

CUTERA INC
Form 10-K
March 16, 2009
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K
ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

For fiscal year ended December 31, 2008

Commission file number: 000-50644

Cutera, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

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

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

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

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

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

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

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

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

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

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

Large accelerated filer Accelerated filer Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

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

The aggregate market value of the registrant's common stock, held by non-affiliates of the registrant as of June 30, 2008 (which is the last business day of registrant's most recently completed second fiscal quarter) based upon the closing price of such stock on the NASDAQ Global Market on that date, was \$73 million. For purposes of this disclosure, shares of common stock held by entities and individuals who own 5% or more of the outstanding common stock and shares of common stock held by each officer and director have been excluded in that such persons may be deemed to be affiliates as that term is defined under the Rules and Regulations of the Securities Exchange Act of 1934. This determination of affiliate status is not necessarily conclusive.

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

DOCUMENTS INCORPORATED BY REFERENCE

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

Table of Contents**TABLE OF CONTENTS**

	Page
PART I	
Item 1. <u>Business</u>	3
Item 1A. <u>Risk Factors</u>	19
Item 1B. <u>Unresolved Staff Comments</u>	32
Item 2. <u>Properties</u>	32
Item 3. <u>Legal Proceedings</u>	32
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	33
PART II	
Item 5. <u>Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	34
Item 6. <u>Selected Financial Data</u>	36
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	37
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	53
Item 8. <u>Financial Statements and Supplementary Data</u>	55
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	86
Item 9A. <u>Controls and Procedures</u>	86
Item 9B. <u>Other Information</u>	87
PART III	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	88
Item 11. <u>Executive Compensation</u>	88
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	88
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	88
Item 14. <u>Principal Accounting Fees and Services</u>	88
PART IV	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	89

Table of Contents

PART I

ITEM 1. BUSINESS

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

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

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

Solera- In 2004, we introduced our Solera platform a compact tabletop system designed to support a single technology platform. Solera systems use either infrared (Solera Titan) or pulsed light (Solera Opus) and can be used to remove unwanted hair, treat vascular lesions and rejuvenate the skin. The Solera Opus can support one or more pulsed light applications in a single system.

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

We offer our customers the ability to select the systems and applications that best fit their practice and to subsequently upgrade their systems to add new applications. This upgrade path allows our customers to cost-effectively build their aesthetic practices and provides us with a source of recurring revenue.

The Structure of Skin and Conditions that Affect Appearance

The skin is the body's largest organ and is comprised of layers called the epidermis and dermis. The epidermis is the outer layer, and serves as a protective barrier for the body. It contains cells that determine pigmentation, or skin color. The underlying layer of skin, the dermis, contains hair follicles and large and small blood vessels that are found at various depths below the epidermis. Collagen, also found within the dermis, provides strength and flexibility to the skin.

Many factors, such as age, smoking and sun damage, can result in aesthetically unpleasant changes in the appearance of the skin. These changes can include:

Undesirable hair growth;

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

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

Uneven pigmentation or sun spots due to long-term sun exposure.
People with unwanted hair or any of the above-mentioned skin conditions often seek aesthetic treatments to improve their appearance.

Table of Contents

The Market for Non-Surgical Aesthetic Procedures

The market for non-surgical aesthetic procedures has grown significantly over the past several years. The American Society of Plastic Surgeons estimates that in 2007 there were nearly 10 million minimally-invasive aesthetic procedures performed, a 9% increase over 2006 and an 81% increase over 2000. We believe there are several factors contributing to the growth of these aesthetic procedures, including:

Aging of the U.S. Population- The baby boomer demographic segment, ages 44 to 62 in 2008, represented approximately 26% of the U.S. population as of July 1, 2005. The size of this aging segment, and its desire to retain a youthful appearance, has driven the growth for aesthetic procedures.

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

Broader Base of Customers- Managed care and government payer reimbursement restrictions in the United States, and similar payment related constraints outside the United States, may help motivate qualified practitioners from differing specialties to establish or expand their elective aesthetic practices with procedures that are paid for directly by patients. As a result, in addition to the core users such as dermatologists and plastic surgeons, many other non-core practitioners, such as gynecologists, family practitioners, primary care physicians, physicians offering aesthetic treatments in non-medical offices, and other qualified practitioners are offering aesthetic procedures.

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

Many alternative therapies are available for improving a person's appearance by treating specific structures within the skin. These procedures utilize injections or abrasive agents to reach different depths of the dermis and the epidermis. In addition, non-invasive and minimally-invasive treatments have been developed that employ laser and other light-based technologies to achieve similar therapeutic results. Some of these more common therapies and their limitations are described below.

Hair Removal- Techniques for hair removal include waxing, depilatories, tweezing, shaving, electrolysis and laser and other light-based hair removal. The only techniques that provide a long-lasting solution are electrolysis and light-based hair removal. Electrolysis is usually painful, time-consuming and expensive for large areas, but is the most common method for removing light-colored hair. During electrolysis, an electrologist inserts a needle directly into a hair follicle and activates an electric current in the needle. Since electrolysis only treats one hair follicle at a time, the treatment of an area as small as an upper lip may require numerous visits and many hours of treatment. In addition, electrolysis can cause blemishes and infection related to needle use.

Leg and Facial Veins- The current aesthetic treatment methods for leg and facial veins include sclerotherapy and laser and other light-based treatments. With these treatments, patients seek to eliminate visible veins and improve overall skin appearance. Sclerotherapy requires a skilled practitioner to inject a saline or detergent-based solution into the target vein, which breaks down the vessel causing it to collapse and be absorbed into the body. The need to correctly position the needle on the inside of the vein makes it difficult to treat smaller veins, which limits the treatment of facial vessels and small leg veins. The American Society of Plastic Surgeons estimates that over 383,000 sclerotherapy procedures were performed in 2007.

Skin Rejuvenation- Skin rejuvenation treatments include a broad range of popular alternatives, including Botox and collagen injections, chemical peels, microdermabrasions, radiofrequency treatments and lasers and other light-based treatments. With these treatments, patients hope to improve overall skin tone and texture, reduce pore size, tighten skin and remove other signs of aging, including mottled pigmentation, diffuse redness and wrinkles. All of these procedures are temporary solutions and must be repeated within several weeks or

Table of Contents

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

Some skin rejuvenation treatments, such as chemical peels and microdermabrasions, can have undesirable side effects. Chemical peels use acidic or caustic solutions to peel away the epidermis, and microdermabrasion generally utilizes sand crystals to resurface the skin. These techniques can lead to stinging, redness, irritation and scabbing. In addition, more serious complications, such as changes in skin color, can result from deeper chemical peels. Patients that undergo these deep chemical peels are also advised to avoid exposure to the sun for several months following the procedure. The American Society of Plastic Surgeons estimates that in 2007, 4.6 million injections of Botox and over 1.5 million injections of collagen and other soft-tissue fillers were administered, and 1.0 million chemical peels and over 890,000 microdermabrasion procedures were performed.

In radiofrequency tissue tightening, energy is applied to heat the dermis of the skin with the goal of shrinking and tightening the collagen fibers. This approach may result in a more subtle and incremental change to the skin than a surgical facelift. Drawbacks to this approach may include surface irregularities that may resolve over time, and the risk of burning the treatment area.

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

Laser and Other Light-Based Aesthetic Treatments

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

Ablative skin resurfacing is a method of improving the appearance of the skin by removing the outer layers of the skin. Ablative skin resurfacing procedures are considered invasive or minimally invasive, depending on how much of the epidermis is removed during a treatment.

Non-ablative skin resurfacing is a method of improving the appearance of the skin by treating the underlying structure of the skin without damaging the outer layers of the skin. Practitioners can use laser and other light-based technologies to selectively target hair follicles, veins or collagen in the dermis, as well as cells responsible for pigmentation in the epidermis, without damaging surrounding tissue. They can also use these technologies to safely remove portions of the epidermis and deliver heat to the dermis as a means of generating new collagen growth.

Safe and effective laser and other light-based treatments require an appropriate combination of the following four parameters:

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

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

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

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

For example, in the case of hair removal, by utilizing the correct combination of these parameters, a practitioner can use a laser or other light source to selectively target melanin within the hair follicle to absorb the laser energy and destroy the follicle, without damaging other delicate structures in the surrounding tissue. Wavelength and spot size permit the practitioner to target melanin in the base of the hair follicle, which is found in the dermis. The combination of pulse duration and energy level may vary, depending upon the thickness of the targeted hair follicle. A shorter pulse length with a high energy level is optimal to destroy fine hair, whereas coarse hair is best

Table of Contents

treated with a longer pulse length with lower energy levels. If treatment parameters are improperly set, non-targeted structures within the skin may absorb the energy thereby eliminating or reducing the therapeutic effect. In addition, improper setting of the treatment parameters or failure to protect the surface of the skin may cause burns, which can result in blistering, scabbing and skin discoloration.

Technology and Design of Our Systems

Our unique CoolGlide, Xeo and Solera platforms provide the long-lasting benefits of laser and other light-based aesthetic treatments. Our technology allows for a combination of a wide variety of applications available in a single system. Key features of our solutions include:

Multiple Applications Available in a Single System- Our multi-application systems enable practitioners to perform multiple aesthetic procedures using a single device. These procedures include hair removal, treatment of unsightly veins and skin rejuvenation, including the treatment of discoloration, laxity, fine lines, pore size and uneven texture. Because practitioners can use our systems for multiple indications, the cost of a unit may be spread across a potentially greater number of patients and procedures, and therefore may be more rapidly recovered.

Technology and Design Leadership- We offer innovative laser and other light-based solutions for the aesthetic market. Our laser technology combines long wavelength, adjustable energy levels, variable spot sizes and a wide range of pulse durations, allowing practitioners to customize treatments for each patient and condition. Our proprietary pulsed light hand pieces for the treatment of discoloration, hair removal and vascular treatments optimize the wavelength used for treatments and incorporate a monitoring system to increase safety. Our Titan hand pieces utilize a novel light source that had not been previously used for aesthetic treatments. And our Pearl and Pearl Fractional hand pieces, with proprietary YSGG technology, represent the first application of the 2790 nm wavelength for minimally-invasive cosmetic dermatology.

Upgradeable Platform- We design our products to allow our customers to cost-effectively upgrade to our multi-application systems, which provide our customers with the option to add additional applications to their existing systems and provides us with a source of recurring revenue. We believe that product upgradeability allows our customers to take advantage of our latest product offerings and provide additional treatment options to their patients, thereby expanding the opportunities for their aesthetic practices.

Treatments for Broad Range of Skin Types and Conditions- Our products remove hair safely and effectively on patients of all skin types, including harder-to-treat patients with dark or tanned skin. In addition, the wide parameter range of our systems allows practitioners to effectively treat patients with both fine and coarse hair. Practitioners may use our products to treat spider and reticular veins, which are unsightly small veins in the leg, as well as small facial veins. And they can treat color, texture, pore size, fine lines and laxity on any type of skin with our skin rejuvenation systems. The ability to customize treatment parameters enables practitioners to offer safe and effective therapies to a broad base of their patients.

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

Table of Contents

Strategy

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

Continuing to Develop New Products- We have introduced at least one new product every year since 2000. In 2008, we introduced Pearl Fractional a minimally invasive, 2790 nm YSGG laser for the fractional ablative market to be used for rejuvenation applications. We plan to continue developing our existing technology platforms and develop other platforms with the intent of offering new applications for our customers.

Increasing Sales of Existing Products in the United States- Although the U.S. economy is currently in a recession, we believe that the U.S. market for aesthetic systems will continue to offer growth opportunities. In 2008, we restructured our U.S. direct sales force with the goals of managing expenses in line with our business, and improving productivity by retaining our key performers and expanding their sales territories. We also continued to leverage our relationship with PSS World Medical Shared Services, Inc., or PSS, a wholly-owned subsidiary of PSS World Medical. PSS operates medical supply distribution service centers with over 700 sales consultants serving physician offices throughout the United States.

Expanding our International Presence- We believe that the international market continues to be a significant growth opportunity for us. As such, in 2008 we remained focused on building global brand-recognition by increased sales and marketing activities. In 2008, we increased our direct international sales force and ended the year with distributors in over 30 countries. We plan on continuing to manage our international direct sales employees, distributors and support staff to increase sales and strengthen customer relationships in the international markets.

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

Leveraging our Installed Base with Sales of Upgrades- Each time we have introduced a major new product, we have designed it to allow existing customers to upgrade their previously purchased systems to offer additional capabilities. We believe that providing upgrades to our existing installed base of customers continues to represent a potentially significant opportunity for recurring revenue. We also believe that our upgrade program aligns our interest in generating revenue with our customers' interest in improving the return on their investment by expanding the range of applications that can be performed with their existing systems. In 2009, we plan on continuing to market upgrades to our installed base, including our Pearl and Pearl Fractional applications introduced in 2007 and 2008, respectively.

Generating Revenue from Services and Refillable Hand Pieces- Our Titan hand pieces and pulsed-light hand pieces are refillable products, which provide us with a source of recurring revenue from our existing customers. We offer post-warranty services to our customers either through extended service contracts to cover preventive maintenance or replacement parts and labor, or through direct billing for parts and labor. These post-warranty services serve as additional sources of recurring revenue.

Table of Contents**Products**

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

Applications:				Hair Removal:	Vascular Lesions:	Dyschromia:	Skin Rejuvenation Texture, Lines and Wrinkles:	Skin Laxity:
System Platforms:	Products:	Year:	Energy Source:					
CoolGlide	CV	2000	a	x				
	Excel	2001	a		x			
	Vantage	2002	a				x	
Xeo:	Nd:YAG	2003	a	x	x		x	
	OPS600	2003	b			x		
	LP560	2004	b			x		
	Titan S	2004	c					x
	ProWave 770	2005	b	x				
	AcuTip 500	2005	b		x			
	Titan V/XL	2006	c					x
	LimeLight	2006	b			x		
	Pearl	2007	d			x	x	
Pearl Fractional	2008	d				x		
Solera	Titan S	2004	c					x
	ProWave 770	2005	b	x				
	OPS 600	2005	b			x		
	LP560	2005	b			x		
	AcuTip 500	2005	b		x			
	Titan V/XL	2006	c					x
LimeLight	2006	b			x			

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

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

Control Console

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

Table of Contents

Hand Pieces

1064 nm Nd:YAG Hand Piece- Our 1064nm Nd:YAG hand piece delivers laser energy to the treatment area for hair removal, leg and facial vein treatment, and skin rejuvenation procedures to treat skin texture and fine lines, and reduce pore size. The 1064nm Nd:YAG hand piece consists of an energy-delivery component, consisting of an optical fiber and lens, and a copper cooling plate with imbedded temperature monitoring. The hand piece weighs approximately 14 ounces, which is light enough to be held with one hand. The lightweight nature and ergonomic design of the hand piece allows the operation of the device without user fatigue. Its design allows the practitioner an unobstructed view of the treatment area, which reduces the possibility of unintended damage to the skin and can increase the speed of treatment. The 1064nm Nd:YAG hand piece also incorporates our cooling system, providing integrated pre- and post cooling of the treatment area through a temperature-controlled copper plate to protect the outer layer of the skin. The hand piece is available in either a fixed 10 millimeter spot size for our CoolGlide CV system, or a user-controlled variable 3, 5, 7 or 10 millimeter spot size for our CoolGlide Excel and CoolGlide Vantage systems.

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

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

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

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

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

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

Table of Contents

Pearl Fractional Hand Piece- The Pearl Fractional hand piece, introduced in 2008, also uses proprietary YSGG technology and is designed to treat wrinkles and deep dermal imperfections (although it is cleared in the United States by the FDA only for skin resurfacing and coagulation). This hand piece penetrates the deep dermis producing a series of microcolumns across the skin, which can result in the removal of damaged tissue and the production of new collagen. The Pearl Fractional hand piece consists of a custom monolithic laser source, scanner and power monitoring electronics. The scanner includes multiple scan patterns to allow simple and fast treatments of the face. The hand piece includes an attachment for a smoke evacuator, allowing the practitioner to use one hand during treatment.

Our Applications and Procedures

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

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

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

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

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

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

Table of Contents

Texture; Lines and Wrinkles- When using a 1064nm Nd:YAG laser to improve skin texture, reduce pore size and treat fine lines, cooling is not applied and the hand piece is held directly above the skin. A large number of pulses are directed at the treatment site, repeatedly covering an area, such as the cheek. By delivering many pulses of laser light to a treatment area, a gentle heating of the dermis occurs and collagen growth is stimulated to rejuvenate the skin and reduce wrinkles. Patients typically receive four to six treatments for this procedure. The treatment typically takes less than a half hour and there are typically two to four weeks between treatments.

When treating texture and fine lines with a Pearl hand piece, the hand piece is held at a controlled distance from the skin and the scanner delivers a preset pattern of spots to the treatment area. Cooling is not applied to the epidermis during the treatment. The energy delivered by the hand piece ablates a portion of the epidermis while leaving a coagulated portion that will gently peel off over the course of a few days. Heat is also delivered into the dermis which can result in the production of new collagen. Treatment of the full face can usually be performed in 15 to 30 minutes. Patients receive on average between one and three treatments at monthly intervals.

When treating wrinkles and deep dermal imperfections with a Pearl Fractional hand piece, the hand piece is held at a controlled distance from the skin and the scanner delivers a preset pattern of spots to the treatment area. Cooling is not applied to the epidermis during the treatment. The energy delivered by the hand piece penetrates the deep dermis producing a series of microcolumns across the skin, which can result in the removal of damaged tissue and the production of new collagen. Treatment of the full face can usually be performed in less than an hour. Patients receive on average between one and three treatments at monthly intervals.

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

Dyschromia- Our pulsed-light technologies allow our customers to safely and effectively treat red and brown dyschromia, which is skin discoloration, pigmented lesions and rosacea. The practitioner delivers a narrow spectrum of light to the surface of the skin through our LP560 or LimeLight hand pieces. These hand pieces include one of our proprietary wavelength filters, which reduce the energy level required for therapeutic effect and minimize the risk of skin injury.

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

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

Skin Laxity- Our Titan technology allows our customers to use deep dermal heating to tighten lax skin. The practitioner delivers a spectrum of light to the skin through our Titan hand piece. This hand piece includes our proprietary light source and wavelength filter which tailors the delivered spectrum of light to provide heating at the desired depth in the skin.

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

Table of Contents

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

Product Upgrades

Our products are designed to allow our customers to cost-effectively upgrade to our newest technologies, which provides our customers the option to add applications to their system and provides us with a source of recurring revenue. When we introduce a new product, we notify our customers of the upgrade opportunity through a sales call or mailing. In most cases, a field service representative can install the upgrade at the customer site in a matter of hours, which results in very little downtime for practitioners. In some cases, where substantial upgrades are necessary, customers will receive fully-refurbished systems before sending their prior systems back to our headquarters.

Post-Warranty Service and Titan Hand Piece Refills

Each Titan hand piece is a refillable product, which provides us with a source of recurring revenue from our existing customers. We offer post-warranty services to our customers either through extended service contracts to cover preventive maintenance or replacement parts and labor, or through direct billing for parts and labor. These post-warranty services serve as additional sources of recurring revenue from our installed base.

Sales and Marketing

In the United States we market and sell our products primarily through a direct sales organization. Generally, each direct sales employee is assigned a specific territory. As of December 31, 2008, we had a U.S. direct sales force of 35 employees. In addition to direct sales employees, we have a distribution relationship with PSS World Medical that operates medical supply distribution service centers with over 700 sales representatives serving physician offices throughout the United States. For the years ended December 31, 2008, 2007 and 2006, revenue from PSS was \$12.1 million, \$14.6 million and \$15.4 million, respectively. In January 2009, we had a company-wide reduction in force of approximately 10%, which included members of our direct sales force.

International sales are generally made through a direct international sales force of 31 employees, as well as a worldwide distributor network in over 30 countries as of December 31, 2008. As of December 31, 2008, we had direct sales offices in Australia, Canada, France, Japan, Spain, Switzerland and the United Kingdom. Our international revenue represented 50%, 37% and 31% of total revenue for the years ended December 31, 2008, 2007 and 2006, respectively.

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

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

We seek to establish strong ongoing relationships with our customers through the upgradeability of our products, sales of extended service contracts, the refilling of Titan hand pieces, and ongoing training and support. We

Table of Contents

primarily target our marketing efforts to practitioners through office visits, workshops, trade shows, webinars and trade journals. We also market to potential patients through brochures, workshops and our website. We offer clinical forums with recognized expert panelists to promote advanced treatment techniques using our products to further enhance customer loyalty and uncover new sales opportunities.

Competition

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

Competition among providers of laser and other light-based devices for the aesthetic market is characterized by extensive research efforts and innovative technology. While we attempt to protect our products through patents and other intellectual property rights, there are few barriers to entry that would prevent new entrants or existing competitors from developing products that would compete directly with ours. There are many companies, both public and private, that are developing innovative devices that use both light-based and alternative technologies. Some of these competitors have greater resources than we do or product applications for certain sub-markets in which we do not participate. Additional competitors may enter the market, and we are likely to compete with new companies in the future. To compete effectively, we have to demonstrate that our products are attractive alternatives to other devices and treatments by differentiating our products on the basis of performance, brand name, service and price. We have encountered and expect to continue to encounter potential customers who, due to existing relationships with our competitors, are committed to, or prefer the products offered by these competitors. Competitive pressures may result in price reductions and reduced margins for our products.

Research and Development

Our research and development group develops new products and applications and builds clinical support to address unmet or underserved market needs. As of December 31, 2008, our research and development activities were conducted by a staff of 22 employees with a broad base of experience in lasers and optoelectronics. We have developed relationships with outside contract engineering and design consultants, giving our team additional technical and creative breadth. We work closely with thought leaders and customers, both individually and through our sponsored seminars, to understand unmet needs and emerging applications in aesthetic medicine. Research and development expenses for 2008, 2007 and 2006, were \$7.6 million, \$7.2 million and \$6.5 million, respectively.

Service and Support

Our products are engineered to enable quick and efficient service and support. There are several separate components of our products, each of which can easily be removed and replaced. We believe that quick and effective delivery of service is important to our customers. As of December 31, 2008, we had a 40-person global service department. Internationally, we provide direct service support through our Australia, Canada, France, Japan, Spain and Switzerland offices, and also through the network of distributors in over 30 countries and third-party service providers. We provide initial warranties on our products to cover parts and service and offer extended service plans that vary by the type of product and the level of service desired. Our standard warranty on system consoles covers parts and service for a standard period of one or two years. From time to time, we also have promotions whereby we include a post-warranty service contract with the sale of our products. Customers are notified before their initial warranty expires and are able to choose from two different extended service plans covering preventative maintenance or replacement parts and labor. In the event a customer does not purchase an extended service plan, we will offer to service the customer's system and charge the customer for time and materials. Our Titan hand pieces generally include a warranty for a set number of shots instead of for a period of time. We have invested substantial financial and management resources to develop a worldwide infrastructure to meet the service needs of our customers worldwide.

Table of Contents

Manufacturing

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

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

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

We are required to manufacture our products in compliance with the FDA's Quality System Regulation, or QSR. The QSR covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. The FDA enforces the QSR through periodic unannounced inspections. Our single manufacturing facility located in Brisbane, CA, was inspected by the FDA in 2008. There were no significant findings as a result of this audit and our responses have been accepted by the FDA. Our failure to maintain compliance with the QSR requirements could result in the shut down of our manufacturing operations and the recall of our products, which would have a material adverse effect on business. In the event that one of our suppliers fails to maintain compliance with our quality requirements, we may have to qualify a new supplier and could experience manufacturing delays as a result. We have opted to maintain quality assurance and quality management certifications to enable us to market our products in the United States, the member states of the European Union, the European Free Trade Association and countries which have entered into Mutual Recognition Agreements with the European Union. Our manufacturing facility is ISO 13485 certified.

Patents and Proprietary Technology

We rely on a combination of patent, copyright, trademark and trade secret laws, and non-disclosure, confidentiality and invention assignment agreements to protect our intellectual property rights. As of December 31, 2008, we had eleven issued U.S. patents and twenty-eight pending U.S. patent applications. Cutera, CoolGlide, Solera, Xeo, AcuTip, Limelight, Pearl, ProWave 770 and Titan are only some of our trademarks. We have trademark rights to these names and others in the United States and certain other countries. We intend to file for additional patents and trademarks to continue to strengthen our intellectual property rights.

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

Table of Contents

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

Government Regulation

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

Product design and development;

Product testing;

Product manufacturing;