreement with Sound Surgical Technologies, Inc. to distribute their VASER® Lipo System in certain European countries and Canada. Finally, we also have an agreement with BioForm Medical Inc., to distribute their Radiesse® dermal filler product in Japan. Each of these distribution agreements presents its own unique risks and challenges. For example, to sell products in partnership with Obagi we need to invest in creating a sales structure that is experienced in the sale of cosmeceuticals and not in capital equipment. We need to commit resources to training this sales force, obtaining regulatory licenses in Japan and developing new marketing materials to promote the sale of Obagi products. For each of these distribution arrangements, until we can develop our own experienced sales force, we may need to pay third party distributors to sell the products which will result in higher fees and lower margins than if we sell direct to customers. In addition, the minimum commitments and other costs of distributing products manufactured by these companies may exceed the incremental revenue that we derive from the sale of their products thereby reducing our available cash reserves and negatively impacting our profitability.

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

Our international revenue was \$32.7 million in 2009, which represented 61% 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 as we continue to manage our international operations and develop opportunities in additional international territories, our international revenue will be subject to a number of risks, including:

- Difficulties in staffing and managing our foreign operations;
- Export restrictions, trade regulations and foreign tax laws;

- Fluctuating foreign currency exchange rates;
- Foreign certification and regulatory requirements;
- Lengthy payment cycles and difficulty in collecting accounts receivable;
 - Customs clearance and shipping delays;
 - Political and economic instability;
- Lack of awareness of our brand in international markets;
- 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 Cynosure, Elen (in Italy), Iridex, Palomar, Solta, and Syneron and as well as private companies such as 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.

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 such factors as performance, brand name, service and price, and this is difficult to do in a crowded aesthetic market. 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 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. Recently there has been some consolidation in the aesthetic industry leading to companies combining their resources. For example, Thermage acquired Reliant in December 2008 and renamed the combined company, Solta. In addition, in September 2009, Syneron acquired Candela. Our competitors could also form strategic alliances with other companies to develop products and solutions that effectively compete with our products. For example, Syneron has 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/or 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. We have recently started distributing topical skin creams and dermal fillers in the Japanese market and an ultrasonic liposuction device for the body contouring market in Europe and Canada. To grow in the future, we must develop and acquire new and innovative aesthetic products and applications, identify new markets, and successfully launch the newly acquired or developed product offerings.

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 product offerings;
- Convince our existing and prospective customers that our product offerings would be an attractive revenue-generating addition to their practice;
- Sell our product offerings 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.

With the exception of 2009, we have introduced at least one new product every year since 2000. In November 2009, we announced that we postponed indefinitely the release of our TruSculpt body contouring product. Historically, product 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 increase our product offerings that we can sell to new and existing customers. However, 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.

In addition, our former Executive Vice President of Research & Development, who is also one of our founders, resigned from his employment with us effective March 2009 to pursue personal interests. Although we have appointed a new Vice President of Research & Development and our founder continues to provide consulting services to us, our founder's full-time employment, experience and leadership contributed to our historical product development initiatives. As a result, we may not be able to continue our trend of regular new product introductions. Also, we may need additional research and development resources to make new product introductions, which may be more costly and time consuming to our organization.

Some of our competitors release new products more often and more successfully than we do. 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.

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. Revenue from PSS declined significantly in 2009, compared to 2008. Our revenue from PSS as a percentage of U.S. revenue was 18% in 2009, 29% in 2008 and 23% in 2007. Although we continue to work closely with, and focus our attention on, our PSS relationship, there is no assurance that this 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.

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 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. On August 25, 2009, following negotiations between the parties, the parties entered into a settlement agreement that would resolve the case on a class-wide basis. The Court gave its preliminary approval to the proposed settlement on August 27, 2009, and a final hearing on the settlement is scheduled for April 6, 2010. Under the terms of the settlement, we will cause to be paid a total of \$950,000 in exchange for a full release of facsimile-related claims. See “Item 3 – Legal Proceedings” set forth in Part III, Item 1 for further details.

If the proposed settlement does not receive final approval and the matter is certified as a class action and goes to trial, we may incur substantial additional expenses defending ourselves and, if our practices are shown to have violated the TCPA, this could result in an award of substantial damages, which may have a material adverse effect on our profitability and 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 and both parties presented oral arguments to the Court of Appeals in February 2010. No decision has yet been rendered by the Court of Appeals. See “Item 3 – Legal Proceedings” set forth in Part III, Item 1 of this annual report on Form 10-K for further details.

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.

Adverse conditions in the global banking industry and credit markets may adversely impact the value of our investments or impair our liquidity.

We invest our excess cash primarily in money market funds and in highly liquid debt instruments (including auction rare securities) of the U.S. government and its agencies, and U.S. municipalities. As of December 31, 2009, our balance in marketable investment was \$76.8 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, 2009 would have potentially decreased by approximately \$421,000, 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).

We may be required to record impairment charges in future quarters as a result of the decline in value of our investments in auction rate securities (ARS).

Included under the caption of “Long-term investments” in the Consolidated Balance Sheet as of December 31, 2009, are \$7.3 million of ARS. These ARS are designed to provide liquidity through an auction process that resets the applicable interest rate at predetermined calendar intervals, generally every 35 days. Though approximately \$4.4

million (par value) of our original holdings of \$13.4 million (par value) of ARS, have been redeemed at full par value in 2009, auctions for the majority of the remaining ARS in our portfolio at December 31, 2009 have continued to fail since February 2008 due to the lack of liquidity and overall credit concerns in capital markets. Upon an auction failure, the interest rates do not reset at a market rate but instead reset based on a formula contained in the security, which rate is generally higher than the current market rate. The failure of the auctions impacts our ability to readily liquidate our 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.

If the auctions for our ARS investments continue to fail, and there is a further decline in the valuation, then we would have to: (i) record additional reductions to the fair value of our ARS investments; and (ii) record unrealized losses in our accumulated comprehensive income (loss) for the losses in value that are associated with market risk. If the decline in fair value is considered other-than-temporary then we would have to record an impairment charge in our Consolidated Statement of Operations for the loss in value associated with the worsening of the credit worthiness (credit losses) of the issuer, which would reduce future earnings, harm our business and may 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, 2009, approximately 58% 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.

The public market price of our common stock has in the past fluctuated substantially and, due to the current concentration of stockholders, it 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 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 by us or our competitor;
- 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 either remain depressed or to decline further.

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

Our competitors or other patent holders may assert that our present or future products and the methods we employ are covered by their patents. In addition, we do not know whether our competitors own or will obtain patents that they may claim prevent, limit or interfere with our ability to make, use, sell or import our products. Although we may seek to resolve any potential future claims or actions, we may not be able to do so on reasonable terms, or at all. If, following a successful third-party action for infringement, we cannot obtain a license or redesign our products, we may have to stop manufacturing and selling the applicable products and our business would suffer as a result. In addition, a court could require us to pay substantial damages, and prohibit us from using technologies essential to our products, any of which would have a material adverse effect on our business, results of operations and financial condition.

We may become involved in litigation not only as a result of alleged infringement of a third party's intellectual property rights but also to protect our own intellectual property. For example, we have been, and may hereafter

become, involved in litigation to protect the trademark rights associated with our company name or the names of our products. Infringement and other intellectual property claims, with or without merit, can be expensive and time-consuming to litigate, and could divert management's attention from our core business.

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

We rely on patent, copyright, trade secret and trademark laws and confidentiality agreements to protect our technology and products. At December 31, 2009, we had thirteen 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 heating for the temporary relief of muscle aches and pains; and to market our Pearl Fractional product in the United States only for skin resurfacing. Therefore we are prevented from promoting or advertising Titan in the United States and Pearl Fractional in the United States for any other indications. If we fail to comply with these regulations, it could result in enforcement action by the FDA which could lead to such consequences as warning letters, adverse publicity, criminal enforcement action and/or third-party civil litigation, each of which could adversely affect us.

We have obtained 510(k) clearance for the indications for which we market our products. However, our clearances can be revoked if safety or effectiveness problems develop. We also are subject to Medical Device Reporting regulations, which require us to report to the FDA if our products cause or contribute to a death or serious injury, or malfunction in a way that would likely cause or contribute to a death or serious injury. Our products are also subject to state regulations, which are, in many instances frequently changing. 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.

We have made modifications to our devices in the past and may make additional modifications in the future that we believe do not or will not require additional clearance or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices, which could harm our operating results and require us to redesign our products.

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

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

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 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, 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.

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.

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 and incur costs associated with the termination of existing purchase order commitments, 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 are subject to fluctuations in the exchange rate of the U.S. dollar and foreign currencies.

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 revenue. 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).

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.

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 of which two expire in May 2010, and one expires in July 2010.
Switzerland	Approximately 2,885	Two leases expire in March and April 2010. The company entered into a lease agreement for 3,174 square feet effective April 2010, which expires in March 2013.
France	Approximately 450	Lease expires in November 2011, but may be cancelled at any time with a three-month notice.
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 the Company's 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, on April 16, 2009 the plaintiffs filed their opening brief with that Court, on June 17, 2009 we filed our response to plaintiffs' brief, on July 1, 2009 the plaintiffs filed their response to our brief, and on February 11, 2010 both parties presented oral argument to the Court of Appeals. No decision has yet been rendered by the Court of Appeals. 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. On August 25, 2009, following negotiations between the parties, the parties entered into a settlement agreement that would resolve the case on a class-wide basis. The Court gave its preliminary approval to the proposed settlement on August 27, 2009, and a final hearing on the settlement is scheduled for April 6, 2010. Under the terms of the settlement, we will cause to be paid a total of \$950,000 in exchange for a full release of facsimile-related claims. We included \$850,000 for the estimated cost of the settlement, net of administrative expenses and amounts that are expected to be recoverable from our insurance carrier, in our Consolidated Statement of Operations in 2009. If the proposed settlement does not receive final approval and the matter is certified as a class action and goes to trial, we may incur substantial additional expenses defending ourselves and, if our practices are shown to have violated the TCPA, this could result in an award of substantial damages, which may have a material adverse effect on our profitability and business. If the proposed settlement does not receive final approval, we intend to defend this case vigorously.

ITEM 4. [RESERVED]

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 Select Market under the symbol "CUTR." As of February 26, 2010, the closing sale price of our common stock was \$9.40 per share.

Common Stockholders

We had 10 stockholders of record as of February 26, 2010. Since many stockholders choose to hold their shares under the name of their brokerage firm, we believe, the actual number of stockholders was approximately 4,200.

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			
	2009		2008	
	High	Low	High	Low
4th Quarter	\$ 9.63	\$ 7.97	\$ 10.58	\$ 7.47
3rd Quarter	9.40	7.85	12.28	9.10
2nd Quarter	9.03	5.93	13.91	8.98
1st Quarter	8.71	5.57	15.53	11.70

Performance Graph

Below is a graph showing the cumulative total return to our stockholders during the period from December 31, 2004 through December 31, 2009 in comparison to the cumulative return on the NASDAQ Composite Index (U.S.) and the NASDAQ Medical Equipment Index during that same period. (1) The results assume that \$100 was invested on December 31, 2004.

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.

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,

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

	2009	2008	2007	2006	2005
Net revenue	\$ 53,682	\$ 83,379	\$ 101,726	\$ 100,692	\$ 75,620
Cost of revenue	21,759	32,358	35,002	29,859	19,792
Gross profit	31,923	51,021	66,724	70,833	55,828
Operating expenses:					
Sales and marketing	24,286	35,354	38,277	32,890	25,021
Research and development	6,810	7,550	7,169	6,473	5,353
General and administrative	10,320	11,270	11,721	15,192	8,782
Litigation settlement	850	—	—	18,935	—
Total operating expenses	42,266	54,174	57,167	73,490	39,156
Income (loss) from operations	(10,343)	(3,153)	9,557	(2,657)	16,672
Interest and other income, net	1,572	3,046	4,207	3,596	2,034
Other-than-temporary impairments of long-term investments	—	(3,554)	—	—	—
Income (loss) before income taxes	(8,771)	(3,661)	13,764	939	18,706
Provision (benefit) for income taxes	8,908	(792)	3,260	(1,184)	4,905
Net income (loss)	\$ (17,679)	\$ (2,869)	\$ 10,504	\$ 2,123	\$ 13,801
Net income (loss) available to common stockholders used in basic net income per share	\$ (17,679)	\$ (2,869)	\$ 10,504	\$ 2,123	\$ 13,801
Net income (loss) per share:					
Basic	\$ (1.33)	\$ (0.22)	\$ 0.80	\$ 0.17	\$ 1.20
Diluted	\$ (1.33)	\$ (0.22)	\$ 0.74	\$ 0.15	\$ 1.00
Weighted-average number of shares used in per share calculations:					
Basic	13,279	12,770	13,153	12,558	11,535
Diluted	13,279	12,770	14,228	14,278	13,864

As of December 31,

Consolidated Balance Sheet Data
(in thousands):

	2009	2008	2007	2006	2005
Cash and cash equivalents	\$ 22,829	\$ 36,540	\$ 11,054	\$ 11,800	\$ 5,260
Marketable investments	76,780	60,653	88,510	96,285	86,736
Long-term investments	7,275	9,627	7,429	—	—
Working capital (current assets less current liabilities)	96,015	101,644	106,894	111,999	98,318
Total assets	121,352	137,476	138,653	133,875	111,958
Retained earnings	17,254	31,410	34,279	23,866	21,743

Total stockholders' equity	100,853	112,108	109,353	109,732	97,177
----------------------------	---------	---------	---------	---------	--------

I MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION ITEM 7. 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, 2009. 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 15. 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 Guidance.** This section describes the issuance and effect of new accounting pronouncements that are and may be applicable to us.
- **Results of Operations.** This section provides our analysis and outlook for the significant line items on our Consolidated Statements 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, 2009.

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 aesthetic systems on three platforms—Xeo, CoolGlide, 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, from where we conduct our manufacturing, warehousing, research and development, regulatory, sales and marketing, service, and administrative activities. In the 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, 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 contained in the hand piece, such as with our Pearl and Pearl Fractional applications, 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 Upgrade revenue. Service revenue relates to amortization of pre-paid 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 has been used. In addition, we distribute BioForm, Inc.'s (BioForm) Radiesse® dermal filler product in Japan.

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

- Continuing to expand our product offerings.
- Investments made in our global sales and marketing infrastructure.
- Use of clinical results to support new aesthetic products and applications.
- Enhanced luminary development and reference selling efforts (to develop a location where our products can be displayed and used to assist in selling efforts).
- 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, Upgrade, and Titan hand piece refill revenue from our growing installed base of customers.

Our U.S. revenue decreased 50% and our international revenue decreased 22% in 2009, compared to 2008. International revenue as a percent of total revenue was 61% in 2009 and 50% in 2008. We believe that the decline in U.S. and international revenue was primarily attributable to the global recession that has caused our prospective customers to be reluctant to spend significant amounts of money on capital equipment during these unstable economic times. Historically a significant portion of our U.S. revenue was sourced from the non-core market of practitioners such as primary care physicians, gynecologists and physicians offering aesthetic treatments in spa environments. We believe our U.S. revenue declined greater than our international revenue, because the recession impacted the U.S. market, and particularly the non-core market, more severely than our international market, which is primarily comprised of core physicians. Further, we also believe that those prospective customers who do not have established medical offices, are finding it more difficult to obtain credit financing, which also contributed to the reduced U.S. revenue.

Our service revenue increased 16% in 2009, compared to 2008. Service contract amortization is the primary component of our total service revenue. Due to an increasing installed base of customers, our revenue from contract amortization has consistently increased. However, our deferred service revenue balance decreased by \$3.5 million, or 30%, to \$8.1 million as of December 31, 2009, compared to December 31, 2008. We believe this decline was primarily attributable to: (i) fewer customers purchasing extended service contracts in response to improved product reliability and the tougher economy; (ii) a decrease in unit sales volume in the U.S. that historically included an element of deferred revenue for service contracts beyond our standard warranty terms; (iii) a shift by customers towards purchasing more quarterly, rather than annual or multi-year, service contracts; and (iv) a reduction of our service contract pricing, but including prorated charges for hand piece usage (only in the first nine months of 2009), which resulted in a reduction of our deferred service revenue balance as of December 31, 2009.

Our gross margin decreased slightly to 59% for 2009, compared to 61% in 2008. This decrease, was due primarily to: (i) lower overall revenue, due to lower volume, which resulted in reduced leverage of our manufacturing and service department expenses; (ii) higher Service and Titan refill revenue as a percentage of our total revenue, which has a lower gross margin than our total revenue; and (iii) higher international distributor revenue as a percentage of total revenue, which has a lower gross margin than our direct business; partially offset by (iv) reduced manufacturing expenses resulting primarily from headcount reductions and improved product reliability.

Our sales and marketing expenses, as a percentage of net revenue, increased to 45% in 2009, compared to 42% in 2008. This increase in expenses as a percentage of net revenue in 2009, was due primarily to lower revenue in 2009, compared to 2008. In absolute dollars, sales and marketing expenses decreased by \$11.1 million to \$24.3 million in 2009, compared to 2008. The decrease in absolute dollars was due primarily to reduced personnel expenses in the United States, attributable to lower headcount, and reduced sales commission expenses resulting from lower revenue.

Our research and development (R&D) expenses, as a percentage of net revenue, increased to 13% in 2009, compared to 9% in 2008. The increase in expenses as a percentage of net revenue was due primarily to lower revenue in 2009, compared to 2008. In absolute dollars, R&D expenses decreased by \$740,000 to \$6.8 million in 2009, compared to 2008. The decrease in absolute dollars was due primarily to lower headcount (partially resulting from a reduction-in-force that we implemented in the first-half of 2009) and consulting services of \$689,000.

General and administrative (G&A) expenses, as a percentage of net revenue, increased to 19% in 2009, compared to 14% in 2008. The increase in expenses as a percentage of net revenue was due primarily to lower revenue in 2009, compared to 2008. In absolute dollars, G&A expenses decreased by \$950,000 to \$10.3 million in 2009, compared to 2008. The decrease in G&A expenses in 2009, was due primarily to a decrease in legal, audit, tax, and consulting fees.

We are a defendant in a Telephone Consumer Protection Act class action lawsuit. See “Item 3 - Legal Proceedings” in Part 1, of this Form 10-K. We have included \$850,000 in our Consolidated Statement of Operations in 2009, for the estimated cost of the tentative settlement, net of administrative expenses and amounts that are expected be recoverable from our insurance carrier.

In response to the economic environment and our reduced revenue in 2008 and 2009, we reduced our company-wide workforce by approximately 18% and implemented other cost-reduction measures in the first half of 2009. The headcount reductions impacted all departments and functions and resulted in restructuring charges of approximately \$880,000 in first half of 2009. As of June 30, 2009, there were no service requirements outstanding from the employees who were affected. As a result of these cost-reduction measures our operating expenses declined in 2009, compared to 2008.

We recognized an income tax provision of \$8.9 million in 2009, despite losses before taxes. The provision is primarily due to the recording of a valuation allowance at the end of the third quarter of 2009 to reduce certain U.S. federal and state net deferred tax assets to their anticipated realizable value, of which \$10.2 million related to our U.S. deferred tax assets as of December 31, 2008. This valuation allowance was offset by \$1.3 million of certain tax benefits resulting from losses generated during fiscal 2009 that can be carried-back to prior periods. See “Provision (Benefit) for Income Taxes” below for further discussion. We also performed an evaluation as of December 31, 2009, and determined the full valuation allowance was still required.

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 expand our product offerings 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 (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.

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 Product revenue, including Upgrade revenue, and revenue from Titan hand piece refills, when title and risk of ownership has been transferred, provided that:

- Persuasive evidence of an arrangement exists;
- Delivery has occurred or services have been rendered;
- The fee is fixed or determinable; and
- Collectability is reasonably assured.

Determination of whether persuasive evidence of an arrangement exists and whether delivery has occurred or services have been rendered, are based on management’s judgments regarding the fixed nature of the fee charged for services rendered and products delivered, and the collectability of those fees. In instances where final 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.

Fair Value Measurement of our 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 through 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 some of ARS have continued to fail to settle on their respective settlement dates while some have been redeemed in full at their respective par values. The current portfolio of investments shown as "Long term investments" in our Consolidated Financial Statements represents those investments that 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 to 2028 to 2043.

At December 31, 2009, total financial assets measured and recognized at fair value were \$103.4 million and of these assets, \$7.3 million, or 7%, were ARS that were measured and recognized using significant unobservable inputs (Level 3). During 2009, \$4.4 million of ARS were redeemed at their full par value, as a result, we transferred \$2.3 million from Level 3 assets to cash and \$100,000 of Level 3 assets into marketable investments (Level 2). This redemption resulted in a gain of \$1.9 million being recorded to accumulated comprehensive income (loss) in 2009.

As of December 31, 2009, we had \$8.9 million par value (\$7.3 million fair value) of long-term ARS investments and \$100,000 par value of ARS recorded in marketable investments. The aggregate loss in value is included as an unrealized loss in accumulated other comprehensive income (loss). Given observable market information was not available to determine the fair values of our ARS portfolio, we valued these investments based on a discounted cash flow model. While our ARS valuation model was based on both Level 2 (credit quality and interest rates) and Level 3 inputs (pricing models), 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. The expected future cash flows of the ARS were discounted using a risk adjusted discount rate that compensated for the illiquidity. Projected future cash flows over the economic life of the ARS were modeled based on the contractual penalty rates for the security added to a tax adjusted LIBOR interest rate curve. The discount rates that were applied to the cash flows were based on a premium over the projected yield curve and included an adjustment for credit, illiquidity, and other risk factors. See Note 2 “Balance Sheet Details- Fair Value of Financial Instruments” in Notes to Consolidated Financial Statement in Part II, Item 8 of this Form 10-K for more information.

The valuation of our investment portfolio is subject to uncertainties that are difficult to predict. Factors that may impact the 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 auctions for our ARS investments continue to fail, and there is a further decline in their valuation, then we would have to: (i) record additional reductions to the fair value of our ARS investments; and (ii) record unrealized losses in our accumulated comprehensive income (loss) for the losses in value that are associated with market risk. If the decline in fair value is considered other-than-temporary then we would have to record an impairment charge in our Consolidated Statement of Operations for the loss in value associated with the worsening of the credit worthiness (credit losses) of the issuer, which would reduce future earnings and harm our business.

Recognition and Presentation of Other-Than-Temporary-Impairments

We review any impairments on a quarterly basis in order to determine the classification of the impairment as “temporary” or “other-than-temporary.” Beginning April 1, 2009, if an entity intends to sell or if it is more likely than not that it will be required to sell an impaired debt security prior to recovery of its cost basis, the security is other-than-temporarily impaired and the full amount of the impairment is required to be recognized as a loss through earnings. Otherwise, losses on securities which are other-than-temporarily impaired are separated into: (i) the portion of loss which represents the credit loss; or (ii) the portion which is due to other factors. The credit loss portion is recognized as a loss through earnings while the loss due to other factors is recognized in other comprehensive income (loss), net of taxes and related amortization. Prior to April 1, 2009, all declines in fair value deemed to be other-than-temporary were reflected in earnings as realized losses.

With respect to the ARS that we held as of April 1, 2009, we determined that the cumulative effect adjustment required to reclassify the non-credit portion of previously recognized other-than-temporarily impaired adjustments was \$3.5 million. Therefore, we increased our accumulated earnings and decreased our accumulated other comprehensive income (loss) by the \$3.5 million cumulative effect adjustment. With respect to the \$9.0 million of par value ARS investments held as of December 31, 2009, the unrealized losses included in accumulated comprehensive income (loss) was \$1.6 million.

Stock-based Compensation Expense

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, 2009, the unrecognized compensation cost, net of expected forfeitures, related to stock options and employee stock purchase plan awards was \$7.2 million and \$40,000, respectively, which will be recognized using the straight-line attribution method over an estimated weighted-average amortization period of 2.73 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 historically provided a standard one-year or two-year warranty coverage on our systems. Beginning in September 2009, we changed our warranty policy to a one-year standard warranty on all 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. Actual warranty costs could differ from the estimated amounts. On a quarterly basis, we review the accrued balances of our warranty obligations and update the historical warranty cost trends. If we were required to accrue additional warranty cost in the future due to actual product failure rates, material usage, service delivery costs or overhead costs differing from our estimates, revisions to the estimated warranty liability would be required, which would negatively impact our operating results.

Provision for Income Taxes

We are subject to taxes on earnings in both the United States and numerous foreign jurisdictions. As a global taxpayer, significant judgments and estimates are required in evaluating our uncertain tax positions and determining our provision for income taxes on earnings. We perform a two-step approach to recognizing and measuring uncertain tax positions. 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, certain benefits realized related to stock option activity, and changes in valuation allowance. 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 (102)% in 2009, 22% in 2008, and 24% in 2007. Our future effective tax rates could be 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, interpretations thereof, net operating loss carryback, research and development tax credits, and due to changes in the valuation allowance of our U.S. deferred tax assets. 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; and
- An excess of appreciated asset value over the tax basis of our net assets in an amount sufficient to realize the deferred tax asset.

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 evaluating the ability to recover deferred tax assets, we considered available positive and negative evidence, giving greater weight to our recent cumulative losses and our ability to carry-back losses against prior taxable income and lesser weight to its projected financial results due to the challenges of forecasting future periods. We also considered, commensurate with its objective verifiability, the forecast of future taxable income including the reversal of temporary differences. At the end of the quarter ended September 30, 2009, changes in previously anticipated expectations and continued operating losses resulted in a valuation allowance against our tax benefits since we no longer considered them “more-likely-than-not” realizable. We also performed this evaluation as of the year ended December 31, 2009 and determined the full valuation allowance was still required.

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. Through December 31, 2009, there have been no such impairments.

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. See “Item 3 - Legal Proceedings” in Part I, of this Form 10-K.

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.

35

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,					
	2009		2008		2007	
Operating Ratios:						
Net revenue	100	%	100	%	100	%
Cost of revenue	41	%	39	%	34	%
Gross profit	59	%	61	%	66	%
Operating expenses:						
Sales and marketing	45	%	42	%	38	%
Research and development	13	%	9	%	7	%
General and administrative	19	%	14	%	12	%
Litigation settlement	1	%	—	%	—	%
Total operating expenses	78	%	65	%	57	%
Income (loss) from operations	(19))%	(4))%	9	%
Interest and other income, net	3	%	4	%	4	%
Other-than-temporary impairment of long-term investments	—	%	(4))%	—	%
Income (loss) before income taxes	(16))%	(4))%	13	%
Provision (benefit) for income taxes	17	%	(1))%	3	%
Net income (loss)	(33))%	(3))%	10	%

Total Revenue

(Dollars in thousands)	Year Ended December 31,					
	2009	% Change	2008	% Change	2007	
Revenue mix by geography:						
United States	\$ 21,019	(50)%	\$ 41,683	(35)%	\$ 64,084	
Japan	9,636	(12)%	10,929	29%	8,453	
Asia, excluding Japan(1)	4,727	(17)%	5,713	(5)%	6,009	
Europe	7,087	(33)%	10,522	14%	9,258	
Rest of the world(1)	11,213	(23)%	14,532	4%	13,922	
Total international revenue	32,663	(22)%	41,696	11%	37,642	
Consolidated total revenue	\$ 53,682	(36)%	\$ 83,379	(18)%	\$ 101,726	
United States as a percentage of total revenue	39%		50%		63%	
International as a percentage of total revenue	61%		50%		37%	
Revenue mix by product category:						
Products	\$ 28,554	(51)%	\$ 57,998	(22)%	\$ 74,502	
Upgrades	6,343	(24)%	8,361	(37)%	13,342	
Service	13,186	16%	11,358	24%	9,128	
Titan hand piece refills	5,599	(1)%	5,662	19%	4,754	
Consolidated total revenue	\$ 53,682	(36)%	\$ 83,379	(18)%	\$ 101,726	

(1) Beginning in 2009, we classified revenue from Australia and New Zealand in the geography category 'Rest of the world', previously we classified revenue from Australia and New Zealand in the geography category 'Asia, excluding Japan'; as such we reclassified the 2008 and 2007 revenue from Australia and New Zealand from 'Asia, excluding Japan' to 'Rest of the world'

Our U.S. revenue decreased 50% in 2009, compared to 2008, and 35% in 2008, compared to 2007. Our International revenue decreased 22% in 2009, compared to 2008. We believe that the decline in U.S. and international revenue was primarily attributable to the global recession that has caused our prospective customers to be reluctant to spend significant amounts of money on capital equipment during these unstable economic times. Historically a significant portion of our U.S. revenue was sourced from the non-core market of practitioners such as primary care physicians, gynecologists and physicians offering aesthetic treatments in spa environments. International sales increased 11% in 2008, compared to 2007. The increase in 2008 was primarily attributable to continuing investments in building our international sales distribution channels. International revenue as a percent of total revenue was 61% in 2009, 50% in 2008 and 37% in 2007. We believe our U.S. revenue declined greater than our international revenue, because the recession impacted the U.S. market, and particularly the non-core market, more severely than our international market. Further, we also believe that those prospective customers who do not have established medical offices, are finding it more difficult to obtain credit financing, which also contributed to the reduced U.S. revenue.

Our Product revenue decreased 51% in 2009, compared to 2008, and 22% in 2008, compared to 2007. Our Upgrade revenue decreased 24% in 2009, compared to 2008, and 37% in 2008, compared to 2007. We believe these decreases in Product and Upgrade revenue were primarily driven by the global recession that has caused our prospective customers to be reluctant on spending significant amounts of money on capital equipment during these unstable economic times. We also believe that those prospects who do not have established medical offices are finding it more difficult to obtain credit financing. Product revenue included BioForm's Radiesse® dermal filler product sales in Japan.

Our Service revenue increased 16% in 2009, compared to 2008, and 24% in 2008, compared to 2007. Service contract amortization is the primary component of our total service revenue. These increases were due primarily to an increasing installed base of customers.

Our Titan hand piece refill revenue decreased 1% in 2009, compared to 2008. We believe that this slight decrease was due primarily to a decline in consumer spending in 2009 on Titan procedures as a result of the global recession. Our Titan hand piece refill revenue increased 19% in 2008, compared to 2007. We believe that this increase was due primarily to an increase in the installed base and as a result of greater utilization of this application.

Gross Profit

(Dollars in thousands)	Year Ended December 31,				
	2009	% Change	2008	% Change	2007
Gross Profit	\$ 31,923	(37)%	\$ 51,021	(24)%	\$ 66,724
As a percentage of total revenue	59%		61%		66%

Our cost of revenue consists primarily of: material, personnel expenses, royalty expense, warranty and manufacturing overhead expenses. Gross margin as a percentage of net revenue was 59% in 2009, 61% in 2008 and 66% in 2007. We believe the decrease in gross margin in 2009, compared to 2008, and the 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 revenue as a percent of total revenue, which has slightly lower gross margins than our direct business.

Sales and Marketing

(Dollars in thousands)	Year Ended December 31,				
	2009	% Change	2008	% Change	2007
Sales and marketing	\$ 24,286	(31)%	\$ 35,354	(8)%	\$ 38,277
As a percentage of total revenue	45%		42%		38%

Sales and marketing expenses consist primarily of: personnel expenses, expenses associated with customer-attended workshops and trade shows, and advertising. Sales and marketing expenses decreased \$11.1 million in 2009, compared to 2008. This decrease was due primarily to the following:

- (i) A decrease in personnel expenses of \$5.4 million in 2009, compared to 2008, due primarily to lower headcount (partially resulting from a reduction-in-force that we implemented in the first-half of 2009) and reduced sales commission expenses resulting from lower revenue;
- (ii) A decrease in travel and related expense of \$1.8 million in 2009, compared to 2008, due primarily to lower headcount; and
- (iii)

Edgar Filing: CUTERA INC - Form 10-K

A decrease in marketing expenses of \$983,000 in 2009, compared to 2008, associated with lower spending on workshops, advertising and other promotional activities.

Sales and marketing expenses as a percentage of total revenue, increased to 45% in 2009, compared with 42% in 2008, due primarily to lower revenue in 2009.

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 revenue in 2008.

Research and Development (R&D)

(Dollars in thousands)	Year Ended December 31,					
	2009	% Change	2008	% Change	2007	
Research and development	\$ 6,810	(10)%	\$ 7,550	5%	\$ 7,169	
As a percentage of total revenue	13%		9%		7%	

Research and development expenses consist primarily of personnel expenses, clinical, regulatory and material costs. R&D expenses decreased by \$740,000 in 2009, compared to 2008. This decrease was due primarily to lower headcount (partially resulting from a reduction-in-force that we implemented in the first-half of 2009) and consulting services of \$689,000. R&D expenses as a percentage of total revenue, increased to 13% in 2009, compared with 9% in 2008, due primarily to lower revenue in 2009.

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 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.

General and Administrative (G&A)

(Dollars in thousands)	Year Ended December 31,					
	2009	% Change	2008	% Change	2007	
General and administrative	\$ 10,320	(8)%	\$ 11,270	(4)%	\$ 11,721	
As a percentage of total revenue	19%		14%		12%	

General and administrative expenses consist primarily of: personnel expenses, legal fees, accounting, audit and tax consulting fees, and other general and administrative expenses. G&A expenses decreased by \$950,000 in 2009, compared to 2008. This decrease was due mainly to the following:

- (i) A decrease in legal, audit and tax consulting fees of \$587,000, due to reduced fees from the consulting firms, partially offset by higher consulting fees related to our 2009 Option Exchange Program; and
- (ii) A decrease in personnel expenses of \$206,000 in 2009, compared to 2008, due primarily to lower headcount (resulting from a reduction-in-force that we implemented in the first-half of 2009); partly offset by
- (iv) An increase in bad debt expense of \$392,000, resulting primarily from one leasing company that defaulted on its payment in the second quarter of 2009 due to it having significant financial problems.

G&A expenses as a percentage of total revenue, increased to 19% in 2009, compared with 14% in 2008, due primarily to lower revenue in 2009.

G&A expenses decreased \$451,000 in 2008, compared to 2007. This 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.

Litigation Settlement

We are a defendant in a Telephone Consumer Protection Act class action lawsuit. See "Item 3 - Legal Proceedings," in Part I, of this Form 10-K. We have included \$850,000 in our Consolidated Statement of Operations in 2009 for the estimated cost of the tentative settlement, net of administrative expenses and amounts that may be recoverable from our insurance carrier.

Interest and Other Income, Net

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

(Dollars in thousands)	Year Ended December 31,					
	2009	% Change	2008	% Change	2007	
Interest income	\$ 1,383	(56)%	\$ 3,170	(22)%	\$ 4,083	
Other income (expense), net	189	NA%	(124)	NA	124	
Total Interest and other income, net	\$ 1,572	(48)%	\$ 3,046	(28)%	\$ 4,207	

Interest income decreased 56 % in 2009, compared to 2008, and decreased 22% in 2008, compared to 2007. These decreases were due primarily to reduced tax-exempt interest yields as a result of the Federal Reserve cutting interest rates. Our cash, cash equivalents, marketable investments and long-term investments measured and recognized at fair value were \$106.9 million at December 31, 2009, \$106.8 million at December 31, 2008 and \$107.0 million December 31, 2007.

Other-Than-Temporary Impairments of Long-Term Investments

(Dollars in thousands)	Year Ended December 31,		Year Ended December 31,		2007
	2009	% Change	2008	% Change	
Other-than-temporary impairment of long-term investments	\$ —	(100)%	\$ 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,		Year Ended December 31,		2007
	2009	\$ Change	2008	\$ Change	
Income (loss) before income taxes	\$ (8,771)	\$ (5110)	\$ (3,661)	\$ (17,425)	\$ 13,764
Provision (benefit) for income taxes	8,908	9,700	(792)	(4,052)	3,260
Effective tax rate	(102)%		22%		24%

We recognized an income tax provision of \$8.9 million in 2009, despite losses before taxes. The provision is primarily due to the recording of a valuation allowance at the end of the third quarter of 2009 to reduce certain U.S. federal and state net deferred tax assets to their anticipated realizable value, of which \$10.2 million related to our U.S. deferred tax assets as of December 31, 2008. This valuation allowance was offset by \$1.3 million of certain tax benefits resulting from losses generated during fiscal 2009 that can be carried-back to prior periods.

ASC 740 requires the consideration of a valuation allowance to reflect the likelihood of realization of deferred tax assets. Significant management judgment is required in determining any valuation allowance recorded against deferred tax assets. In evaluating the ability to recover deferred tax assets, we considered available positive and negative evidence, giving greater weight to our recent cumulative losses and our ability to carry-back losses against prior taxable income and lesser weight to our projected financial results due to the challenges of forecasting future periods. We also considered, commensurate with its objective verifiability, the forecast of future taxable income including the reversal of temporary differences. At the end of the quarter ended September 30, 2009, revisions in previously anticipated expectations and continued operating losses resulted in a valuation allowance against our tax benefits since they were no longer considered "more-likely-than-not" realizable. We also performed this evaluation as of the year ended December 31, 2009 and determined the full valuation allowance was still required. We also performed this evaluation as of December 31, 2009, and determined the full valuation allowance was still required. Under current tax laws, this valuation allowance will not limit our ability to utilize federal and state deferred tax assets provided we can generate sufficient future taxable income in the U.S.

We anticipate we will continue to record a valuation allowance against the losses of certain jurisdictions, primarily federal and state, until such time as we are able to determine it is "more-likely-than-not" the deferred tax asset will be realized. Such position is dependent on whether there will be sufficient future taxable income to realize such deferred tax assets. We expect our future tax provisions (benefits), during the time such valuation allowances are recorded, will consist primarily of the tax expense of our non-US jurisdictions that are profitable. Our effective tax rate may vary from period to period based on changes in estimated taxable income or loss by jurisdiction, changes to the valuation allowance, changes to federal, state or foreign tax laws, future expansion into areas with varying country, state, and local income tax rates, deductibility of certain costs and expenses by jurisdiction.

Edgar Filing: CUTERA INC - Form 10-K

Net Income (Loss) and Net Income (Loss) per Diluted Share

Year Ended December 31,

(Dollars in thousands, except per share data)

	2009	% Change	2008	% Change	2007
Net income (loss)	\$ (17,679)	516%	\$ (2,869)	NA	\$ 10,504
Net income (loss) per diluted share	\$ (1.33)	505%	\$ (0.22)	NA	\$ 0.74

The \$14.8 million increase in net loss, and \$1.11 increase in net loss per diluted share, in 2009, compared to 2008, was primarily attributable to lower revenue of \$29.7 million, partially offset by a decrease of \$11.9 million in operating expenses in 2009, compared to 2008.

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. revenue and \$3.6 million in an other-than-temporary impairment of long-term investments.

Liquidity and Capital Resources

Liquidity is the measurement of our ability to meet potential cash requirements, fund the planned expansion of our operations and acquire businesses. Our sources of cash include operations, stock option exercises, and employee stock purchases. 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)	2009	As of December 31,	
		2008	Change
Cash, cash equivalents and marketable securities:			
Cash and cash equivalents	\$ 22,829	\$ 36,540	\$ (13,711)
Marketable investments	76,780	60,653	16,127
Long-term investments	7,275	9,627	(2,352)
Total	\$ 106,884	\$ 106,820	\$ 64

Cash Flows

In summary, our cash flows were as follows:

(Dollars in thousands)	2009	Year ended December 31,	
		2008	2007
Cash flows provided by (used in):			
Operating activities	\$ 41	\$ 4,340	\$ 16,890
Investing activities	(14,360)	20,644	(426)
Financing activities	608	502	(17,210)
Net increase (decrease) in cash and cash equivalents	\$ (13,711)	\$ 25,486	\$ (746)

Cash Flows From Operating Activities

We generated net cash from operating activities of \$41,000 in 2009, which was primarily attributable to:

- \$849,000 used from net loss of \$17.7 million after adjusting for non-cash related items of \$16.8 million, consisting primarily of a valuation allowance on our deferred tax asset of \$10.5 million, stock-based compensation expense of \$4.2 million, net increase in the allowance for doubtful accounts of \$525,000 due primarily to one leasing company that has defaulted on its payment, and an increase in the provision for excess and obsolete inventories of \$611,000 resulting from the reduced future demand for our products; and
- \$3.5 million used as a result of a decrease in deferred revenue due primarily to a decrease in unit sales volume of Products and Upgrades that included purchases of extended service contracts, a reduction in our service contract pricing beginning in 2009, a shift by customers towards purchasing shorter term contracts, and fewer customers purchasing extended service contracts in response to improved product reliability and to a tougher economy; offset by
-

Edgar Filing: CUTERA INC - Form 10-K

\$2.9 million of cash generated by the decrease in gross inventory balance from December 31, 2008 to December 31, 2009, that resulted from slowing our inventory build to better match the reduced sales of our products; and

- \$1.9 of cash generated by the decrease in gross accounts receivable balance from December 31, 2008 to December 31, 2009 that resulted from the collection of the higher 2008 year-end accounts receivable balances.

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; and
- \$4.8 million of cash generated from the collection of the higher accounts receivable balance as of December 31, 2007; offset by
- \$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 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, and
- \$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.

Cash Flows From Investing Activities

We used net cash of \$14.4 million from investing activities in 2009, which was primarily attributable to:

- \$53.7 million of cash used to purchase marketable investments; partially offset by
- \$39.4 million in net proceeds from the sales and maturities of marketable investments.

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 research and development activities.

Cash Flows From Financing Activities

Net cash provided by financing activities in 2009 was \$608,000, which resulted from \$585,000 of cash generated by the issuance of stock through our stock option and employee stock purchase plans and \$23,000 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 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).

41

Adequacy of cash resources to meet future needs

We had cash, cash equivalents, marketable and long-term investments of \$106.9 million as of December 31, 2009. Of this amount, we had \$7.3 million invested in long-term ARS investments (see 'Critical Accounting Policies and 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.

We have certain contractual arrangements that create potential risk for us and are not recognized in our Consolidated Balance Sheets. Discussed below are off-balance sheet arrangements that have or are reasonably likely to have a material current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures, or capital resources.

We lease various real properties under operating leases that generally require us to pay taxes, insurance, maintenance, and minimum lease payments. Some of our leases have options to renew.

Commitments

In December 2009, we entered into an agreement with Obagi Medical Products, Inc., to distribute certain of their proprietary skin care products in Japan (Obagi Agreement). Our Obagi Agreement requires us to purchase a minimum of \$1.25 million of Obagi products in 2010. The minimum purchase requirement for 2011 and beyond has yet to be determined.

See also 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, 2009:

Contractual Obligations	Total	Payments Due by Period (\$'000's)			More Than 5 Years
		Less Than 1 Year	1-3 Years	3-5 Years	
Operating leases	\$ 6,001	\$ 1,520	\$ 2,918	\$ 1,563	\$ —
Purchase Obligations (1)	1,250	1,250	—	—	—
Total	\$ 7,251	\$ 2,770	\$ 2,918	\$ 1,563	\$ —

(1) In December 2009, we entered into an agreement with Obagi Medical Products, Inc., to distribute certain of their proprietary skin care products in Japan (Obagi Agreement). Our Obagi Agreement requires us to purchase a minimum dollar amount of Obagi Medical Products, Inc. product of \$1.25 million in 2010. The minimum purchase requirement for 2011 and beyond has yet to be determined.

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, 2009. As a result, this amount is not included in the contractual obligations table above.

Income Tax Liability

We have included in our Consolidated Balance Sheet \$749,000 in long-term income tax liability with respect to unrecognized tax benefits and accrued interest as of December 31, 2009. At this time, we are unable to make a reasonably reliable estimate of the timing of payments in individual years beyond 12 months due to uncertainties in the timing of tax audit outcomes. As a result, this amount is not included in the contractual obligations table above.

Indemnifications

In the normal course of business, we enter into agreements that contain a variety of representations, warranties, and indemnification obligations. For example, we have entered into indemnification agreements with each of our directors and executive officers. In 2007, two of our officers were named as defendants in securities class action litigation—see also “Item 3 - Legal Proceedings,” in Part I, of this Form 10-K. 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 \$421,000 as of December 31, 2009.

We hold interest bearing ARS that represent investments in pools of student loans issued by the Federal Family Education Loan Program. 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 holdings in ARS investments and auctions for all of our investments in these securities failed until December 31, 2008. In 2009, approximately \$4.4 million of our original \$13.4 million par value portfolio has been redeemed in full and as of December 31, 2009 we had \$8.9 million par value (fair value of \$7.3 million) of long-term ARS, whose auctions continue to fail. These 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 auctions for our ARS investments continue to fail, and there is a further decline in the valuation, then we would have to: (i) record additional reductions to the fair value of our ARS investments; and (ii) record unrealized losses in our accumulated comprehensive income (loss) for the losses in value that are associated with market risk. If the decline in fair value is considered other-than-temporary then we would have to record an impairment charge in our Consolidated Statement of Operations for the loss in value associated with the worsening of the credit worthiness (credit losses) of the issuer, which would reduce future earnings and harm our business.

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 denominated assets and liabilities was a gain of approximately \$134,000 in 2009, which is included 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.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

CUTERA, INC. AND SUBSIDIARY COMPANIES

ANNUAL REPORT ON FORM 10-K

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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

	Page
Report of Independent Registered Public Accounting Firm	46
Consolidated Balance Sheets	47
Consolidated Statements of Operations	48
Consolidated Statements of Stockholders' Equity	49
Consolidated Statements of Cash Flows	50
Notes to Consolidated Financial Statements	51

The following Consolidated Financial Statement Schedule of the Registrant and its subsidiaries for the years ended December 31, 2009, 2008 and 2007 is filed as a part of this Report as required to be included in Item 15(a) and should be read in conjunction with the Consolidated Financial Statements of the Registrant and its subsidiaries:

Schedule	Page
II Valuation and Qualifying Accounts	71

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.

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, 2009 and December 31, 2008, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2009 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, 2009, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements and financial statement schedule, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting 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 other-than-temporary impairments in 2009.

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

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

/S/ PRICEWATERHOUSECOOPERS LLP

San Jose, California
March 15, 2010

46

CUTERA, INC.

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

	December 31,	
	2009	2008
Assets		
Current assets:		
Cash and cash equivalents	\$22,829	\$36,540
Marketable investments	76,780	60,653
Accounts receivable, net of allowance for doubtful accounts in 2009 and 2008 of \$586 and \$61, respectively	3,327	5,792
Inventories	6,408	9,927
Deferred tax asset	175	4,257
Other current assets and prepaid expenses	2,785	1,771
Total current assets	112,304	118,940
Property and equipment, net	847	1,357
Long-term investments	7,275	9,627
Intangibles, net	829	1,025
Deferred tax asset, net of current portion	97	6,527
Total assets	\$121,352	\$137,476
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$1,081	\$1,690
Accrued liabilities	9,048	8,848
Deferred revenue	6,160	6,758
Total current liabilities	16,289	17,296
Deferred rent	1,493	1,713
Deferred revenue, net of current portion	1,968	4,907
Income tax liability	749	1,452
Total liabilities	20,499	25,368
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: 13,436,163 and 12,806,035 shares in 2009 and 2008, respectively	13	13
Additional paid-in capital	85,248	80,318
Retained earnings	17,254	31,410
Accumulated other comprehensive income (loss)	(1,662)	367
Total stockholders' equity	100,853	112,108
Total liabilities and stockholders' equity	\$121,352	\$137,476

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

CUTERA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Year Ended December 31,		
	2009	2008	2007
Net revenue	\$ 53,682	\$ 83,379	\$ 101,726
Cost of revenue	21,759	32,358	35,002
Gross profit	31,923	51,021	66,724
Operating expenses:			
Sales and marketing	24,286	35,354	38,277
Research and development	6,810	7,550	7,169
General and administrative	10,320	11,270	11,721
Litigation settlement	850	—	—
Total operating expenses	42,266	54,174	57,167
Income (loss) from operations	(10,343)	(3,153)	9,557
Interest and other income, net	1,572	3,046	4,207
Other-than-temporary impairments of long-term investments	—	(3,554)	—
Income (loss) before income taxes	(8,771)	(3,661)	13,764
Provision (benefit) for income taxes	8,908	(792)	3,260
Net income (loss)	\$ (17,679)	\$ (2,869)	\$ 10,504
Net income (loss) per share:			
Basic	\$ (1.33)	\$ (0.22)	\$ 0.80
Diluted	\$ (1.33)	\$ (0.22)	\$ 0.74
Weighted-average number of shares used in per share calculations:			
Basic	13,279	12,770	13,153
Diluted	13,279	12,770	14,228

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

CUTERA, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands, except share amounts)

	Common Stock		Additional	Deferred	Retained	Accumulated	Total
	Shares	Amount	Paid-in Capital	Stock-Based Compensation	Earnings	Other Comprehensive Income (loss)	Stockholders' Equity
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
Change in accounting principle (Uncertain Tax Positions)	—	—	—	—	(91)	—	(91)
Components of other comprehensive income:							
Net income	—	—	—	—	10,504	—	10,504
Other comprehensive income	—	—	—	—	—	248	248

Edgar Filing: CUTERA INC - Form 10-K

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 benefit from exercises of stock-based payment awards	—	—	(231)	—	—	—	(231)
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
Issuance of common stock for employee purchase plan	59,365	—	326	—	—	—	326
Exercise of stock options	527,721	—	291	—	—	—	291
Issuance of common stock in settlement of restricted stock units, net of shares withheld for employee taxes, and stock awards	43,042	—	(32)	—	—	—	(32)

Edgar Filing: CUTERA INC - Form 10-K

Share-based compensation expense	—	—	4,236	—	—	—	4,236
Tax benefit from exercises of stock-based payment awards	—	—	109	—	—	—	109
Change in accounting principle (see Note 1)	—	—	—	—	3,523	(3,523)	—
Components of other comprehensive loss:							
Net loss	—	—	—	—	(17,679)	—	(17,679)
Other comprehensive income, net of tax of \$230	—	—	—	—	—	1,494	1,494
Comprehensive loss	—	—	—	—	—	—	(16,185)
Balance at December 31, 2009	13,436,163	\$ 13	\$ 85,248	\$ —	\$ 17,254	\$ (1,662)	\$ 100,853

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

CUTERA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,		
	2009	2008	2007
Cash flows from operating activities:			
Net income (loss)	\$ (17,679)	\$ (2,869)	\$ 10,504
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Stock-based compensation	4,236	5,220	5,627
Tax benefit (deficit) from stock-based compensation	109	(231)	4,195
Excess tax benefit related to stock-based compensation	(23)	(44)	(3,652)
Depreciation and amortization	860	904	913
Provision for excess and obsolete inventories	611	409	279
Other-than-temporary impairments of long-term investments	—	3,554	—
Change in allowance for doubtful accounts	525	52	(25)
Change in deferred tax asset net of valuation allowance	10,512	(1,892)	(2,662)
Other	—	6	(6)
Changes in assets and liabilities:			
Accounts receivable	1,940	4,848	(1,066)
Inventories	2,908	(2,803)	(2,592)
Other current assets	911	1,348	747
Accounts payable	(609)	(660)	138
Accrued liabilities	42	(4,739)	367
Deferred rent	(62)	74	215
Deferred revenue	(3,537)	1,101	3,792
Income tax liability	(703)	62	116
Net cash provided by operating activities	41	4,340	16,890
Cash flows from investing activities:			
Acquisition of property and equipment	(154)	(703)	(1,000)
Purchase of intangibles	—	—	(20)
Proceeds from sales of marketable and long-term investments	27,914	55,104	69,103
Proceeds from maturities of marketable investments	11,535	30,065	31,508
Purchase of marketable and long-term investments	(53,655)	(63,822)	(100,017)
Net cash provided by (used in) investing activities	(14,360)	20,644	(426)
Cash flows from financing activities:			
Proceeds from exercise of stock options and employee stock purchase plan	585	458	4,138
Repurchase of common stock	—	—	(25,000)
Excess tax benefit related to stock-based compensation	23	44	3,652
Net cash provided by (used in) financing activities	608	502	(17,210)
Net increase (decrease) in cash and cash equivalents	(13,711)	25,486	(746)
Cash and cash equivalents at beginning of year	36,540	11,054	11,800
Cash and cash equivalents at end of year	\$ 22,829	\$ 36,540	\$ 11,054
Supplemental and non-cash disclosure of cash flow information:			
Change in deferred stock-based compensation, net of terminations	\$ —	\$ —	\$ (9)
Cash paid (received) for income taxes	\$ (578)	\$ 2,098	\$ (808)

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

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. The Xeo and Solera platforms offer multiple hand pieces and applications, which allow customers to upgrade their systems (Upgrade revenue). In addition to systems and upgrade revenue, the Company generates revenue from the sale of post warranty service contracts, providing services for products that are out of warranty, Titan hand piece refills, and dermal fillers.

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 the Financial Accounting Standards Board Accounting Standards Codification (ASC) topic 210, subtopic 10, 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 and other income, net.

The Company holds a variety of interest bearing auction rate securities (ARS) that represent investments in pools of student loan assets issued by the Federal Family Education Loan Program (FELP). At the time of acquisition, the majority of 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 the majority of ARS investments and auctions for the Company's investments in these securities have failed to settle on their respective settlement dates. However, in 2009 \$4.4 million of ARS were redeemed at full par value. Maturity dates for the ARS investments in the Company's portfolio range from 2028 to 2043.

As of December 31, 2009, the Company had \$7.3 million of ARS classified as long-term investments and \$100,000 included in marketable investments representing the ARS that were refinanced by the issuers at par in January 2010. 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 \$7.4 million at December 31, 2009 and \$9.9 million at December 31, 2008.

The Company reviews the impairment of its investments on a quarterly basis in order to determine the classification of the impairment as "temporary" or "other-than-temporary." Beginning April 1, 2009, if the fair value of a debt security is less than its amortized cost, the Company assesses whether the impairment is other-than-temporary. An impairment is considered other-than-temporary if: (i) the Company has the intent to sell the security; (ii) it is more likely than not that the Company will be required to sell the security before recovery of the entire amortized cost basis; or (iii) the Company does not expect to recover the entire amortized cost basis of the security. If an impairment is considered other than temporary based on condition (i) or (ii) described above, the entire difference between the amortized cost and the fair value of the debt security is recognized in earnings. If an impairment is considered other than temporary based on condition (iii) described above, the amount representing credit losses (defined as the difference between the present value of the cash flows expected to be collected and the amortized cost basis of the debt security) will be recognized in earnings and the amount relating to all other factors will be recognized in OCI. Prior to April 1, 2009, declines in the fair value of debt securities deemed to be other-than-temporary were reflected in earnings as realized losses. Once an other-than-temporary impairment is recorded, a new cost basis in the investment is established.

With respect to the ARS that were held as of April 1, 2009, The Company determined that the cumulative effect adjustment required to reclassify the non-credit portion of previously recognized other-than-temporarily impaired adjustments was \$3.5 million. Therefore, the Company increased its accumulated earnings and decreased its accumulated other comprehensive income (loss) by the \$3.5 million cumulative effect adjustment. With respect to the \$9.0 million of par value ARS investments held as of December 31, 2009, the unrealized losses included in accumulated comprehensive income (loss) was \$1.6 million.

Fair Value Measurements.

Fair value is defined 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. The fair value hierarchy 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 are described below:

- Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities.
- 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.

Fair Value of Financial Instruments.

Carrying amounts of the Company's financial instruments, including cash and cash equivalents, marketable investments, accounts receivable, accounts payable and accrued liabilities, approximate their fair values as of the balance sheet dates because of their generally short maturities. The fair value of marketable investments is based on quoted market prices.

Concentration of Credit Risk and Other Risks and Uncertainties.

Financial instruments that potentially subject the Company to concentrations of risk consist principally of cash, cash equivalents, marketable investments and accounts receivable. The Company's cash and cash equivalents are primarily invested in deposits and money market accounts with two major banks in the United States. In addition, the Company has operating cash balances in banks in each of the international locations in which it operates. Deposits in these banks may exceed the amount of insurance provided on such deposits, if any. Management believes that these financial institutions are financially sound and, accordingly, believes that minimal credit risk exists. The Company has

not experienced any losses on its deposits of cash and cash equivalents. Accounts receivable are typically unsecured and are derived from revenue earned from 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. By policy, the Company restricts its exposure to any single 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, acquire, manufacture and market its products. There can be no assurance that current or recently acquired 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 or acquired 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.

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.

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. The Company would recognize an impairment loss 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, 2009, there have been no such impairments.

Warranty Obligations.

The Company historically provided a standard one-year or two-year warranty coverage on its systems. Beginning in September 2009, the Company changed its warranty policy to a one-year standard warranty on all 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.

Product, Upgrade, and Titan hand piece refill revenue, 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;

- Delivery has occurred or services have been rendered; and
- Collectability is reasonably assured.

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

The Company also offers customers extended service contracts. Revenue under service contracts is recognized on a straight-line basis over the period of the applicable service contract. Service revenue, from customers whose systems are not under a service contract, is recognized as the services are provided. Service revenue for the years ended December 31, 2009, 2008, and 2007 was \$13.2 million, \$11.4 million, and \$9.1 million, respectively

Research and Development Expenditures.

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

Advertising Costs.

Advertising costs are included as part of sales and marketing expense and are expensed as incurred. Advertising expense were \$891,000 in 2009, \$1.9 million in 2008 and \$2.1 million in 2007.

Stock-based Compensation.

The Company elected to use the Black-Scholes-Merton (BSM) pricing model to determine the fair value of stock options on the dates of grant. Restricted stock units (RSUs) and stock awards are measured based on the fair market values of the underlying stock on the dates of grant. Shares are issued on the vesting dates, 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 will be fewer than the actual number of RSUs outstanding. Furthermore, the Company records the liability for withholding amounts to be paid by us as a reduction to additional paid-in capital when the shares are issued. Also, the Company recognizes stock-based compensation using the straight-line method.

The Company includes as part of cash flows from financing activities the benefits of tax deductions in excess of the tax-effected compensation of the related stock-based awards for options exercised and RSUs vested during the period. The amount of cash received from the exercise of stock options and employee stock purchases was \$585,000 in 2009, \$458,000 in 2008 and \$4.1 million in 2007, and the total direct tax benefit (deficit) realized, including the excess tax benefit (deficit), from stock-based award activity was \$109,000 in 2009, (\$231,000) in 2008, and \$4.2 million in 2007. 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 recognizes income taxes under the liability method. The Company recognizes deferred income taxes for differences between the financial reporting and tax bases of assets and liabilities at enacted statutory tax rates in effect for the years in which differences are expected to reverse. The Company recognizes the effect on deferred taxes of a change in tax rates in income in the period that includes the enactment date. 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.

The measurement of deferred taxes often involves an exercise of judgment related to the computation and realization of tax basis. The deferred tax assets and liabilities reflect management's assessment that tax positions taken, and the resulting tax basis, are more likely than not to be sustained if they are audited by taxing authorities. Also, assessing tax rates that the Company expects to apply and determining the years when the temporary differences are expected to affect taxable income requires judgment about the future apportionment of our income among the states in which the Company operates. These matters, and others, involve the exercise of significant judgment. Any changes in our practices or judgments involved in the measurement of deferred tax assets and liabilities could materially impact our financial condition or results of operations.

Valuation allowances are established when necessary to reduce deferred income tax assets to amounts that the Company believes are more likely than not to be recovered. The Company evaluates its deferred tax assets quarterly to determine whether adjustments to our valuation allowance are appropriate. In making this evaluation, the Company relies on its recent history of pre-tax earnings, estimated timing of future deductions and benefits represented by the deferred tax assets, and its forecasts of future earnings, the latter two of which involve the exercise of significant judgment. As of September 30, 2009, the Company could not sustain a conclusion that it was more likely than not that the Company would realize any of its deferred tax assets resulting from its cumulative losses reported in the recent

past as well as other factors. Consequently, the Company established a valuation allowance against those deferred tax assets. The Company also performed this evaluation as of December 31, 2009, and determined the full valuation allowance was still required.

The Company establishes reserves for uncertain tax positions in accordance with the Income Taxes subtopic of the ASC. The subtopic prescribes the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. Additionally, the subtopic provides guidance on derecognition, measurement, classification, interest and penalties, and transition of uncertain tax positions. 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).

On April 1, 2009, the Company adopted updates issued by the FASB to the recognition and presentation of other-than-temporary impairments. A cumulative effect adjustment was required to accumulated earnings and a corresponding adjustment to accumulated other comprehensive income (loss) to reclassify the non-credit portion of previously other-than-temporarily impaired securities which were held at the beginning of the period of adoption and for which the Company does not intend to sell and it is more likely than not that the Company will not be required to sell such securities before recovery of the amortized cost basis. As a result of the implementation of this pronouncement, the Company reclassified the cumulative effect of the non-credit portion of previously recognized other-than-temporarily impaired adjustments of \$3.5 million by increasing accumulated earnings and decreasing accumulated other comprehensive 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, 2009. 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, 2009.

Recent Accounting Pronouncements.

Updates issued and adopted

On September 30, 2009, the Company adopted updates issued by the Financial Accounting Standards Board (FASB) to the authoritative hierarchy of GAAP. These changes establish the FASB Accounting Standards CodificationTM (ASC) as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with GAAP. Rules and interpretive releases of the Securities and Exchange Commission (SEC) under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. The FASB will no longer issue new standards in the form of Statements, FASB Staff Positions, or Emerging Issues Task Force Abstracts; instead the FASB will issue Accounting Standards Updates. Accounting Standards Updates will not be authoritative in their own right as they will only serve to update the Codification. These changes and the Codification itself do not change GAAP. Other than the manner in which new accounting guidance is referenced, the adoption of these changes had no impact on the Consolidated Financial Statements.

In August 2009, the FASB issued updates to fair value accounting for liabilities. These changes clarify existing guidance that in circumstances in which a quoted price in an active market for the identical liability is not available, an entity is required to measure fair value using either a valuation technique that uses a quoted price of either a similar liability or a quoted price of an identical or similar liability when traded as an asset, or another valuation technique that is consistent with the principles of fair value measurements, such as an income approach (e.g., present value technique). This guidance also states that both a quoted price in an active market for the identical liability and a quoted price for the identical liability when traded as an asset in an active market when no adjustments to the quoted price of the asset are required are Level 1 fair value measurements. These changes are effective for the Company's Consolidated Financial Statements for the year ended December 31, 2009. The adoption of these changes had no impact on the Consolidated Financial Statements.

On June 30, 2009, the Company adopted updates issued by the FASB to accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued, otherwise known as “subsequent events.” Specifically, these changes set forth the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements, and the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. The adoption of these changes had no impact on the Consolidated Financial Statements.

On June 30, 2009, the Company adopted updates issued by the FASB to fair value accounting. These changes provide additional guidance for estimating fair value when the volume and level of activity for an asset or liability have significantly decreased and includes guidance for identifying circumstances that indicate a transaction is not orderly. This guidance is necessary to maintain the overall objective of fair value measurements, which is that fair value is 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 under current market conditions. The adoption of these changes had no impact on the Consolidated Financial Statements.

On April 1, 2009, the Company adopted updates issued by the FASB to the recognition and presentation of other-than-temporary impairments. These changes amend existing other-than-temporary impairment guidance for debt securities to make the guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities. The recognition provision applies only to fixed maturity investments that are subject to the other-than-temporary impairments. If an entity intends to sell, or if it is more likely than not that it will be required to sell an impaired security prior to recovery of its cost basis, the security is other-than-temporarily impaired and the full amount of the impairment is recognized as a loss through earnings. Otherwise, losses on securities which are other-than-temporarily impaired are separated into: (i) the portion of loss which represents the credit loss; or (ii) the portion which is due to other factors.

The credit loss portion is recognized as a loss through earnings, while the loss due to other factors is recognized in other comprehensive income (loss), net of taxes and related amortization. A cumulative effect adjustment is required to accumulated earnings and a corresponding adjustment to accumulated other comprehensive income (loss) to reclassify the non-credit portion of previously other-than-temporarily impaired securities which were held at the beginning of the period of adoption and for which the Company does not intend to sell and it is more likely than not that the Company will not be required to sell such securities before recovery of the amortized cost basis. These changes were effective for interim and annual periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. The Company adopted these changes effective April 1, 2009. As a result of the implementation of this pronouncement, the Company reclassified the cumulative effect of the non-credit portion of previously recognized other-than-temporarily impaired adjustments of \$3.5 million by increasing accumulated earnings and decreasing accumulated other comprehensive income (loss).

On June 30, 2009, the Company adopted updates issued by the FASB to fair value disclosures of financial instruments. These changes require a publicly traded company to include disclosures about the fair value of its financial instruments whenever it issues summarized financial information for interim reporting periods. Such disclosures include the fair value of all financial instruments, for which it is practicable to estimate that value, whether recognized or not recognized in the statement of financial position; the related carrying amount of these financial instruments; and the method(s) and significant assumptions used to estimate the fair value. Other than the required disclosures, the adoption of these changes had no impact on the Consolidated Financial Statements.

On January 1, 2009, the Company adopted updates issued by the FASB to fair value accounting and reporting as it relates to nonfinancial assets and nonfinancial liabilities that are not recognized or disclosed at fair value in the financial statements on at least an annual basis. These changes define fair value, establish a framework for measuring fair value in GAAP, and expand disclosures about fair value measurements. This guidance applies to other GAAP that require or permit fair value measurements and is to be applied prospectively with limited exceptions. The adoption of these changes, as it relates to nonfinancial assets and nonfinancial liabilities, had no impact on the Consolidated Financial Statements. These provisions will be applied at such time a fair value measurement of a nonfinancial asset or nonfinancial liability is required, which may result in a fair value that is materially different than would have been calculated prior to the adoption of these changes.

On January 1, 2009, the Company adopted updates issued by the FASB to accounting for intangible assets. These changes amend the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset in order to improve the consistency between the useful life of a recognized intangible asset outside of a business combination and the period of expected cash flows used to measure the fair value of an intangible asset in a business combination. The adoption of these changes had no impact on the Consolidated Financial Statements.

On January 1, 2009, the Company adopted updates issued by the FASB to the calculation of earnings per share. These changes state that unvested share-based payment awards that contain nonforfeitable rights to dividends or dividend equivalents (whether paid or unpaid) are participating securities and shall be included in the computation of earnings per share pursuant to the two-class method for all periods presented. The adoption of these changes had no impact on the Consolidated Financial Statements.

Updates issued but not yet adopted

In October 2009, the FASB issued updates to revenue recognition guidance. These changes provide application guidance on whether multiple deliverables exist, how the deliverables should be separated and how the consideration should be allocated to one or more units of accounting. This update establishes a selling price hierarchy for determining the selling price of a deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific or third-party evidence is available. The Company will

be required to apply this guidance prospectively for revenue arrangements entered into or materially modified after January 1, 2011; however, earlier application is permitted. The Company has not determined the impact that this update may have on its Consolidated Financial Statements.

In January 2010, the FASB issued guidance to amend the disclosure requirements related to recurring and nonrecurring fair value measurements. The guidance requires new disclosures on the transfers of assets and liabilities between Level 1 (quoted prices in active market for identical assets or liabilities) and Level 2 (significant other observable inputs) of the fair value measurement hierarchy, including the reasons and the timing of the transfers. Additionally, the guidance requires a roll forward of activities on purchases, sales, issuance, and settlements of the assets and liabilities measured using significant unobservable inputs (Level 3 fair value measurements). The guidance will become effective for us with the reporting period beginning January 1, 2010, except for the disclosure on the roll forward activities for Level 3 fair value measurements, which will become effective for us with the reporting period beginning January 1, 2011. Other than requiring additional disclosures, adoption of this new guidance will not have a material impact on our financial statements.

NOTE 2—INVESTMENT SECURITIES:

Cash and cash equivalents, marketable investments and long-term investments at December 31, 2009 and 2008 consist of the following (in thousands):

December 31, 2009	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market
-------------------	-------------------	------------------------------	-------------------------------	----------------