CUTERA INC
Form 10-K
March 15, 2016
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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, 2015

Commission file number: 000-50644

Cutera, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**77-0492262**
(State or other jurisdiction of incorporation or organization)	**(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 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 (§229.405 of this chapter) 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 the definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" 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

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

The aggregate market value of the registrant's common stock, held by non-affiliates of the registrant as of June 30, 2015 (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 June 30, 2015, was approximately $116 million. For purposes of this disclosure, shares of common stock held by entities and individuals who own 5% or more of the outstanding common stock and shares of common stock held by each officer and director have been excluded in that such persons may be deemed to be "affiliates" as that term is defined under the Rules and Regulations of the Securities Exchange Act of 1934. This determination of affiliate status is not necessarily conclusive.

The number of shares of Registrant's common stock issued and outstanding as of February 29, 2016 was 12,992,503.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates by reference certain information from the registrant's definitive proxy statement for the 2016 Annual Meeting of Stockholders.

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PART I

ITEM 1. BUSINESS

We are a global medical device company founded as a Delaware corporation in 1998, headquartered in Brisbane, California, specializing in the design, development, manufacture, marketing and servicing of laser and other energy based aesthetics systems for practitioners worldwide. We offer easy-to-use products based on the following key product platforms: *enlighten*™, *excel HR*™, *truSculpt*™ , *excel V*™, and *xeo*®— each of which enables physicians and other qualified practitioners to perform safe and effective aesthetic procedures for their customers. Each of our laser and other energy-based platforms consists of one or more hand pieces and a console that incorporates a universal graphical user interface, a laser or other energy-based module, control system software and high voltage electronics. However, depending on the application, the laser or other energy-based module is sometimes contained in the hand piece itself.

Our trademarks include: "Cutera," *"CoolGlide,""enlighten," "excel HR," "excel V,"* "*GenesisPlus,""solera," "titan," "truSculpt," and* "*xeo."* Our logo and our other trade names, trademarks and service marks appearing in this document are our property. Other trade names, trademarks and service marks appearing in this annual report on Form 10-K are the property of their respective owners. Solely for convenience, our trademarks and trade names referred to in this annual report on Form 10-K appear without the ™ or ® symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and trade names.

A description of each of our hand pieces, and the aesthetic conditions they are designed to treat, is contained in the section below entitled "Products" and a summary of the features of our primary products is as follows:

enlighten- In December 2014, we introduced our *enlighten* platform, a dual wavelength (1064 nm + 532 nm) and dual pulse duration (750 picosecond, or "ps," and 2 nanosecond, or "ns") laser system for tattoo removal and the treatment of benign pigmented lesions. In June 2015 we added a low-energy 532 nm enhancement to this platform, which significantly extended the treatment settings, enabling more effective treatment of benign pigmented lesions.

excel HR- In June 2014, we introduced our *excel HR* platform, a premium hair removal solution for all skin types, combining Cutera's proven long-pulse 1064 nm Nd:YAG laser and a high-power 755 nm Alexandrite laser with sapphire contact cooling.

truSculpt- In August 2012, we commenced shipments of our *truSculpt* platform with a 25cm^2 hand piece. *truSculpt* is a high-powered radio frequency ("RF") platform designed for deep tissue heating. This system is designed to treat all body areas and with its unique electrode design is able to achieve comfortable, uniform heating of subcutaneous tissue. In the fourth quarter of 2012, we commenced shipping a larger 40cm^2 hand piece that enables faster treatments of larger areas. In the third quarter of 2013, we commenced shipping a smaller 16 cm^2 hand piece.

excel V- In February 2011, we introduced our *excel V* platform, a high-performance, vascular and benign pigmented lesion treatment platform designed specifically for the core-market of Dermatologists and Plastic Surgeons. This platform provides a combination of the 532 nanometer, or "nm" green laser with Cutera®'s award-winning 1064 nm Nd:YAG technology, to provide a single, compact and efficient system that treats the entire range of cosmetic vascular and benign pigmented lesion conditions, without the need for costly consumables.

xeo- In 2003, we introduced the *xeo* platform, which can combine pulsed light and laser applications in a single system. The *xeo* is a multi-application platform on which a customer can purchase hand piece applications for the removal of unwanted hair, treatment of vascular lesions, and skin revitalization by treating discoloration, and treating fine lines and laxity.

Other than the above mentioned five primary systems, we continue to generate revenue from our legacy products such as *GenesisPlus*™, *CoolGlide*®, *solera*®, and a third-party sourced system called *myQ*™ for the Japanese market.

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 incremental revenue.

In addition to systems and upgrades, we generate revenue from the sale of post warranty services, Titan hand piece refills, and skincare products (Japanese market only).

The Structure of Skin and Conditions that Affect Appearance

The skin is the body's largest organ and is comprised of two 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.

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Many factors, including advancing 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, leading to uneven texture, wrinkles and skin laxity; and
- Uneven pigmentation or sun spots due to long-term sun exposure.

In addition to these skin conditions, people seek removal of unwanted tattoos as well as removal of fat in certain body areas in order to improve their appearance and confidence.

The Market for Non-Surgical Aesthetic Procedures

The market for non-surgical aesthetic procedures has grown significantly over the past several years. Medical Insight, an independent industry research and analysis firm, estimated that in 2015 total sales of products in the global aesthetic market exceeded $7 billion and indicates that total sales should increase 11.8% annually through 2019. For North America, the American Society of Plastic Surgeons estimates that in 2014 there were over 13.9 million minimally-invasive aesthetic procedures performed, a 4% increase over 2013 and a 154% increase over 2000.

We believe there are several factors contributing to the global growth of aesthetic treatment procedures and aesthetic laser equipment sales, including:

- ***Improved Economic Environment and Expanded Physician Base-*** The improvements in overall global economic conditions since the last recession has created increased demand for aesthetic procedures, which in turn has resulted in an expanding physician base to satisfy the demand.
- ***Aging Demographics of Industrialized Countries-*** The aging population of industrialized countries, the amount of discretionary income available to the "baby boomer" demographic segment ages 51 to 69 in 2015 and their desire to retain a youthful appearance, has increased the demand for aesthetic procedures. In 2015, there were approximately 75 million people in the baby boomer category, which is nearly 25%, of the U.S. population.
- ***Broader Range of Safe and Effective Treatments-*** Technical developments, as well as advances in treatable conditions with new product introductions, 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 on physicians, has motivated them to establish or seek to 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 have expanded their practices and are offering aesthetic procedures.

Reductions in Cost per Procedure: Due in part to increased competition in the aesthetic market, the cost per procedure has been reduced in the past few years. This has attracted a broader base of clients and patients for aesthetic procedures.

Wide Acceptance of Aesthetic Procedures and Increased Focus on Body Image and Appearance- According to an ASAPS survey in 2010, 51% of Americans (including 53% of women and 49% of men) approved of cosmetic surgery, and 67% of Americans responded that they would not be embarrassed if their friends or family knew they had undergone a cosmetic procedure. Broader social acceptance of aesthetic treatments, has also driven the growth in 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 energy-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 energy-based hair removal. The only techniques that provide a long-lasting solution are electrolysis and other energy-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.

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Leg and Facial Veins- Current aesthetic treatment methods for leg and facial veins include sclerotherapy and laser and other energy-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 approximately 321,000 sclerotherapy procedures were performed in 2013.

Tattoo removal- The only effective way to remove tattoos on the body is to utilize laser systems that deliver very short pulse durations with high peak power intensity in order to break up the ink particles that tattoos are comprised of. According to a Tattoo Incidence Study published in ORC International in June 2015, up to 27% of Americans have one or more tattoos, and that 1 in 4 tattoo bearing American adults have “tattoo regret”. Despite the effectiveness of lasers for tattoo removal, common complaints concerning laser tattoo removal center upon a low rate of complete clearance (sometimes no better than 50% after several treatments) as well as the high number of treatments for satisfactory clearance (often 10 or more treatments spaced 4-8 weeks apart). The latest generation of picosecond pulse duration lasers, pulses in the trillionths of a second, meaningfully improve clearance as well as a reduction in total number of treatments.

Skin Rejuvenation- Skin rejuvenation treatments include a broad range of popular alternatives, including Botox and collagen injections, chemical peels, microdermabrasions, radio frequency treatments and lasers and other energy-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 microdermabrasion, 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 2014, approximately 6.7 million injections of Botulinum Toxin and 2.3 million injections of collagen and other soft-tissue fillers were administered; and 1.25 million chemical peels and 882,000 microdermabrasion procedures were performed.

In radio frequency tissue tightening, energy is applied to heat the dermis of the skin with the goal of shrinking and tightening 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 however resolve over time, and the risk of burning the treatment area.

Laser and other energy-based non-surgical treatments for hair removal, veins, skin rejuvenation and body contouring are discussed in the following section and in the section entitled “Our Applications and Procedures” below.

Laser and Other Energy-Based Aesthetic Treatments

Laser and other energy-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 energy-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. Practitioners 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 energy-based treatments require an appropriate combination of the following four parameters:

Energy Level- the amount of light or radio frequency emitted to heat a target;
Pulse Duration- the time interval over which the energy is delivered;
Spot Size or Electrode Size- the diameter of the energy beam, which affects treatment depth and area; and
Wavelength or Frequency- the position in the electromagnetic spectrum which impacts the absorption and therefore the effective depth of the energy delivered.

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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 *xeo*, *GenesisPlus*, *excel V*, *truSculpt, excel HR* and *enlighten* platforms provide the long-lasting benefits of laser and other energy-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 platforms feature multiple-applications that enable practitioners to perform a variety of aesthetic procedures using a single device. These procedures include hair removal, vascular treatments and skin rejuvenation including the treatment of discoloration, fine lines, and uneven texture. Because practitioners can use our systems for multiple indications, the cost of a unit may be spread across a potentially greater number of patients and procedures and therefore may be more rapidly recovered.

Technology and Design Leadership- We offer innovative laser and other energy-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. 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. *excel V* is a stand-alone laser device that combines a new high power green laser with Cutera's award winning Nd:YAG technology, to provide a system that treats the entire range of cosmetic vascular conditions, without the need for costly consumables. *truSculpt* is a mono-polar radio frequency platform and has a unique electrode design that delivers high-powered energy at 1 MHz for the deep and uniform heating of the subcutaneous tissues at sustained therapeutic temperatures. This system includes real-time skin temperature sensing and a large 40cm^2 surface area for faster treatments over large areas of the body.

Upgradeable Platform- We have designed some of our products to allow our customers to cost-effectively upgrade to our multi-application systems (*solera* and *xeo*), which provide our customers with the option to add additional applications to their existing systems and provides us with a source of incremental 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 (unsightly small veins in the leg); facial veins; and perform skin rejuvenation procedures for discoloration, texture, fine lines, and wrinkles on any type of skin. 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 graphical 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 energy-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 energy-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. We launched *GenesisPlus* in 2010, *excel V* in 2011, *truSculpt* in 2012, the *ProWave LX* and *truSculpt* 16 cm^2 hand pieces in 2013 and *excel HR* and *enlighten* in 2014. Such products will allow us to leverage our existing customer call points and provide us with new customer call points 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. We continue to build brand recognition, add additional products to our international distribution channel, and are focused on enhancing our global distribution network, all of which we expect will increase our revenue.

Increasing Focus on Practitioners with Established Medical Offices- We believe there is growth opportunity in targeting our products to a broad customer base. We believe that our customers' success is largely dependent upon having an existing medical practice, in which our systems provide incremental revenue sources to augment their practice revenue. The success of our *excel V* platform has resulted from strong adoption by core customers in dermatology and plastic and reconstructive surgery.

Leveraging our Installed Base - With the introduction of *excel V*, *truSculpt,* and now *excel HR* and *enlighten,* we are able to effectively offer additional platforms into our existing installed base. In addition, each of these platforms allows for potential future upgrades to offer additional indications or capabilities. We believe this 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 in their practice.

Generating Revenue from Services and Refillable Hand Pieces- Our *Titan* 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.

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Products

Our *CoolGlide*, *xeo*, *solera*, *GenesisPlus*, *excel V*, *truSculpt*, *myQ*, *excel HR* and *enlighten* platforms allow for the delivery of multiple laser and energy-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 currently offered products and each checked box represents the applications that were included in the product in the years noted. In the fourth quarter of 2014, we discontinued the manufacture and sale of the *VariLite* product, but continue to provide services for this product to our existing installed base of customers.

Applications:				**Hair Removal:**	**Vascular Lesions:**	**Skin Rejuvenation**			**Non Invasi Body Conto**
System Platforms:	**Products:**	**Year:**	**Energy Source:**			**Dyschromia:**	**Texture, Lines and Wrinkles:**	**Skin Laxity:**	**Melasma &Tattoo Removal:**
CoolGlide	*CV*	2000	a	x					
	Excel	2001	a	x	x				
	Vantage	2002	a	x	x		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		
		2013	b	x					

	ProWave LX												
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						
GenesisPlus		2010	a						x				
excel V		2011	e			x	x		x				
myQ		2011	e									x	
truSculpt		2012	g										x
excel HR		2014	h	x									
enlighten		2014	e									x	

** Our CE Mark allows us to market the truSculpt in the European Union, Australia and certain other countries outside the U.S. for fat reduction, body shaping and body contouring. In the U.S. we have 510(k) clearance for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as relief of pain, muscle spasms, increase in local circulation, and the temporary improvement in the appearance of cellulite.*

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Energy Source: a. 1064nm Nd:YAG laser; b. flashlamp; c. Infrared laser; d. 2790 nm YSGG laser; e. combined frequency-doubled 532 nm and 1064 nm Nd:YAG laser; f. combined frequency-doubled 532 nm and 940 nm diode laser; g. radio frequency at 1 MHz; h. combined frequency 755 nm Alexandrite laser and 1064 nm Nd:YAG 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 graphical user interface, control system software and high voltage electronics. All *CoolGlide* systems, *GenesisPlus*, *excel V* 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 graphical 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. Our *truSculpt* control console includes a high-powered, mono-polar RF generator at 1MHz capable of delivering up to 300 watts of energy. The truSculpt system dynamically adjusts current, voltage and power during treatment as needed to reach and maintain the appropriate treatment levels.

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. 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.

excel V Hand Piece- The *excel V* system introduced in February 2011 delivers 1064 nm and 532 nm laser energy to the skin for the treatment of vascular and benign pigmented lesion. The *excel V* system supports two hand pieces, both consisting of an energy-delivery component housing an optical fiber and lens. One hand piece includes a sapphire window cooling plate with temperature monitoring. This hand piece offer a spot size range from 1.5 to 12 mm in 0.1 mm increments, and is capable of delivering either the 1064 nm or 532 nm laser energy. The second hand piece does not have a cooling plate and includes a non-contact temperature sensor to monitor the treatment area temperature. In addition, this second hand piece includes dual aiming beams that facilitate consistent treatments by maintaining the correct distance of the hand piece to the skin to ensure that the fixed 8 mm spot size is maintained.

GenesisPlus Hand Piece- Our *GenesisPlus* system launched in 2010 delivers 1064 nm laser energy to the treatment area for the temporary increase of clear nail in patients with onychomycosis and for the treatment of fine wrinkles, diffuse redness and rosacea. This lightweight 1064nm Nd:YAG hand piece consists of an energy-delivery component, housing an optical fiber and lens. The hand piece includes a non-contact temperature sensor to monitor the treatment area temperature. In addition, the hand piece includes dual, coaxial aiming beams that facilitate consistent treatments by maintaining the correct distance of the hand piece to the skin. This hand piece offers a single 5 mm spot size.

Pulsed Light Hand Piece- The *LP560*, *ProWave 770*, *ProWave LX*, *AcuTip 500*, and *LimeLight* hand pieces are designed to produce a pulse of light over a wavelength spectrum to treat discoloration such as age and sun spots and other dyschromia, 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*, *ProWave LX*, 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.

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Titan Hand Piece- The *Titan* hand pieces are designed to produce a sustained pulse of light over a wavelength spectrum tailored to induce heating in the dermis. We are aware that some practitioners use the *Titan* hand piece to treat skin laxity (although the hand piece is cleared in the U.S. 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 U.S. by the FDA only for skin resurfacing and coagulation). This hand piece penetrates the deep dermis producing a series of micro-columns 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.

truSculpt Hand Pieces- The *truSculpt* product introduced in August 2012 is used for the non-invasive heating of subcutaneous tissue. We sold three different *truSculpt* hand pieces in 2013. The original 25cm^2 hand piece (now discontinued), 40 cm^2 for larger body parts and the 16cm^2 for smaller parts of the body. Each of the *truSculpt* hand pieces is light weight and ergonomically designed for operator comfort, which allows for the uniform heat distribution delivered by the hand pieces. In addition, the hand pieces have a built-in, real time, temperature sensing system to

monitor the temperature during the treatment.

excel HR Hand Piece- The dual wavelength *excel HR* system introduced in June 2014 delivers 1064 nm and 755 nm laser energy to the treatment area for hair removal. *excel HR's* single hand piece consists of an energy-delivery component housing an optical fiber and lens. The hand piece features a sapphire window and peripheral cooling plate with temperature monitoring. The sapphire window allows for 30 watts of temperature regulation with user selectable settings ranging from 4 to 20 degrees centigrade and provides cooling of the skin before, during, and immediately after each laser pulse. This "pre, parallel, and post" cooling provides an anesthetic benefit that makes treatments more comfortable than systems without contact cooling, and also increases the safety profile of treatments by reducing the chances of burning skin. The hand piece has a wide spot-size range between 3 to 18 mm (5 to 18 mm, alexandrite mode).

enlighten Hand Piece- The dual wavelength and dual pulse mode *enlighten* system introduced in December 2014 delivers 532 nm and 1064 nm laser energy to treat benign pigmented lesions as well as the removal of multi-color tattoos. *enlighten's* single hand piece consists of an energy-delivery component housing a motorized focus lens assembly connected to an articulated arm. The hand piece features spot size adjustability from 2 to 8mm, adjustable in 1 mm increments. As with all Cutera laser and light-based systems, the hand piece does not require manual power calibration through a separate calibration port. The power calibration is automatic and built into the laser system.

Upgrades

Our *excel V, xeo* and *solera* platforms are multi-application products that are designed to allow our customers to cost-effectively upgrade to our newest technologies, which provide our customers the option to add applications to their system and provides us with a source of additional revenue, which we treat as Product revenue.

Service

We offer post-warranty services to our customers through extended service contracts (that cover preventive maintenance and/or replacement parts and labor), or by direct billing for detachable hand piece replacements, parts and labor. These post-warranty services serve as additional sources of recurring revenue from our installed base.

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Hand Piece Refills

We treat our customer's purchase of replacement *Titan* or *truSculpt* hand pieces as "refill" revenue, which provides us with a source of recurring revenue from existing customers. Following the launch of *truSculpt* product in 2012, we charged customers for hand piece refills, however, beginning in the third quarter of 2013 we now include *truSculpt* refills as part of our standard warranty and service contract product offerings.

Skincare

We distribute ZO Skin Health, Inc.'s ("ZO") physician-dispensed, topical skincare products and through the second quarter of 2014, we also distributed Merz's *Radiesse®* dermal filler product to physicians in the Japanese market.

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 energy-based system.

Hair Removal- Our laser technology allows our customers to treat all skin types and hair thicknesses. Our 1064 nm Nd:YAG and 755 nm Alexandrite lasers 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 and 755 nm Alexandrite hand pieces allows our customers to treat all skin types, while our *ProWave 770* and *ProWave LX* hand pieces, with pulsed light technology, treat the majority of skin types quickly and effectively.

For hair removal treatments, the treatment site on the skin is first cleaned and shaved. The practitioner then applies a thin layer of gel to improve contact and aid gliding of the hand piece across the skin. If using the *CoolGlide* 1064nm Nd:YAG hand piece, the hand piece is applied directly to the skin to cool the area to be treated, then moved and a laser pulse is delivered to the pre-cooled area. To remove hair using the *excel HR, excel V, ProWave 770* and *ProWave LX* hand pieces, 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 light which is converted to heat 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 to 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 *CoolGlide* and *xeo* 1064nm Nd:YAG hand piece's adjustable spot size of 3, 5, 7 or 10 millimeters; the *excel V* 1064 nm and 532 nm hand piece with adjustable spot sizes from 1.5 to 12 mm; and the *excel HR* 1064 nm and 755 nm hand pieces with adjustable spot sizes from 3 mm to 18 mm, 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 *excel V* and *excel HR* hand pieces the cooling can be performed pre, during and post-delivery of the laser pulse. 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 Nd:YAG laser and other energy based technologies allow our customers to perform non-invasive and minimally-invasive treatments that reduce redness, fine lines and wrinkles, improve skin texture, and treat other aesthetic conditions.

Tattoo Removal- Our *enlighten* dual wavelength, dual pulse duration system featuring picosecond technology and our *myQ* Q-switched laser can be used for tattoo removal, for the treatment of benign pigmented lesions, and for laser skin toning.

Texture, Lines and Wrinkles- When using a 1064nm Nd:YAG laser to improve skin texture 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.

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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 micro-columns 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 U.S. for the treatment of wrinkles and deep dermal imperfections. However, in the U.S. we have a 510(k) clearance only for skin resurfacing and coagulation.

Toenail Fungus- In addition to performing skin rejuvenation, our CE Mark allows us to market *GenesisPlus* in the European Union, Australia and certain other countries outside the U.S. for the treatment of onychomycosis (“toenail fungus”). Tiny pulses of light from an Nd:YAG laser pass through the toenail to the fungus underneath, which is irradiated without any damage to the surrounding nail or skin. The *GenesisPlus* has dual aiming beams that facilitate consistent treatments by maintaining the correct distance of the hand piece to the skin. In addition, during the treatment an integrated sensor is used to actively monitor the temperature of the treatment area. In the U.S. we have 510(k) clearance to market *GenesisPlus* for the temporary increase of clear nail in patients with onychomycosis.

Dyschromia- Our pulsed-light technologies allow our customers to safely and effectively treat red and brown dyschromia, which is skin discoloration, benign 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 benign 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.

The 532 nm wavelength green laser option of the *excel V* and *enlighten systems, as well as* the 755 nm infrared wavelength of the *excel HR,* can be used to treat benign pigmented lesions in substantially the same way as described above with the pulsed light devices.

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 U.S. for the treatment of wrinkles through skin tightening. However, in the U.S. we have a 510(k) clearance for only deep dermal heating.

Non-Invasive Body Contouring- our *truSculpt* technology allows physicians to apply a hand piece directly to the skin and deliver high-powered RF energy that results in the deep and uniform heating of the subcutaneous fat tissue at sustained therapeutic temperatures. This heating can cause selective destruction of fat cells, which are eliminated from the treatment area through the body’s natural wound healing processes. The treatment takes approximately 45 minutes and two or more treatments may be required to obtain the desired aesthetic results.

Our CE Mark allows us to market the truSculpt in the European Union, Australia and certain other countries outside the U.S. for fat reduction, body shaping and body contouring. In the U.S. we have 510(k) clearance for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as relief of pain, muscle spasms, increase in local circulation, and the temporary improvement in the appearance of cellulite.

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Sales and Marketing

In the U.S. 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, 2015, we had a U.S. direct sales force of 34 employees. We internally manage our U.S. and Canadian sales organization as one North American sales region with 40 territories as of December 31, 2015.

International sales are generally made through a worldwide distributor network in over 40 countries, as well as a direct international sales force of 32 employees, as of December 31, 2015. As of December 31, 2015, we had direct sales offices in Australia, Belgium, Canada, France, Japan and Switzerland. Our international revenue as a percentage of total revenue represented 48% in 2015, 55% in 2014 and 58% in 2013.

We also sell certain items like *Titan* hand piece refills and marketing brochures through 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. 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, podiatrists 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) skincare products. 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-energy-based treatments, such as electrolysis, Botox and collagen injections, chemical peels, microdermabrasion and sclerotherapy. Our products also compete against laser and other energy-based products offered by public companies, such as Cynosure, Elen (in Italy), Lumenis (acquired by XIO Group in September 2015), Syneron and Zeltiq, as well as private companies, including, Alma, Sciton, and several others.

Competition among providers of laser and other energy-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 energy-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, 2015, our research and development activities were conducted by a staff of 34 employees with a broad base of experience in lasers, optoelectronics, software and other fields. 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 approximately $10.7 million in 2015, $10.7 million in 2014 and $9.2 million in 2013.

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, 2015, we had a 45-person global service department. Internationally, we provide direct service support through our Australia, Belgium, Canada, France, Hong Kong, Japan, Spain and Switzerland offices, and also through the network of distributors and third-party service providers in over 40 countries.

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We provide a standard one-year warranty coverage for all of our systems. 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 year. 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 purchase extended service plans covering replacement parts and labor.

In countries where we are represented by distributor partners, our customers are serviced through the distributor network. Distributors are generally provided 14 months warranty coverage for parts only, with labor being provided to the end customer by the distributor.

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. With respect to the *truSculpt* and other hand pieces, if a customer's system is out of warranty, and they have not purchased an extended service contract that covers hand piece replacements, then the customer is charged for their replacement hand piece.

Our *Titan* hand pieces generally include a warranty for a set number of shots, instead of for a period of time.

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. We had an FDA full quality system audit for three weeks during March 2014. 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 shutdown 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 U.S., 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. In January 2016, we passed our surveillance recertification audit establishing compliance with the most current requirements of EN ISO 13485:2012, CAN/CSA ISO 13485:2003, and MDD 93/42/EEC. 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, 2015, we had 34 issued U.S. patents and 4 pending U.S. patent applications. In the U.S. and several foreign countries, we have registered our Company name and several of our product names as trademarks, including Cutera, *Acutip 500*, *CoolGlide*, *CoolGlide Excel*, *enlighten, Limelight*, *myQ*, *Pearl*, *ProWave 770*, *ProWave LX*, *solera*, *Titan*, *xeo* and *truSculpt*. We may have common law rights in other product names, including *excel V*, *Pearl Fractional*, *solera Titan* and *excel HR.* We intend to file for additional patents and trademarks to continue to strengthen our intellectual property rights.

We licensed certain patents from Palomar (acquired by Cynosure in 2013) and paid ongoing royalties based on sales of applicable hair-removal products. The royalty rate on these products ranged from 3.75% to 7.50% of revenue. The remaining U.S. patents expired in February 2015 and the remaining international patents expired in February 2016. As a result, all our revenue from February 2016 onwards will not be subject to royalties. Our revenue from systems that do not include hair-removal capabilities (such as our *solera Titan*, *xeo SA*, *GenesisPlus*, *myQ, excel V and enlighten*), and other revenue from service contracts, *Titan*, skincare products, were 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 was being amortized on a straight-line basis over their expected useful life of 9-10 years.

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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;
Product sales and distribution; and
Complaint Handling.

FDA's Pre-market Clearance and Approval Requirements

Unless an exemption applies, each medical device we wish to commercially distribute in the U.S. 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.

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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 pseudo folliculitis barbae, commonly referred to as razor bumps, and for the reduction of red pigmentation in scars	June 2002
- treatment of wrinkles	October 2002
- treatment to increase clear nail in patients with onychomycosis	April 2011
- expanded spot size to 5 mm for clear nail in patients with onychomycosis	May 2013
- addition of Alexandrite 755 nm laser wavelength for hair removal, permanent hair reduction and the treatment of vascular and benign pigmented lesions	December 2013
- *enlighten* picosecond and nanosecond 532/1064 nm for the treatment of benign pigmented lesions	August 2014
- *enlighten* picosecond and nanosecond 532/1064 nm for tattoo removal	November 2014
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
***truSculpt* radio frequency ("RF") product** for deep tissue heating for the temporary relief of minor muscle and joint pain and for a temporary improvement in the appearance of cellulite	
- 16cm^2 to 25cm^2 hand pieces for smaller body parts	April 2008
- 16cm^2 to 40cm^2 hand pieces for larger body parts	November 2012
- Product labeling and technology updates for existing clearances	September 2014

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, although 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.

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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.

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The primary regulatory environment in Europe is that of the European Union, which consists of a 28 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 and in March 2006, March 2010, February 2011 and January 2012 we passed ISO 13485 recertification audits. Our most recent recertification audit occurred in January 2015. We passed the audit establishing compliance with the most current requirements of EN ISO 13485:2012, CAN/CSA ISO 13485:2003, and MDD 93/42/EEC.

Employees

As of December 31, 2015, we had 262 employees, compared to 266 employees as of December 31, 2014. Of the 262 employees at December 31, 2015, 103 were in sales and marketing, 56 in manufacturing operations, 45 in technical service, 34 in research and development and 24 in general and administrative. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel. None of our employees are 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 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 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 operate in a rapidly changing economic and technological environment that presents numerous risks, many of which are driven by factors that we cannot control or predict. Our business, financial condition and results of operations may be impacted by a number of factors. In addition to the factors discussed elsewhere in this report, the following risks and uncertainties could materially harm our business, financial condition or results of operations, including causing our actual results to differ materially from those projected in any forward-looking statements. The following list of significant risk factors is not all-inclusive or necessarily in order of importance. Additional risks and uncertainties not presently known to us, or that we currently deem immaterial, also may materially adversely affect us in future periods. You should carefully consider these risks and uncertainties before investing in our securities.

Revenue from the U.S. represents a significant part of our total revenue. In 2015, our U.S. revenue increased by 38%, compared to 2014. Unless our U.S. revenue continues to improve, we could experience a material adverse effect on our total revenue, profitability, employee retention and stock price.

Revenue from the U.S. represented 52% of our total revenue in 2015 compared to 45% in 2014. U.S revenue increased by 38% in 2015, compared to 2014, due to several factors, including:

- In 2014 and in 2015, we continued to expand our North American direct sales force, restructured their compensation arrangements, and hired new sales management experienced in the medical equipment industry.
- Historically, following a new product introduction, we experience revenue growth, compared to the same period in the prior year. We experienced revenue growth from our new *enlighten* and *excel HR* products launched in the fourth and second quarter of 2014, respectively.

There can be no assurance that we will continue to introduce new products each year, or that the new product introductions will translate into increased revenue in the long term in the U.S., or that the new direct sales employees and management hired to replace the departed sales employees will continue to be effective and result in improved sales productivity. Further, if the current economic recovery does not continue, or there is another recession in the U.S., our future revenue would be adversely impacted and we could experience a material adverse effect on total revenue, profitability, employee retention and stock price.

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In over seven years we have only had three profitable quarters and we are unable to predict whether we will return to sustained quarterly profits in the future.

Although we had a profitable fourth quarter in 2009, 2012 and 2015, we have otherwise had net quarterly losses in each quarter since the third quarter of 2008. There is no guarantee that we will be profitable in the future and you should not rely on our operating results for any prior quarterly or annual periods as an indication of our future operating performance. Any predictions about the performance of our operations in the future may not be as accurate as they could be if we had a longer history of profitability.

Revenue growth in our business is driven by several factors and one such factor is new product introductions. While our recently released products in 2014 — *enlighten- Q4'14* and *excel HR- Q2'14* — have resulted in the growth of our revenue over the last seven quarters ended December 31, 2015, sales of our *tru*Sc*ulpt* product introduced in 2012 have not penetrated the market to the degree we had expected.

In an effort to improve our revenue, we have invested in the restructuring and expansion of our global sales force, re-evaluated and changed the structure of their compensation arrangements, hired new senior sales management with prior experience in the aesthetic medical device industry, and increased our marketing and promotional activities. We have also invested heavily in training our new sales employees to sell our products and in marketing efforts to generate additional revenue.

For the full-year 2015, compared to 2014, our revenue increased by $16.6 million but our combined cost of revenue and operating expenses increased by $10.5 million. Our ability to return to sustained profitability depends on the extent to which we can increase revenue and control our costs to be able to leverage our expenses. In addition, we need to be able to counter any unforeseen difficulties, complications, product delays or other unknown factors that may require additional expenditures. Because of the numerous risks and uncertainties associated with our growth prospects, product development, sales and marketing and other efforts, unforeseen litigation expenses, etc., we are unable to predict the extent of our future profitability or losses.

If our revenue does not continue to improve, or we do not achieve adequate growth in the future, or if we are not able to control our costs to leverage our expenses, like we had in the four quarters of 2015, then we may not be able to sustain quarterly profitability or be able to continue to generate cash in our operations in the future.

We rely heavily on our sales professionals to market and sell our products worldwide. If we are unable to hire, effectively train, manage, improve the productivity of, and retain the sales professionals, our business will be harmed, which would impair our future revenue and profitability.

Our success largely depends on our ability to hire, train, manage and improve the productivity levels of our sales professionals worldwide. Because of our focus on the non-core market in the past, several of our sales professionals do not have established relationships with the core market, consisting of dermatologists and plastic surgeons, or where those relationships exist, they are not very strong.

We have experienced direct sales employee and sales management turnover in North America for several reasons. One such reason was a change in sales leadership in 2014. Further, competition for sales professionals who are familiar and trained to sell in the aesthetic equipment market continues to be strong. As a result, we have lost some of our sales people to our competitors. However, we have also hired a record number of new sales people, including several from our competitors. Several of our sales employees and sales management have been recently hired or recently transferred into different roles, and it will take time for them to be fully trained to improve their productivity. In addition, due to the competition for sales professionals in our industry, we have recruited sales professionals from outside the industry. Sales professionals from outside the industry take longer to train and to become familiar with our products and the procedures in which they are used. As a result of a lack of industry knowledge, these sales professionals may take longer to become productive members of our sales force.

Over the past approximately fifteen months, we restructured and have been expanding our North American direct sales force and sales management. We have increased our efforts to hire industry experienced sales professionals but there can be no guarantee that we will be able to retain all of the hired sales professionals or that they will all become productive in a short period of time. Our industry is characterized by a few established companies that compete vigorously for talented sales professionals. Further, as the economy in North America has rebounded from the recent recession, some of those sales professionals have left our company for jobs that they perceive to be better opportunities, both within and outside of the aesthetic industry. We believe that the sales employee turnover, restructuring and expansion of the sales force had a negative impact on our North American productivity in 2014.

We train our existing and recently recruited sales professionals to better understand our existing and new product technologies and how they can be positioned against our competitors' products. These initiatives are intended to improve the productivity of our sales professionals and our revenue and profitability. It takes time for the sales professionals to become productive following their training and there can be no assurance that the recently recruited sales professionals will be adequately trained in a timely manner, or that our direct sales productivity will improve, or that we will not experience significant levels of attrition in the future.

Measures we implement in an effort to recruit, retain, train and manage our sales professionals, strengthen their relationships with core market physicians, and improve their productivity may not be successful and may instead contribute to instability in our operations, additional departures from our sales organization, or further reduce our revenue and harm our business. If we are not able to improve the productivity and retention of our North American and international sales professionals, then our total revenue, profitability and stock price may be adversely impacted.

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If our revenue does not improve, or if our cost of revenue and/or operating expenses increase by a greater percentage than our revenue, our gross margins and operating margins may be adversely impacted, our loss from operations will increase, and our cash used in operating activities will increase, which could reduce our assets and have a material adverse effect on our stock price.

Our gross margin (revenue less cost of revenue) was 57% in 2015, compared to 56% in 2014. Our gross margin is impacted by the revenue that we generate and the costs incurred to generate the revenue. To the extent that our revenue declines, it is difficult to improve our gross margins as our fixed costs must be spread over a lower revenue base. Our future revenue may be adversely affected by a number of factors including the competitive market environment in which we operate, which may result in a decrease in the number of units sold, a decrease in the number of applications per system purchased by customers, a decrease in the average selling prices achieved for our product sales, a shift in our product mix towards products with lower average selling prices, or a shift in our product mix towards products with lower margins.

Our cost of revenue may also be adversely impacted by various factors such as obsolescence of our inventory, impairment of our intangibles, increased expenses associated with the repair of defective products covered by our warranty program, utilization of our relatively fixed manufacturing costs, and a shift in our product mix towards products that have a higher cost of manufacturing.

We have also been investing significant resources in our research and development and sales and marketing activities. We have expanded our global direct sales force, and while the increase in revenue exceeded the increase in sales and marketing expenses in 2015, the productivity of our new sales professionals may not continue to improve and be accretive to our operating income. We plan to continue making such investments in order to bring new products to market and to distribute them effectively. If these investments do not yield increased revenue, our profitability may not improve in the future.

If our revenue does not improve, or if our cost of revenue increases by a greater percentage than our revenue, or if we are not able to reduce expenses in the event of a decline in revenue, we may continue to generate losses from operations and use cash, which could reduce our assets and have a material adverse effect on our operations and stock price.

In February 2016, a lawsuit was filed against us by Kendall Jenner and Kendall Jenner Inc. ("Plaintiffs"), alleging trademark infringement, false endorsement and violation of Jenner's right of publicity. There can be no assurance regarding the potential outcome of this litigation, or its impact upon us, at this time. The expense of defending and resolving this lawsuit may adversely impact our future earnings, cash flows and stock price.

On February 11, 2016, Kendall Jenner and Kendall Jenner Inc. ("Plaintiffs"), filed a lawsuit against the Company in the U.S. District Court, Central District of California, alleging trademark infringement, false endorsement and violation of Jenner's right of publicity. The claims arise out of alleged advertising referring to news articles describing Jenner's blog posting regarding her use of our Laser Genesis treatment for her acne. In their complaint, the Plaintiffs state that they are seeking "at least $10 million" in compensatory damages and reasonable costs and attorney's fees. We are presently investigating the matter and intend to defend the matter vigorously.

While we believe we have meritorious defenses to the claims made, there can be no assurance regarding the potential outcome of this litigation, or its impact upon us, at this time. The expense of defending and resolving this lawsuit may adversely impact our future earnings, cash flows and stock price.

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 body contouring, hair removal, treatment of veins, tattoo removal, and skin rejuvenation, including the treatment of diffuse redness, skin laxity, fine lines, wrinkles, skin texture, pore size and benign pigmented lesions, etc. In the fourth quarter of 2014, we launched *enlighten*, a dual wavelength, dual pulse duration tattoo removal and benign pigmented lesions treatment system featuring picosecond technology. Additionally, in the second quarter of 2014 we launched *excel HR*, a premium hair removal platform for all skin types. To grow in the future, we must continue to develop and/or 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 are 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.

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Historically, product introductions have been a significant component of our financial performance. To be successful in the aesthetics industry, we need to continue to innovate. Our business strategy has therefore been based, in part, on our expectation that we will continue to increase our product offerings. We need to continue to devote substantial research and development resources to make new product introductions, which can be costly and time consuming to our organization.

We also believe that, to increase revenue from sales of new products, 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. 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. If we fail to successfully commercialize new products, our business may 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. We expect that any competitive advantage we may enjoy from current and future innovations 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.

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

- Our ability to develop and market our products to the core market specialties of dermatologists and plastic surgeons;
- 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 higher insurance costs; and
- The lack of credit financing for some of our potential customers.

If we do not achieve anticipated demand for our products, there could be a material adverse effect on our total revenue, profitability, employee retention and stock price.

Macroeconomic political and market conditions, and catastrophic events may adversely affect our business, results of operations, financial condition and stock price.

Our business is influenced by a range of factors that are beyond our control, including:

- General economic and business conditions;
- The overall demand for our products by the core market specialties of dermatologists and plastic surgeons;
- Governmental budgetary constraints or shifts in government spending priorities;
- General political developments;
- Natural disasters; and
- Currency exchange rate fluctuations.

Macroeconomic developments, like the global recession and the financial crisis in the U.S. and certain countries in the European Union during 2007 to 2009, could negatively affect our business, operating results or financial condition which, in turn, could adversely affect our stock price. A general weakening of, and related declining corporate confidence in, the global economy or the curtailment in government or corporate spending could cause current or potential customers to reduce their budgets or be unable to fund product or upgrade application purchases, which could cause customers to delay, decrease or cancel purchases of our products and services or cause customers not to pay us or to delay paying us for previously purchased products and services.

In addition, political unrest in regions like the Middle East, terrorist attacks around the globe and the potential for other hostilities in various parts of the world, potential public health crises and natural disasters continue to contribute to a climate of economic and political uncertainty that could adversely affect our results of operations and financial condition, including our revenue growth and profitability.

Macroeconomic declines, negative political developments, adverse market conditions and catastrophic events may cause a decline in our revenue, negatively affect our operating results, adversely affect our cash flow and could result in a decline in our stock price.

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

While our international revenue in 2015 increased by 8%, compared to 2014, it was negatively impacted by the appreciation of the U.S. Dollar versus the major currencies in which we transact. International revenue is a material component of our business strategy, and represented 48% of our total revenue in 2015, compared to 55% in 2014. 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. For example, our direct business in Japan declined in 2015, negatively impacting our revenue from international operations.

We have experienced significant turnover of our European sales team in the past. While we continue to have a direct sales and service organization in France, Belgium, Spain, Switzerland and the United Kingdom, a significant portion of our European revenue is generated through our network of distributors. Though we continue to evaluate and replace non-performing distributors, and have recently brought greater focus on collaborating with our distributor partners, there can be no assurance given that these initiatives will result in improved European-sourced revenue or profitability in the future.

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. If we are not able to increase or maintain international revenue growth, our total revenue, profitability and stock price may be adversely impacted.

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:

- Fluctuating foreign currency exchange rates;
- Difficulties in staffing and managing our foreign operations;
- Political and economic instability;
- Foreign certification and regulatory requirements;
- Lengthy payment cycles and difficulty in collecting accounts receivable;
- Export restrictions, trade regulations and foreign tax laws;
- Customs clearance and shipping delays;
- 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 are subject to fluctuations in the exchange rate of the U.S. Dollar and foreign currencies.

Foreign currency fluctuations could result in volatility of our 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 and Canadian Dollar. As a result, changes in the exchange rates of these currencies to the U.S. Dollar will affect our results from operations. For example, as a result of the recent strengthening of the U.S. Dollar, relative to many other major currencies, our products priced in U.S. Dollars have become more expensive relative to products of our foreign competitors. In addition, our revenue earned in foreign currencies, such as our locally generated revenue in Japan, has been negatively impacted upon translation into U.S. Dollars. Both these factors had a negative impact on our international revenue in 2015, compared to 2014. Future foreign currency fluctuations could adversely impact and increase the volatility of our revenue, profitability and stock price.

Our ability to effectively compete and generate additional revenue from new and existing products depends upon our ability to distinguish our company and our products from our competitors and their products, and to develop and effectively market new and existing products. Our success is dependent on many factors, including the following:

Speed of new and innovative product development;
Effective strategy and execution of new product launches;
Identification and development of clinical support for new indications of our existing products;
Product performance;