CUTERA INC
Form 10-K
March 18, 2019

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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, 2018

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 that 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, every Interactive Data File required to be submitted 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 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, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

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

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If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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, 2018 (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, 2018, was approximately $418 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 March 1, 2019 was 14,014,511.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates by reference certain information from the registrant's definitive proxy statement for the 2019 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2018.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" that involve risks and uncertainties. Our actual results could differ materially from those discussed in the forward-looking statements. The statements contained in this report that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements are often identified by the use of words such as, but not limited to, "anticipate," "believe," "can," "continue," "could," "estimate," "might," "expect," "intend," "may," "plan," "project," "seek," "should," "strategy," "ta variations of these terms and similar expressions, or the negative of these terms or similar expressions intended to identify forward-looking statements. Forward-looking statements are necessarily based on estimates and assumptions that, while considered reasonable by Cutera and its management based on their knowledge and understanding of the business and industry, are inherently uncertain. Forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section titled "Risk Factors" included under Part I, Item 1A below. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, the Company undertakes no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

The following discussion and analysis should be read in conjunction with and are qualified in their entirety by reference to the discussions included in Item 1A - Risk Factors, Item 7 - Management's Discussion & Analysis of Financial Condition and Results of Operations, and elsewhere in this Annual Report on Form 10-K.

In this Annual Report on Form 10-K, unless the context otherwise requires, references to the "Company," "Cutera," "we," "us" and "our" refers to Cutera, Inc.

PART I

ITEM 1. BUSINESS

In this Annual Report on Form 10-K, "Cutera," "the Company," "we," "us" and "our" refer to Cutera, Inc. and its consolidated subsidiaries. *Cutera*®, *AcuTip*®, *CoolGlide*®, *CoolGlide excel*®, *enlighten*®, *excel HR*®, *excel V*®, *LimeLight*®, *myQ*®,

Pearl®, *PicoGenesis*™, *ProWave 770*, *Solera*®, *Titan*®, *truSculpt*®, *Vantage*® and *xeo*® are trademarks or registered trademarks of the Company.

Company Background

Cutera was formed in 1988 as a Deleware corporation and is a global provider of laser and energy-based aesthetic systems for practitioners worldwide. The Company designs, develops, manufactures, distributes and markets light and energy-based product platforms for use by physicians and other qualified practitioners (collectively, "practitioners"), enabling them to offer safe and effective aesthetic treatments to their customers. In addition, the Company distributes third-party manufactured skincare products. The Company currently offers easy-to-use products based on the following key platforms: *enlighten*, *excel HR*, *truSculpt*, *excel V*, *xeo*, *Juliet™,* and *Secret™ RF*— each of which enables physicians and other qualified practitioners to perform safe and effective aesthetic procedures, including treatment for body contouring, skin resurfacing and revitalization, tattoo removal, removal of benign pigmented lesions, vascular conditions, hair removal, toenail fungus and women's health. The Company's platforms are designed to be easily upgraded to add additional applications and hand pieces, which provide flexibility for the Company's customers as they expand their practices. The Company's ongoing research and development activities primarily focus on developing new products, as well as improving and enhancing the Company's portfolio of existing products. The Company also explores ways to expand the Company's product offerings through alternative arrangements with other companies, such as distribution arrangements. The Company introduced *Juliet*, a product for women's health, in December 2017, *Secret RF*, a fractional RF microneedling device for skin revitalization, in January 2018, *enlighten SR* in April 2018, and *truSculpt iD* in July 2018.

The Company's trademarks include: *"Cutera," "AcuTip," "CoolGlide," "CoolGlide excel," "enlighten," "excel HR," "excel V," "LimeLight," 'myQ," "Pearl," "PicoGenesis," "ProWave 770," "Solera," "Titan," "truSculpt," "Vantage" and "xeo."* The Company's logo and 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 the Company 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.

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A description of each of the Company's 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 platforms is as follows:

truSculpt iD –In July 2018 the Company introduced a hands-free version of our *truSculpt* platform, the *truSculpt iD*, for the non-surgical body sculpting market. It includes consumable cycles that need to be ordered by the practitioner after a set number of treatments are performed, resulting in recurring revenue. This product is a high-powered RF system designed for body contouring, lipolysis and deep tissue heating, and is able to treat all body and skin types. The *truSculpt iD* delivers targeted energy at 2 MHz, causing lipolysis of the subcutaneous adipose tissue. The Company received 510(k) clearance from the United States ("U.S.") Food and Drug Administration ("FDA") for lipolysis of abdominal fat in 2018. It was primarily sold in the U.S. and Canada in 2018 and is planned to be sold to a broader international customer base in 2019. Prior *truSculpt* platforms include the *truSculpt 3D*, a 2 MHZ device for tissue heating and temporary reduction in the abdomen, and the original *truSculpt* platform which was launched in August 2012 and delivered treatments at 1 MHz. In December 2016, the Company received 510(k) clearance from the FDA to market the *truSculpt* platform for the temporary reduction in circumference of the abdomen. The *truSculpt 3D* includes a consumable hand piece that needs to be "refilled" after a set number of treatments are performed, resulting in recurring revenue.

Juliet – In December 2017, the Company introduced the *Juliet* laser for women's intimate health. *Juliet* is a versatile multi-application platform utilizing an Er:YAG laser with the 2940 nm wavelength. This Erbium wavelength produces noticeable results due to its high peak absorption in water. Additionally, *Juliet's* Erbium technology allows for a controlled thermal delivery to tissue, keeping the procedure safe for patients while minimizing downtime. *Juliet* delivers two passes of energy to the target area during treatment. The first pass uses ablation to vaporize the tissue and create micro-channels of injury. The second pass uses coagulation to deliver a thermal injury to the area, which further stimulates the body's normal wound healing process, revitalizing, and remodeling damaged tissue and introducing the formation of new blood vessels. *Juliet* also has a disposable tip, which must be changed for every procedure. As a result, the replacements of the tips results in recurring revenue.

Secret RF – In January 2018, the Company introduced a new fractional radio frequency ("RF") microneedling device that delivers heat into the deeper layers of the skin using controlled RF energy. The targeted energy revitalizes, rebuilds and firms up tissue, effectively remodeling collagen, improving mild wrinkles and diminishing scars while leaving the outer layer of skin intact, minimizing downtime. Each time a procedure is performed, it requires the physician to use a new hand piece tip. The sale of the replacement tip results in recurring revenue.

enlighten – In December 2014, the Company introduced the *enlighten* laser platform with a dual wavelength (1064 nanometer, or "nm" + 532 nm) and in December 2016, we introduced a three wavelength model (1064 nm + 532 nm + 670 nm)*, enlighten III.* The *enlighten* system is a dual pulse duration (750 picosecond, or "ps," and 2 nanosecond, or "ns") laser system and is cleared for multi-colored tattoo removal and for the treatment of benign pigmented lesions and acne scars. In 2018, the Company introduced an expanded performance *enlighten III* and in April 2018, the Company introduced *enlighten SR,* which is a lighter version of *enlighten* with reduced optical performance. Clinical studies were conducted to support an FDA clearance in October 2018 for treatment of acne scars on patients with Fitzpatrick

skin types II-V when used with the Micro Lens Array (MLA) hand piece attachment.

excel HR – In June 2014, the Company introduced the *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.

excel V+ – In March 2019, the Company introduced the *excel V+*, a new iteration of the *excel V* vascular platform originally introduced in 2011. The *excel V+*, a high-performance, vascular and benign pigmented lesion treatment platform designed specifically for the core-market of dermatologists and plastic surgeons. The *excel V+* has 50% higher power than its predecessor and provides greater range of parameters for faster more customizable treatments. The *excel V* and *excel V+* are solid-state laser platforms providing a combination of the 532 nm green laser with 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.

xeo – In 2003, the Company introduced the *xeo* platform, which combines intense pulsed light technology with 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, fine lines and laxity.

In addition to the above mentioned seven primary systems, the Company continues to generate revenue from its legacy products such as *GenesisPlus, CoolGlide*, and the distribution of ZO's skincare products, a third-party product sold in the Japanese market. The Company also generates revenue from the sale of post-warranty services, as well as the sales of *Titan* hand piece refills.

The Company offers its 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.

The Market for Non-Surgical Aesthetic Procedures

The market for non-surgical aesthetic procedures has grown significantly over the past several years. According to data presented at the IMCAS Global Market Summit in February 2019, the medical aesthetic global market has doubled from $6.3 billion to $11 billion from 2014 to 2018, and is projected to reach $15 billion by 2022. The market growth rate for 2018 was 5.1% and a 6.3% growth is estimated in 2019. Body sculpting is expected to grow at a CAGR of 9.7%.

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The Company believes 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 have created increased demand for aesthetic procedures, which in turn has resulted in an expanding practitioner 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 54 to 72 in 2018 and their desire to retain a youthful appearance, contribute to the increased demand for aesthetic procedures.

Broader Range of Safe and Effective Treatments – Technical developments, as well as an increase in treatable conditions due to new product introductions, lead 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 advancements enable practitioners to offer a broader range of treatments. These technical developments reduce treatment and recovery times, which in turn lead to greater patient demand.

Broader Base of Customers – Managed care and government payor reimbursement restrictions motivate physicians 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 core practitioners such as dermatologists and plastic surgeons, many other practitioners, such as gynecologists, family practitioners, primary care physicians, physicians performing aesthetic treatments in non-medical offices, and other qualified practitioners ("non-core practitioners") expand their practices and offer 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 attracts a broader base of customers and patients seeking aesthetic procedures.

Wide Acceptance of Aesthetic Procedures and Increased Focus on Body Image and Appearance – According to the American Society for Aesthetic Plastic Surgery survey in 2016, both surgical and non-surgical procedures increased compared to 1997. Surgical procedures increased by 99%, while non-surgical procedures increased by 650% over this 20-year period.

Non-Surgical Aesthetic Procedures for Improving the Body and/or 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 common aesthetic procedures and their limitations are described below.

Non-Invasive Body Contouring – Treatments for non-invasive body sculpting can be done utilizing a variety of technologies including radio frequency, laser, cooling and ultrasound. Procedures address reduction of unwanted fat on the abdomen, flanks, arms, thighs, submentum and back, and can require one or more treatments. Systems with the ability to induce non-invasive lipolysis (breakdown of fat) offer a more permanent solution with an average fat reduction of greater than 20%. Side effects to this approach may include nodules that typically resolve over time, and the risk of burning the treatment area.

Tattoo removal – The most effective way to remove tattoos on the body is to utilize laser systems that deliver very short pulse durations with high peak power in order to break up the ink particles that comprise tattoos. According to a Tattoo Incidence Study published in ORC International in June 2015, up to 27% of Americans have one or more tattoos, and 1 in 4 tattoo bearing American adults have “tattoo regret”. Despite the effectiveness of lasers for tattoo removal, common complaints concerning laser tattoo removal include 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 four to eight weeks apart). However, the latest generation of tattoo removal lasers produce picosecond pulse durations, (a trillionth of a second) and thereby, can meaningfully improve tattoo clearance and reduce the total number of treatments.

Hair Removal – Techniques for hair removal include waxing, depilatories, tweezing, shaving, electrolysis, laser as well as other energy-based hair removal modalities. The only techniques that provide a long-lasting solution are electrolysis, laser, and other energy-based technology such as an Intense Pulsed Light (“IPL”). 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. In comparison, lasers can quickly treat large areas with a high degree of safety and efficacy.

Skin Revitalization – Skin revitalization treatments include a broad range of popular alternatives, including Botox and collagen injections, chemical peel, microdermabrasion, radio frequency treatment and laser 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.

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Other skin revitalization 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.

Microneedling – (also known as collagen induction therapy) is a minimally invasive revitalization treatment that involves using fine needles to create hundreds of tiny, invisible puncture wounds in the top layer of the skin, which stimulates the body's natural wound healing processes, resulting in cell turnover and increased collagen and elastin production. Our recently introduced *Secret RF* product is a RF fractional microneedling system that helps deliver tailored energy to improve fine lines, wrinkles, and scars from the inside out.

Women's Intimate Health – Lasers and RF technology have emerged as a treatment for issues unique to women's health such as vulvar vaginal atrophy and genitourinary symptoms of menopause. The condition causes vaginal dryness, inflammation and irritation, which can lead to painful or frequent urination. Traditional treatments use estrogen therapy to combat vulvar vaginal atrophy and genitourinary symptoms of menopause to restore vaginal health, but not all women suffering from the symptoms are candidates. Lasers have been shown to ablate the vaginal tissue generating a healing response that may lead to system improvement.

Leg and Facial Veins – Current aesthetic treatment methods for leg and facial veins include sclerotherapy, as well as 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.

Laser and other energy-based non-surgical treatments for hair removal, veins, skin revitalization 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 resulted in a well-established market for these procedures.

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. Ablative skin resurfacing improves 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 improves the appearance of the skin by treating the underlying structure of the skin.

Safe and effective laser and energy-based treatments require an appropriate combination of the 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 the effective depth of the energy delivered.

For example, in the case of hair removal, by utilizing the correct combination of these parameters, a practitioner can use a laser or other light source to selectively target melanin within the hair follicle to absorb the laser energy and destroy the follicle, without damaging other delicate structures in the surrounding tissue.

Technology and Design of the Company's Systems

The Company's *enlighten, excel HR, excel V*, *Juliet, Secret RF, truSculpt, and xeo* platforms provide the long-lasting benefits of laser and other energy-based aesthetic treatments. Our technology allows for a wide variety of applications in a single system. Key features of our solutions include:

Multiple Applications Available in a Single System – Many of 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 revitalization including the treatment of discoloration, fine lines, and uneven texture. Because practitioners can use our systems for multiple indications, the investment in a unit is spread across a greater number of patients and procedures, and the acquisition cost may be more rapidly recovered.

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Technology and Design Leadership – Our innovative laser technology combines multiple wavelengths, 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 not 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.

Upgradeable Platform – Some of our products allow our customers to upgrade their system to our newest technologies or add new applications to their system, each of which provide us with a source of incremental revenue. The Company believes 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 – For hair removal, our products are safe and effective 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 veins on the leg; to treat facial veins; and perform skin revitalization procedures for discoloration, texture, fine lines, and wrinkles on any type of skin. The ability to customize treatment parameters based on skin type enables practitioners to offer safe and effective therapies to a broad base of their patients.

Ease of Use – The Company designs its products to be easy to use. Our proprietary hand pieces are lightweight and ergonomic, minimize user fatigue, and facilitate clear views of the treatment area, reducing the possibility of unintended damage and increasing the speed of application. Our control console contains an intuitive user interface with simple, independently adjustable controls from which to select a wide range of treatment parameters to suit each patient’s profile. For instance, the clinical navigation user interface on the *xeo* platform provides recommended clinical treatment parameter ranges based on patient criteria entered. Our *Pearl* and *Pearl Fractional* hand pieces include a scanner with multiple scan patterns to allow simple and fast treatments of the face. Finally, our *truSculpt iD* embodies the best of many of the above features. Unlike other body sculpting treatments on the market that require certain body types, or pinchable fat, *truSculpt iD* is "body agnostic" with the ability to customize treatments to the patient's needs and body type. In addition, our proprietary algorithms and navigation enable the practitioner to treat a 300cm2 area in only 15 minutes.

Business Strategy

The Company’s goal is to maintain and expand its position as a leading worldwide provider of light and energy-based aesthetic devices and complementary aesthetic products by executing the following strategies:

Continue to Expand our Product Offering – Though the Company believes that its current portfolio of products is comprehensive, our research and development group has a pipeline of potential products under development. The Company launched *excel V* in 2011, *truSculpt* in 2012, *ProWave LX* in 2013, and *excel HR* and *enlighten* in 2014. In addition, the Company continues to expand offerings on the Company's current platforms with further enhancement such as the *enlighten III* launched in 2016, *enlighten SR* launched in April 2018, *truSculpt 3D* launched in 2017 and *truSculpt iD* launched in July 2018. The Company also introduced *Juliet*, a product for women's health, in December 2017, and *Secret RF*, a fractional RF microneedling device for skin revitalization, in January 2018. Just recently, in March 2019, the Company introduced the *excel V+*, an enhanced iteration of our *excel V* vascular platform originally launched in 2011. These products allow the Company to leverage existing customer call points, and create new customer call points.

Increase Revenue and Improve Productivity – The Company believes that the market for aesthetic systems will continue to offer growth opportunities. The Company continues to build brand recognition, add additional products to our international distribution channel, and focus on enhancing the Company's global distribution network, all of which the Company expects will contribute to increased revenue.

Increase Focus on Practitioners with Established Medical Offices – The Company believes there is growth opportunity in targeting our products to a broad customer base. The Company also believes that its customers' success is largely dependent upon having an existing medical practice, in which the Company's systems provide incremental revenue sources to augment their existing practice revenue.

Leverage our Installed Base – With the introduction of *enlighten, excel V*, *excel HR* and *truSculpt,* the Company is able to effectively offer additional platforms into the existing installed base. In addition, each of these platforms allows for potential future upgrades that offer additional capabilities. The Company believes this program aligns our interest in generating revenue with our customers' interest in improving the return on their investment by expanding the range of treatments that can be performed in their practice.

Generate Revenue from Services and Refillable, Consumable, Hand Pieces – The Company's *Titan, truSculpt 3D, truSculpt iD* and pulsed-light hand pieces are refillable products, while our *Juliet* and *Secret RF* tips are consumable products. Each provides us with the opportunity to participate in the procedure based revenue from our existing customers. The Company offers post-warranty services to its 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 revenue.

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Products

The Company's *excel V, excel HR, enlighten, Juliet, Secret RF, truSculpt, xeo*, *CoolGlide*, and *myQ* platforms allow for the delivery of multiple laser and energy-based aesthetic applications from a single system. With our *xeo* platform, practitioners can purchase customized systems with a variety of our multi-technology applications. Each of the Company's products consists of a control console and one or more hand pieces, depending on the model.

The following table lists our currently offered products. Each checked box represents the applications included in the product in the years noted.

Applications:				**Skin Revitalization**						**Noninvasive Body Contouring***	**Women's Health**
System Platforms	**Products**	**Year**	**Energy Source**	**Hair Removal**	**Vascular Lesions**	**BPL's Dyschromia & Melasma**	**Texture, Lines and Wrinkles**	**Acne Scars**	**Tattoo Removal**	**Lipolysis***	**Gynecol**
CoolGlide	*CV*	2000	(a)	x							
	Excel	2001	(a)	x	x						
	Vantage	2002	(a)	x	x		x				
xeo	*Nd:YAG*	2003	(a)	x	x		x				
	ProWave 770	2005	(b)	x							
	AcuTip 500	2005	(b)		x						
	Titan V/XL	2006	(c)								
	LimeLight	2006	(b)		x	x					
	Pearl	2007	(d)			x	x				
	Pearl Fractional	2008	(d)			x	x				
	ProWave LX	2013	(b)	x							
excel V		2011	(e)	x	x	x	x				
myQ		2011	(e)			x			x		
truSculpt		2012	(f)							x	
excel HR		2014	(g)	x	x	x					
enlighten(dual wavelength)		2014	(h)			x			x		

enlighten III (MLA)	2016	(i)		x			x	x				
truSculpt 3D	2017	(f)								x		
Juliet	2018	(j)		x		x						x
Secret RF	2018	(k)				x						
truSculpt iD	2018	(f)								x*		

Energy Sources:

(a) 1064 nm Nd:YAG laser;

(b) Visible and near-infrared Intense Pulsed Light;

(c) Infrared Intense Pulsed Light;

(d) 2790 nm Er:YSGG laser;

(e) Combined frequency-doubled 532 nm and 1064 nm Nd:YAG laser;

(f) Radio frequency at 1 & 2 MHz – mono-polar

(g) Combined 755 nm Alexandrite laser and 1064 nm Nd:YAG laser;

(h) Dual wavelength 532 nm and 1064 nm Nd:YAG picosecond laser;

(i) Three wavelength 532 nm, 670 nm, and 1064 nm Nd:YAG picosecond laser;

(j) 2940 nm Er:YAG laser; and

(k) Radio frequency at 2 MHz mono-polar.

** The Company's CE Mark allows it to market 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. the Company has 510(k) clearance for the reduction in circumference of the abdomen, non-invasive lipolysis (breakdown of fat) of the abdoment and 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.*

Upgrade

The Company's *enlighten, truSculpt,* and *xeo* products, are designed to allow customers to cost-effectively upgrade to our newest technologies or add applications to their system, each of which provide us with a source of additional revenue.

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Service

The Company offers post-warranty service contracts, parts, detachable hand piece replacements (except for *Titan, truSculpt 3D* and *truSculpt iD*) and service labor for the repair and maintenance of products that are out of warranty, all of which are classified as “Service” revenue. These post-warranty services serve as additional sources of recurring revenue from our installed product base.

Hand Piece Refills

The Company treats its customers' purchase of replacement *Titan, truSculpt 3D* and *truSculpt iD* , as well as single use disposable tips applicable to *Juliet* and *Secret RF* as “Consumables” revenue, which provides us with a source of recurring revenue from existing customers. Hand piece refills of our legacy *truSculpt* product are included in the standard warranty and service contract offerings for this product.

Skincare

The Company distributes third party manufactured skincare products ("Skincare” revenue in the Japanese market).

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.

Non-Invasive Body Contouring – Our *truSculpt* technology allows practitioners 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 15 minutes and two or more treatments may be required to obtain the desired aesthetic results. Our CE Mark allows us to market *truSculpt* in the European Union (“EU”), Australia and certain other countries outside the U.S. for fat reduction, body shaping, body contouring and circumferential reduction. In the U.S., *truSculpt* has 510(k) clearance for topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions, such as relief of pain

and muscle spasms and increase in local circulation. Additionally, the 2 MHz setting for the 40 cm2 hand piece is indicated for reduction in circumference of the abdomen and non-invasive lipolysis (breakdown of fat) of the abdomen. The *truSculpt* massage device is intended to provide a temporary reduction in the appearance of cellulite.

Tattoo Removal – Our *enlighten* systems, delivering picosecond and nanosecond pulse duration, and our *myQ* Q-switched laser are used for tattoo removal, the treatment of benign pigmented lesions, and a laser skin toning procedure that the Company refers to as *PicoGenesis*.

Hair Removal – We have two platforms, *excel HR* and *xeo*, which address hair removal for all skin types as well as hair thicknesses. Our *xeo* platform allows practitioners to select between the 1064 nm mode for darker, course hair, and the *ProWave LX* hand piece designed to address finer, vellus hair. Contact cooling is present on both hand pieces for epidermal protection. *excel HR* employs both a 1064 nm Nd:YAG as well as a 755 nm Alexandrite for hair removal. Like the *xeo*, the 1064 nm wavelength addresses darker, course hair while the 755 nm wavelength is used for finer, lighter hair. Both wavelengths are transmitted through the same *CoolView* hand piece with spot sizes up to 20 mm for the 755 nm wavelength and up to 18 mm for the 1064 nm wavelength. The *CoolView* hand piece employs sapphire as a means of contact cooling – epidermal protection. Both platforms are cleared for treating all skin types.

Vascular Lesions – Both our *xeo* as well as *excel V* platforms are capable of treating a wide range of aesthetic vein conditions, including spider and reticular veins, and small facial veins. *xeo* employs the *LimeLight* hand piece for addressing small veins as well as vascular lesions while the Nd:YAG is appropriate for deeper, larger vessels. *LimeLight* is a fixed spot size IPL while the Nd:YAG has adjustable spot sizes up to 10mm. *excel V* is a dual wavelength laser - 1064 nm and 532 nm – with adjustable spot sizes ranging from 2 mm to 12 mm. The 532 nm wavelength can be used to treat over 20 conditions ranging from small veins and vessels to a variety of vascular lesions while the Nd:YAG is appropriate for deeper, larger vessels. For both of these devices, patients receive on average between one and six treatments, with six weeks or longer between treatments.

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Skin Revitalization – Our *xeo*, *excel V*, *excel HR* and enlighten platforms, utilizing an Nd:YAG laser, allow our customers to perform non-invasive and minimally-invasive treatments that reduce redness, dyschromia, fine lines, improve skin texture, and treat other aesthetic conditions. When using a 1064 nm 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 with a spacing of two to four weeks between treatments.

Texture, Lines and Wrinkles – The *xeo* platform can address fine lines and wrinkles using the *Pearl* and *Pearl Fractional* hand pieces. When treating fine lines, texture and wrinkles 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.

Our recently launched *Juliet* laser is a versatile multi-application platform utilizing an Er:YAG laser with the 2940 nm wavelength. This Erbium wavelength produces noticeable results with fewer side effects, due to its high peak absorption in water. Additionally, *Juliet's* Erbium technology allows for a controlled thermal delivery to tissue. The Microspot hand piece delivers fractionated energy to induce skin resurfacing and improved skin quality, tone and texture.

Additionally, our recently launched *Secret RF platform* is a Radio Frequency microneedling device that employs fractionated RF energy (2 MHz) delivered at different pre-programmed depths in the dermis to produce new collagen. The *Secret RF* comes with four treatment tips: a 25-pin tip, both insulated and semi-insulated, and a 64-pin tip, both insulated and semi-insulated. The treatment has minimal side effects, negligible downtime and results in improved skin tone and texture as well as improvement in acne scars.

Dyschromia – Our pulsed-light technologies allow our customers to safely and effectively treat red and brown dyschromia (skin discoloration), benign pigmented lesions, and rosacea. The practitioner delivers a narrow spectrum of light to the surface of the skin through our *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.

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.

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

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

Skin Quality – 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 compromised skin, 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 regrowth. 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.

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Our CE Mark allows us to market the *Titan* in the EU, 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.

Sales and Marketing

In the U.S. the Company markets and sells its products through a direct sales organization. The Company internally manages its U.S. and Canadian sales organization as one North American sales region. As of December 31, 2018, the Company had 68 territories and a direct sales force of 68 employees. In addition, the Company created a new commercial organization in 2018 dedicated to supporting consumable products for procedures performed in physicians' practices. As of December 31, 2018, the Company had nine employees related to consumable sales support.

International sales are made both through a worldwide distributor network in over 40 countries, as well as a direct international sales force. As of December 31, 2018, the Company had a direct sales force in Australia, Belgium, France, Germany, Hong Kong, Japan, Spain, Switzerland and the United Kingdom with a total of 41 direct sales employees.

The Company also sells certain items like hand piece refills, cycle refills, consumable tips and marketing brochures through our web site www.cutera.com.

Customers generally demand quality, performance, ease of use, and high productivity in relation to the cost of ownership. The Company responds to these customer demands by introducing new products focused on these requirements in the markets it serves. Specifically, the Company believes it introduces new products and applications that are innovative, address the specific aesthetic procedures in demand, and are upgradeable on its customers' existing systems. In addition, the Company provides attractive upgrade pricing to new product families. To increase market penetration, the Company also markets to non-core practitioners in addition to our core specialties of plastic surgeons and dermatologists.

The Company seeks to establish strong ongoing relationships with its customers through the upgradeability of the Company's products, sales of extended service contracts, the refilling of hand pieces and replacement of disposable tips, ongoing training and support, and distributing skincare products in Japan. The Company primarily targets its marketing efforts to practitioners through office visits, workshops, trade shows, webinars and trade journals. The Company also markets to potential patients through brochures, workshops and its website. In addition, the Company offers 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

The industry the Company operates in is subject to intense competition. The Company's products compete against conventional non-energy-based treatments, such as electrolysis, Botox and collagen injections, chemical peels, microdermabrasion and sclerotherapy. The products also compete against laser and other energy-based products offered by other public companies, such as Hologic (acquired Cynosure in March 2017), El.En S.p.A, XIO Group (acquired Lumenis in September 2015), Allergan (acquired Zeltiq in April 2017), Bausch Health (Valeant), Vieve, as well as private companies, including Sisram, Syneron Candela (acquired in 2017 by an affiliate of private equity funds advised by Apax Partners), Sciton, InMode, BTL Industries and several others.

Competition among providers of laser and other energy-based devices for the aesthetic market is characterized by extensive research and development efforts, and innovative technology. While the Company attempts to protect its 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 the Company does or product applications for certain sub-markets in which the Company does not participate. Additional competitors may enter the market, and the Company is likely to compete with new companies in the future. To compete effectively, the Company has 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. The Company has encountered, and expects 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

The Company focuses its research and development efforts on innovation and improvement for products and services that align with its mission: the Company consistently strives to understand its customers' expectations for total excellence. The Company accomplishes this by its commitment to continuous improvement in design, manufacturing and service, which the Company believes provides for superior products and services to ensure on going customer satisfaction, trust and loyalty. The Company seeks to comply with all applicable domestic and international regulations to maintain the highest quality.

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As of December 31, 2018, the Company's research and development activities were conducted by a staff of 38 employees with a broad base of experience in lasers, optoelectronics, software, and other related disciplines. The Company develops working relationships with outside contract engineering and design consultants, giving our team additional technical and creative breadth. The Company works closely with thought leaders and customers, to understand unmet needs and emerging applications in aesthetic medicine.

Acquisitions, Investments, and Distribution Agreements

The Company's strategy of providing a broad range of therapeutic capabilities requires a wide variety of technologies, products and capabilities. The rapid pace of technological development in the aesthetic device industry and the specialized expertise required in different areas make it difficult for the Company to develop a broad portfolio of technological solutions. In addition to internally generated growth through research and development efforts, the Company has considered, and expects to continue to consider, acquisitions, investments and distribution agreements to provide access to new products and technologies in both new and existing markets.

The Company expects to further our strategic objectives and strengthen its existing businesses by making future acquisitions, investments, or entering into new distribution agreements in areas that the Company believes it can acquire or stimulate the development of new technologies and products. Mergers and acquisitions of medical technology companies, as well as distribution relationships are inherently risky and no assurance can be given that any acquisition will be successful or will not materially adversely affect the Company's consolidated operations, financial condition and/or cash flows.

Service and Support

The Company's 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. The Company believes that quick and effective delivery of service is important to its customers. As of December 31, 2018, the Company had 65 people in our global service department. Internationally, the Company provides direct service support in Australia, Austria, Belgium, France, Germany, Hong Kong, Japan, Spain, Switzerland and the United Kingdom. Services and support outside of these direct markets are made through a worldwide distributor network in over 40 countries.

The Company offers post-warranty services to its customers through extended service contracts that cover replacement parts and labor for a term of one, two, or three years. The Company also offers services on a time-and-materials basis for detachable hand piece replacements, parts and labor. Customers are notified before their initial warranty expires and are able to purchase extended service plans covering replacement parts and labor.

In countries where the Company is represented by distributor partners, customers are serviced through the distributor. Distributors are generally provided 14 to 16 months warranty coverage for parts only, with labor customarily provided to the end customer by the distributor. The Company's *Titan, truSculpt 3D* and *truSculpt iD* hand pieces generally include a warranty for a set number of shots, instead of for a period of time.

Manufacturing

The Company manufactures its products with components and subassemblies supplied by vendors, and assembles and tests each of its products at the Brisbane, California facility. Quality control, cost reduction and inventory management are top priorities of the manufacturing operations.

The Company purchases certain components, subassemblies and assembled systems from a limited number of suppliers. The Company has flexibility with its suppliers to adjust the number of components and subassemblies as well as the delivery schedules. The forecasts 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. The potential for disruption of supply is reduced 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, the Company has not experienced significant delays in obtaining any of its components or subassemblies. The Company uses small quantities of common cleaning products in its manufacturing operations, which are lawfully disposed of through a normal waste management program. The Company does not forecast any material costs due to compliance with environmental laws or regulations.

The Company is required to manufacture our products in compliance with the FDA's Quality System Regulation ("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. The Company had an FDA full quality system audit in March 2017. There were no significant findings or observations as a result of this audit, however 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 our business. In the event that one of our suppliers fails to maintain compliance with specified quality requirements, the Company may have to qualify a new supplier and could experience manufacturing delays as a result. The Company has 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 EU, the European Free Trade Association and countries which have entered into Mutual Recognition Agreements with the EU. In January 2018, the Company conducted our recertification audit to the requirements of ISO 13485:2003 under the Medical Device Single Audit Program ("MDSAP") for the 5 regulatory jurisdictions signatory to MDSAP (FDA - US, Health Canada - Canada, Therapeutic Goods Administration ("TGA") - Australia, Pharmaceuticals and Medical Devices Agency ("PMDA") - Japan, and Agência Nacional de Vigilancia Sanitária ("ANVISA") - Brazil); and for the EU under Europäische Norm ("EN") International Standards Organization ("ISO") 13485:2012 and Medical Device Directive (MDD") 93/42/EEC. The Company passed the recertification audit establishing compliance with ISO 13485:2003 under MDSAP; EN ISO 13458:2012; and MDD 93/42/EEC. The MDSAP and EU certification can be used to

establish compliance with Good Manufacturing Practices (“GMP”), QSR, and Quality Management System (“QMS”) requirements for all six regulatory jurisdictions, replacing routine audits from each regulatory jurisdiction. Our manufacturing facility is ISO 13485 certified.

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Patents and Proprietary Technology

The Company relies 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 February 28, 2019, the Company had 32 issued U.S. patents and 5 pending U.S. patent applications. The Company intends to file for additional patents and trademarks to continue to strengthen our intellectual property rights. Patents typically have a 20-year term from the application filing date. There can be no assurance that pending patent applications will result in the issuance of patents, that patents issued to or licensed by the Company will not be challenged or circumvented by competitors, or that these patents will be found to be valid or sufficiently broad to protect our technology or to provide the Company with a competitive advantage.

The Company has also obtained certain trademarks and trade names for our products and maintain certain details about our processes, products and strategies as trade secrets. In the U.S. and several foreign countries, the Company registers its Company name and several of its product names as trademarks, including *Cutera*, *AcuTip*, *CoolGlide*, *CoolGlide excel*, *excel*, *enlighten, Juliet, LimeLight*, *myQ*, *Pearl*, *ProWave 770* , *ProWave LX*, *Secret RF, Solera* (discontinued as of January 2018), *Titan*, *truSculpt and xeo*. The Company may have common law rights in other product names, including *excel V*, *Pearl Fractional*, *Solera, Titan* and *excel HR.* The Company intends to file for additional patents and trademarks to continue to strengthen our intellectual property rights.

The Company relies on non-disclosure and non-competition agreements with employees, technical consultants and other parties to protect, in part, trade secrets and other proprietary technology. The Company also requires them to agree to disclose and assign to us all inventions conceived in connection with the relationship. There can be no assurance that these agreements will not be breached, that the Company will have adequate remedies for any breach, that others will not independently develop equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets and proprietary knowledge.

For additional information, please refer to Item 1A. Risk Factors of this Annual Report on Form 10-K, under the section entitled "*Risk Factors - Intellectual property rights may not provide adequate protection for some or all of our products, which may permit third parties to compete against us more effectively, and we may be involved in future costly intellectual property litigation, which could impact our future business and financial performance."*

Government Regulation

United States

The Company's products are medical devices subject to regulation by numerous government agencies, including the FDA and counterpart agencies outside the U.S. To varying degrees, each of these agencies require us to comply with laws and regulations governing the research, development, testing, manufacturing, labeling, pre-market clearance or approval, marketing, distribution, advertising, promotion, record keeping, reporting, tracking, and importing and exporting of medical devices. In the U.S., FDA regulations govern the following activities that the Company performs 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;

record keeping;

pre-market clearance or approval;

advertising and promotion;

production;

product sales and distribution; and

complaint handling.

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FDA's Pre-market Clearance and Approval Requirements

Unless an exemption applies, each medical device the Company wishes to commercially distribute in the U.S. will require either prior 510(k) clearance, de novo 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 more rigorous pre-market approval. All of our current products are class II devices.

510(k) Clearance Pathway

When 510(k) clearance is required, the Company 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 510(k), pre-market notification within 90 days of submission of the application. As a practical matter, clearance often takes significantly longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. Laser devices used for aesthetic procedures, such as hair removal, have generally qualified for clearance under 510(k) procedures.

The following table details the indications for which the Company 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 multi-colored tattoo removal	November 2014
- *enlighten III* picosecond and nanosecond 670 nm wavelength cleared for benign pigmented lesions	November 2016
-*enlighten* picosecond and nanosecond 532/1064 nm higher performance specifications for multi-colored tattoo removal and the treatment of benign pigmented lesions	April 2017
- *enlighten III* picosecond and nanosecond 532/670/1064 nm for multi-colored tattoo removal, adding 670 nm for the treatment of green and blue tattoo inks, and the treatment of benign pigmented lesions with higher performance specifications	October 2017
- *enlighten* Micro Lens Array (MLA) for treatment of acne scars	December 2018
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 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. Additionally, it is cleared for reduction in circumference of the abdomen and non-invasive lipolysis of the abdomen.	
- 16cm2 to 25cm2 hand pieces for smaller body parts	April 2008
- 16cm2 to 40cm2 hand pieces for larger body parts	November 2012
- Product labeling and technology updates for existing clearances	September 2014
- Temporary reduction in circumference of the abdomen	December 2016
-*truSculpt* 2.0: Hands-free treatment powering sequentially six 40 cm2 puck-style applicators	August 2017
-*truSculpt iD*: for non-surgical fat-reduction and circumferential reduction procedures	June 2018

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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 the Company developed to date requires pre-market approval, although development of future devices or clearances may require pre-market approval.

Product Modifications

Pursuant to FDA regulations, 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, requires a new clearance or approval. The FDA requires manufacturers to make this determination initially, but the FDA can review any such decision and may disagree with a manufacturer's determination. To date, the Company has modified aspects of our products after receiving regulatory clearance, and determined that new 510(k) clearances are not required for these modifications. If the FDA disagrees with our determination not to seek a new 510(k) clearance or PMA, the FDA may retroactively require the Company to seek 510(k) clearance or pre-market approval. The FDA could also require the Company 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, the Company 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 ("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 the Company submits and obtains 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.

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.

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The FDA has broad post-market and regulatory enforcement powers. The Company is 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 the Company believes that it is 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.

The Company is 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 and penalties.

The FDA also has the authority to require the Company to repair, replace or refund the cost of any medical device that it has manufactured or distributed. If any of these events were to occur, they could have a material adverse effect on the Company's business.

The Company is 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. The Company believes 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 clearance or approval requirements may be different from those in the U.S.

In Japan, the Company is actively seeking approvals for products to supplement our existing approvals for *enlighten, excel V, excel HR*, *LimeLight*, *ProWave*, *Solera, Titan*, *truSculpt iD* and *xeo*.

In the European Economic Area, or EEA, (which is composed of the 28 Member States of the EU plus Norway, Liechtenstein and Iceland), a single regulatory approval process exists, and conformity with the legal requirements is represented by the CE mark. While it remains somewhat unresolved, the cabinet of the United Kingdom agrees that the UK should maintain conformity with the CE mark process following Brexit. Other countries, such as Switzerland, have entered into Mutual Recognition Agreements and allow the marketing of medical devices that meet EU requirements. The EU 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 to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the EEA 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 EEA, 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, the Company 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, the Company received our ISO 13485:2003 certification and in March 2006, March 2009, and January 2012 we passed ISO 13485 recertification audits. In January 2015, the Company passed a recertification audit establishing compliance with the requirements of EN ISO 13485:2012, CAN/CSA ISO 13485:2003, and MDD 93/42/EEC. In January 2018, the Company conducted our recertification audit to the requirements of ISO 13485:2003 under the Medical Device Single Audit Program (MDSAP) for the 5 regulatory jurisdictions signatory to MDSAP (FDA - US, Health Canada - Canada, TGA - Australia, PMDA - Japan, and ANVISA - Brazil); and for the EU under EN ISO 13485:2012 and MDD 93/42/EEC. The Company passed the recertification audit establishing compliance with ISO 13485:2003 under MDSAP; EN ISO 13458:2012; and MDD

93/42/EEC. In January 2019, the Company passed the upgrade audit establishing compliance with ISO 13485:2016 and the surveillance audit under MDSAP. The MDSAP and EU certification can be used to establish compliance with GMP/QSR/QMS requirements for all six regulatory jurisdictions, replacing routine audits from each regulatory jurisdiction. For cause audits can still occur.

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Applicability of Anti-Corruption Laws and Regulations

The Company's worldwide business is subject to the U.S. Foreign Corrupt Practices Act of 1977 (the "FCPA"), the United Kingdom Bribery Act of 2010 (the "UK Bribery Act") and other anti-corruption laws and regulations applicable in the jurisdictions where the Company operates. The FCPA can be used to prosecute companies in the U.S. for arrangements with physicians, or other parties outside the U.S., if the physician or party is a government official of another country and the arrangement violates the law of that country. The UK Bribery Act prohibits both domestic and international bribery, as well as bribery across both public and private sectors. There are similar laws and regulations applicable to Cutera outside the U.S., all of which are subject to evolving interpretations. For additional information, please refer to Item 1A. Risk Factors of this Annual Report on Form 10-K, under the sections entitled "Risk Factors – the Company's failure to comply with rules relating to bribery, foreign corrupt practices, and privacy and security laws may subject the Company to penalties and adversely impact our reputation and business operations."

Patient Privacy and Security Laws

Various laws worldwide protect the confidentiality of certain patient health and other consumer information, including patient medical records, and restrict the use and disclosure of patient health information by healthcare providers. Privacy standards in Europe and Asia are becoming increasingly strict, enforcement action and financial penalties related to privacy in the EU are growing, and new laws and restrictions are being passed. The management of cross-border transfers of information among and outside of EU member countries is becoming more complex, which may complicate our clinical research and commercial activities, as well as product offerings that involve transmission or use of data. The Company will continue its efforts to comply with those requirements and to adapt our business processes to those standards.

In the U.S., the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology and Clinical Health Act ("HITECH") and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys new general authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts. The Company potentially operates as a business associate to covered entities in a limited number of instances. In those cases, the patient data that the Company receives may include protected health information, as defined under HIPAA. Enforcement actions can be costly and interrupt regular operations of its business. While the Company has not been named in any such actions, if a substantial breach or loss of data from our records were to occur, the Company could become a target of such litigation.

In the EU, Regulation 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data ("General Data Protection Regulation" or "GDPR") came into effect on May 25, 2018. The GDPR replaces Directive 95/46/EC ("Data Protection Directive"). While many of the principles of the GDPR reflect those of the Data Protection Directive, for example in relation to the requirements relating to the privacy, security and transmission of individually identifiable health information, there are a number of changes. In particular: (1) pro-active compliance measures are introduced, such as the requirement to carry out a Privacy Impact Assessment and to appoint a Data Protection Officer where health data is processed on a "large scale;" and (2) the administrative fines that can be levied are significantly increased, the maximum being the higher of €20 million, or 4%, of the total worldwide annual turnover of the group in the previous financial year. While we believe we are compliant with GDPR, the recent implementation of regulation, coupled with the early limited enforcement action make it difficult to assess.

Environmental Health and Safety Laws

The Company is also subject to various environmental health and safety laws and regulations worldwide. Like other medical device companies, our manufacturing and other operations involve the use and transportation of substances regulated under environmental health and safety laws including those related to the transportation of hazardous materials. To the best of our knowledge at this time, the Company does not expect that compliance with environmental protection laws will have a material impact on our consolidated results of operations, financial position or cash flows.

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Employees

As of December 31, 2018, the Company had 402 employees, compared to 367 employees as of December 31, 2017. Of the 402 employees at December 31, 2018, 161 were in sales and marketing, 89 in manufacturing operations, 77 in technical service, 38 in research and development and 37 in general and administrative. The Company believes that its 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 the Company believes its employee relations are good.

Available Information

The Company makes its periodic and current reports, including the Company's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to those reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as well as its charters for the Company's Audit and Compensation Committees and its Code of Ethics, available free of charge, on the Company's website as soon as practicable after such material is electronically filed or furnished with the Securities and Exchange Commission (the "SEC"). The Company's website address is www.cutera.com and the reports are filed under "SEC Filings," on the Company-Investor Relations portion of our website. These reports and other information concerning the Company may be accessed through the SEC's website at www.sec.gov.

ITEM 1A. RISK FACTORS

The Company operates in a rapidly changing economic and technological environment that presents numerous risks, many of which are driven by factors that the Company cannot control or predict. The Company's 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 the Company, or that the Company 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.

The Company's annual and quarterly operating results may fluctuate in the future, which may cause the Company's share price to decline.

The Company’s net sales, expenses and operating results may vary significantly from year to year and quarter to quarter for several reasons, including, without limitation:

the ability of the Company’s sales force to effectively market and promote the Company’s products, and the extent to which those products gain market acceptance;

the inability to meet the Company's debt repayment obligations under the Loan and Security Agreement with Wells Fargo Bank, N.A. (the“Revised Revolving Line of Credit”) due to insufficient cash;

the possibility that cybersecurity breaches, data breaches, and other disruptions could compromise our information or result in the unauthorized disclosure of confidential information;

the existence and timing of any product approvals or changes;

the rate and size of expenditures incurred on the Company’s clinical, manufacturing, sales, marketing and product development efforts;

the Company’s ability to attract and retain personnel;

the availability of key components, materials and contract services, which depends on the Company’s ability to forecast sales, among other things;

investigations of the Company’s business and business-related activities by regulatory or other governmental authorities;

variations in timing and quantity of product orders;

temporary manufacturing interruptions or disruptions;

the timing and success of new product and new market introductions, as well as delays in obtaining domestic or foreign regulatory approvals for such introductions;

increased competition, patent expirations or new technologies or treatments;

impact of the FDA communication letter regarding “vaginal rejuvenation” procedures using energy-based devices on sales of the Company's products;

product recalls or safety alerts;

litigation, including product liability, patent, employment, securities class action, stockholder derivative, general commercial and other lawsuits;

volatility in the global market and worldwide economic conditions;

changes in tax laws, including changes domestically and internationally, or exposure to additional income tax liabilities;

the impact of the new EU privacy regulations (GDPR) on the Company’s resources;

the financial health of our customers and their ability to purchase our products in the current economic environment; and

other unusual or non-operating expenses, such as expenses related to mergers or acquisitions, may cause operating results to vary.

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As a result of any of these factors, the Company's consolidated results of operations may fluctuate significantly, which may in turn cause its share price to fluctuate.

If defects are discovered in the Company's products, the Company may incur additional unforeseen costs, customers may not purchase the Company's product and the Company's reputation may suffer.

The Company's success depends on the quality and reliability of its products. While the Company's subject components are sourced and products manufactured to stringent quality specifications and processes, the Company's products incorporate different components including optical components, and other medical device software, any of which may contain errors or exhibit failures, especially when products are first introduced. In addition, new products or enhancements may contain undetected errors or performance problems that, despite testing, are discovered only after commercial shipment. Because our products are designed to be used to perform complex surgical procedures, due to the serious and costly consequences of product failure, the Company and its customers have an increased sensitivity to such defects. In the past, the Company has voluntarily recalled certain products. Although our products are subject to stringent quality processes and controls, the Company cannot provide assurance that its products will not experience component aging, errors, or performance problems. If the Company experiences product flaws or performance problems, any or all of the following could occur:

- delays in product shipments
- loss of revenue
- delay in market acceptance
- diversion of our resources
- damage to our reputation
- product recalls
- regulatory actions
- increased service or warranty costs or
- product liability claims.

Costs associated with product flaws or performance problems could have a material adverse effect on our business, financial condition, results of operations, or cash flows.

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The success and continuing development of our products depends, in part, upon maintaining strong relationships with physicians and other healthcare professionals.

If the Company fails to maintain our working relationships with physicians and other ancillary healthcare and aesthetic professionals, the Company's products may not be developed and marketed in line with the needs and expectations of the professionals who use and support our products. Physicians assist us as researchers, marketing consultants, product consultants, and public speakers, and the Company relies on these professionals to provide us with considerable knowledge and experience. If the Company is unable to maintain these strong relationships, the development and marketing of our products could suffer, which could have a material adverse effect on our consolidated financial condition and results of operations.

The Company relies heavily on its sales professionals to market and sell its products worldwide. If the Company is unable to hire, effectively train, manage, improve the productivity of, and retain our sales professionals, the Company's business will be harmed, which would impair its future revenue and profitability.

The Company's success largely depends on our ability to hire, train, manage, train, and improve the productivity levels of the Company's sales professionals worldwide. Because of the Company's focus on non-core practitioners in the past, several of its 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 appropriately strong.

Competition for sales professionals who are familiar with, and trained to sell in, the aesthetic equipment market continues to be robust. As a result, the Company occasionally loses our sales people to competitors. The Company's industry is characterized by a few established companies that compete vigorously for talented sales professionals. Some of its sales professionals leave the Company for jobs that they perceive to be better opportunities, both within and outside of the aesthetic industry. For instance, in the second half of 2018, the Company experienced significant turnover of our sales professionals, including several people in key sales leadership positions. Most of these sales professionals went to work for a competitor. We believe the loss of these sales professionals negatively impacted our sales performance in the second half of 2018. The Company believes it has adequate measures in place to protect our proprietary and confidential information when employees leave our Company, however the ability to enforce these measures varies from jurisdiction to jurisdiction and we must make a case-by-case decision regarding legal enforcement action. For instance, covenants not-to-compete are not allowed in many states, and if allowed, difficult to enforce in many jurisdictions. Furthermore, such legal enforcement actions are expensive and we cannot give any assurance that these enforcement actions will be successful.

However, the Company also continues to hire and train new sales people, including several from our competitors. Several of the Company's sales employees and sales management are recently hired or 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, the Company also recruits sales professionals from outside the industry. Sales

professionals from outside the industry typically take longer to train and 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.

The Company trains its 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 newly recruited sales professionals will be adequately trained in a timely manner, or that the Company direct sales productivity will improve, or that the Company will not experience significant levels of attrition in the future.

Measures the Company implements 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 its operations, additional departures from our sales organization, or further reduce our revenue and harm our business. If the Company is not able to improve the productivity and retention of our North American and international sales professionals, then the Company's total revenue, profitability and stock price may be adversely impacted.

The aesthetic equipment market is characterized by rapid innovation. To compete effectively, the Company must develop and/or acquire new products, seek regulatory clearance, market them successfully, and identify new markets for our technology.

The aesthetic light and energy-based treatment system industry is subject to continuous technological development and product innovation. If the Company does not continue to innovate and develop new products and applications, our competitive position will likely deteriorate as other companies successfully design and commercialize new products and applications or enhancements to our current products. The Company created products to apply our technology to body contouring, hair removal, treatment of veins, tattoo removal, and skin revitalization, including the treatment of diffuse redness, skin laxity, fine lines, wrinkles, skin texture, pore size and benign pigmented lesions, etc. For example, the Company introduced *Juliet*, a product for women's intimate health, in December 2017, *Secret RF*, a fractional RF microneedling device for skin revitalization, in January 2018, *enlighten SR* in April 2018, and *truSculpt iD* in July 2018. To grow in the future, the Company 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 the Company's product offerings, the Company must, among other things:

develop or otherwise acquire new products that either add to or significantly improve our current product offerings;

obtain regulatory clearance for these new products;

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 the Company's financial performance. To be successful in the aesthetics industry, the Company believes it needs to continue to innovate. The Company's business strategy is based, in part, on its expectation that the Company will continue to increase or enhance its product offerings. The Company needs to continue to devote substantial research and development resources to make new product introductions, which can be costly and time consuming to its organization.

The Company also believes that, to increase revenue from sales of new products, the Company needs to continue to develop its clinical support, further expand and nurture relationships with industry thought leaders, and increase market awareness of the benefits of its new products. However, even with a significant investment in research and development, the Company may be unable to continue to develop, acquire or effectively launch and market new products and technologies regularly, or at all. If the Company fails to successfully commercialize new products or enhancements, its business may be harmed.

While the Company attempts 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. The Company expects that any competitive advantage the Company may enjoy from current and future innovations may diminish over time as companies successfully respond to our, or create their own, innovations. Consequently, the Company believes that it will have to continuously innovate and improve our products and technology to compete successfully. If the Company is unable to innovate successfully, its products could become obsolete and its revenue could decline as its customers and prospects purchase its competitors' products.

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

inability to develop and market our products to the core market specialties of dermatologists and plastic surgeons;

poor financial performance of market segments that attempt to introduce aesthetic procedures to their businesses;

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

competitive threat from new innovations, product introductions capturing mind and wallet share

reduced patient demand for elective aesthetic procedures;

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

the lack of credit financing, or an increase in the cost of borrowing, for some of our potential customers.

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

The search for a permanent President and Chief Executive Officer ("CEO"), may cause uncertainty regarding the future of the Company's business, impact employee hiring and retention, increase the volatility in our stock price, and adversely impact the Company's revenue, operating results, and financial condition.

On January 4, 2019, James A. Reinstein resigned as President and Chief Executive Officer and a member of the Company's board of directors ("Board"). Since then the Company's current Chief Operating Officer, R. Jason Richey has been acting as Chief Operating Officer and Interim CEO.

The Board is conducting a search for a new President and CEO. The Board's search for a President and CEO, and any related speculation and uncertainty regarding our future business strategy and direction in connection with the search and the appointment of a President and CEO, may cause or result in:

- Disruption of our business or distraction of our employees and management;
- Difficulty recruiting, hiring, motivating and retaining talented and skilled personnel, including a permanent President and CEO;
- Departures of other members of management;
- Increased stock price volatility; and
- Difficulty in establishing, maintaining or negotiating business or strategic relationships or transactions.

If the Company is unable to mitigate these or other potential risks related to the uncertainty caused by the Board's search for and appointment of a President and CEO, it may disrupt the Company's business or adversely impact its revenue, operating results, and financial condition. Further, there can be no assurance that the Company will be able to attract a qualified permanent President and CEO who has the qualifications to lead the Company or that the Company can hire a President and CEO on acceptable terms.

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The Company depends on skilled and experienced personnel to operate its global business effectively. Changes to management or the inability to recruit, hire, train and retain qualified personnel, could harm the Company's ability to successfully manage, develop and expand its business, which would impair the Company's future revenue and profitability.

The Company is highly dependent on the principal members of our management, sales personnel and scientific personnel. For example, in the second half of 2018, the Company experienced significant turnover of our sales professionals, including several people in key sales leadership positions. Most of these sales professionals went to work for a competitor. We believe the loss of these sales professionals negatively impacted our sales performance in the second half of 2018. Additionally, the Company's product development plans depend, in part, on the Company's ability to attract and retain engineers with experience in medical devices. Attracting and retaining qualified personnel will be critical to our success, and competition for qualified personnel is intense. The Company may not be able to attract and retain personnel on acceptable terms given the competition for such personnel among technology and healthcare companies and universities. The loss of any of these persons or the Company's inability to attract, train and retain qualified personnel could harm our business and our ability to compete and become profitable.

Security breaches and other disruptions could compromise our information and impact our business, financial condition or results of operations.

The Company relies on networks, information management software and other technology, or information systems, including the Internet and third-party hosted services, to support a variety of business processes and activities, including procurement and supply chain, manufacturing, distribution, invoicing, order processing and collection of payments. The Company uses information systems to process financial information and results of operations for internal reporting purposes and to comply with regulatory financial reporting, legal and tax requirements. In addition, the Company depends on information systems for digital marketing activities and electronic communications among our locations around the world and between company personnel as well as customers and suppliers. Because information systems are critical to many of our operating activities, our business processes may be impacted by system shutdowns or service disruptions. These disruptions may be caused by failures during routine operations such as system upgrades or user errors, as well as network or hardware failures, malicious or disruptive software, computer hackers, geopolitical events, natural disasters, failures or impairments of telecommunications networks, or other catastrophic events. These events could result in unauthorized disclosure of material confidential information. If our information systems suffer severe damage, disruption or shutdown and the Company business continuity plans do not effectively resolve the issues in a timely manner, we could experience delays in reporting our financial results and we may lose revenue and profits as a result of our inability to timely manufacture, distribute, invoice and collect payments. Misuse, leakage or falsification of information could result in a violation of data privacy laws and regulations and damage our reputation and credibility, and could expose us to liability. The Company may also be required to spend significant financial and other resources to remedy the damage caused by a security breach or to repair or replace networks and information systems. Like most major corporations, the Company's information systems are a target of attacks. As of December 2018, we have not had any disruptions to our information systems that have materially affected our business, financial condition or results of operations. However, there can be no assurance that such disruptions will not have a material adverse effect on us in the future.

Changes in accounting standards and estimates could have a material adverse effect on our results of operations and financial position.

Generally accepted accounting principles and the related authoritative guidance for many aspects of our business, including revenue recognition, inventories, warranties, leases, income taxes and stock-based compensation, are complex and involve subjective judgments. Changes in these rules or changes in the underlying estimates, assumptions or judgments by our management could have a material adverse effect on our results of operations and may retroactively affect previously reported results. For example, recently issued authoritative guidance for lease accounting will result in a significant increase to long-term assets and liabilities given we have a significant number of leases.

The Company's ability to access credit on favorable terms, if necessary, for the funding of our operations and capital projects may be limited due to changes in credit markets.

The Company recently revised its Revolving Credit Facility with Wells Fargo Bank, N.A. The Original Revolving Line of Credit contained financial and other covenants as well as the maintenance of a leverage ratio not to exceed 2.5 to 1.0 and a TTM adjusted EBITDA of not less than $10 million. During the third quarter of 2018, the Company determined that it was in violation of certain financial covenants in the Original Revolving Line of Credit. Upon receipt of this notice, we entered into discussions with Wells Fargo to amend and revise certain terms of the Original Revolving Line of Credit. Following the end of the Company's third quarter, on or about November 2, 2018, it entered into a First Amendment and Waiver to the Loan and Security Agreement with Wells Fargo (the "First Amended Revolving Line of Credit"). The First Amended Revolving Line of Credit provided for an original principal amount of $15 million, with the ability to request an additional $10 million and a waiver of any existing defaults under the Original Revolving Line of Credit as long as the Company is in compliance with the terms of the First Amended Revolving Line of Credit, including revised financial and other covenants as well.

Subsequent to December 2018, the Company again determined that it was in violation of certain financial covenants in the First Amended Revolving Line of Credit. We again entered into discussions with Wells Fargo to amend and revise certain terms of the First Amended Revolving Line of Credit. On or about, March 11, 2019 the Company entered into a Second Amendment and Waiver to the Loan and Security Agreement with Wells Fargo (the "Second Amended Revolving Line of Credit"). The Second Amended Revolving Line of Credit requires the Company to maintain a minimum cash balance of $15 million at Wells Fargo, but removes all other covenants so long as no money is drawn on the line of credit. At such time as the Company elects to draw on the Second Amended Revolving Line of Credit, however, the Company must be in compliance with the various financial covenants or it will not be able to access the credit.

Additionally, although the Company does not currently carry any debt, in the past, the credit markets and the financial services industry have experienced disruption characterized by the bankruptcy, failure, collapse or sale of various financial institutions, increased volatility in securities prices, diminished liquidity and credit availability and

intervention from the U.S. and other governments. Continued concerns about the systemic impact of potential long-term or widespread downturn, energy costs, geopolitical issues, the availability and cost of credit, the global commercial and residential real estate markets and related mortgage markets and reduced consumer confidence have contributed to increased market volatility. The cost and availability of credit has been and may continue to be adversely affected by these conditions. The Company cannot be certain that funding for our capital needs will be available from our existing financial institutions and the credit markets if needed, and if available, to the extent required and on acceptable terms. The Revolving Credit Facility terminates on May 30, 2021 and if the Company cannot renew or refinance this facility or obtain funding when needed, in each case on acceptable terms, such conditions may have an adverse effect on our revenues and results of operations.

The Company's ability to report timely and accurate information could be negatively impacted by its plan to implement a new accounting and enterprise resource planning ("ERP") system.

The Company is in the process of implementing a new accounting and ERP system. The Company has not previously had a comprehensive ERP system and to date has relied on a myriad of non-integrated systems, as well as manual processes. A system implementation of this magnitude entails a significant degree of inherent risk. The key elements of this implementation include the conversion of data from existing systems to the new system and the design of the new system to process and report financial and other transactions in an accurate and complete manner. If these, or other aspects of the implementation are not executed successfully, then its ability to report timely and accurate information could be negatively impacted. Failure to report required information in a timely or accurate fashion could result in financial penalties, fines and other administrative actions. Such events could have a material adverse effect on our total enterprise value and stock price.

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Additionally, the process of implementing a new ERP system is capital intensive and includes the inherent risk of incurring significant additional costs should the time and resource requirements of the implementation be greater than what the Company currently anticipates.

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 macro-economic and business conditions in our key markets of North America, Japan, Asia (excluding Japan), the Middle East, Europe and Australia;

the lack of credit financing, or an increase in the cost of borrowing, for some of our potential customers due to increasing interest rates and lending requirements;

the overall demand for our products by the core market specialties of dermatologists and plastic surgeons;

the timing and success of new product introductions by us or our competitors or any other change in the competitive landscape of the market for non-surgical aesthetic procedures, including consolidation among our competitors;

the level of awareness of aesthetic procedures and the market adoption of our products;

changes in our pricing policies or those of our competitors;

governmental budgetary constraints or shifts in government spending priorities;

general political developments, both domestic and in our foreign markets, including economic and political uncertainty caused by elections;

natural disasters;

tax law changes

currency exchange rate fluctuations; and

any trade restrictions or higher import taxes that may be imposed by foreign countries against products sold internationally by U.S. companies

Macroeconomic developments, like global recessions and financial crises 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.

The price of the Company's common stock has decreased by approximately 60% for the twelve months ended December 31, 2018 and may fluctuate substantially due to several factors, some of which are discussed below. Further, the Company has a relatively limited number of shares of common stock outstanding, a large portion of which is held by a small number of investors, which could result in the increase in volatility of its stock price.

The price of the Company's common stock has decreased by approximately 60% for the twelve months ended December 31, 2018 due in part to the deceleration in total revenue growth and profitability and other factors. As a result of our relatively small public float, our common stock may be less liquid than the stock of companies with broader public ownership. Among other things, trading of a relatively small volume of our common stock may have a greater impact on the trading price for our shares than would be the case if our public float were larger. The public market price of our common stock has in the past fluctuated substantially and, due to the current concentration of stockholders, may continue to do so in the future.

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The market price for our common stock could also be affected by a number of other factors, including:

- the general market conditions unrelated to our operating performance;
- sales of large blocks of our common stock, including sales by our executive officers, directors and our large institutional investors;
- quarterly variations in our, or our competitors', results of operations;
- actual or anticipated changes or fluctuations in our results of operations;
- actual or anticipated changes in analysts' estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' estimates;
- the announcement of new products, service enhancements, distributor relationships or acquisitions by us or our competitors;
- the announcement of the departure of a key employee or executive officer by us or our competitors;
- regulatory developments or delays concerning our, or our competitors' products; and
- the initiation of any litigation by us or against us.

Actual or perceived instability and / or volatility in our stock price could reduce demand from potential buyers of our stock, thereby causing our stock price to either remain depressed or to decline further. In addition, if the market for medical-device company stocks or the stock market in general experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, results of operations or financial condition. The trading price of our common stock might also decline in reaction to events that affect other companies in our industry even if these events do not directly affect us. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Any future securities litigation could result in substantial costs and divert our management's attention and resources from our business. This could have a material adverse effect on our business, results of operations and financial condition.

The Company may fail to meet its publicly announced guidance or other expectations about its business and future operating results, which could cause its stock price to decline.

The Company started providing, and may continue to provide, financial guidance about its business and future operating results. In developing this guidance, the Company's management must make certain assumptions and judgments about its future operating performance, including but not limited to projected hiring of sales professionals, growth of revenue in the aesthetic device market, increase or decrease of its market share, costs of production of its

recently introduced products, and stability of the macro-economic environment in our key markets. Furthermore, analysts and investors may develop and publish their own projections of our business, which may form a consensus about our future performance. The Company's business results may vary significantly from such guidance or that consensus due to a number of factors, many of which are outside of our control, and which could adversely affect its operations and operating results. Furthermore, if the Company makes downward revisions of our previously announced guidance, or if our publicly announced guidance of future operating results fails to meet expectations of securities analysts, investors or other interested parties, the price of our common stock could decline.

To successfully market and sell our products internationally, the Company must address many issues that are unique to the Company's international business. Furthermore, international expansion is a key component of our growth strategy, although our international operations and foreign transactions expose us to additional operational challenges that the Company might not otherwise face.

The Company is focused on international expansion as a key component of our growth strategy and have identified specific areas of opportunity in various international markets. International revenue is a material component of our business strategy, and represented 37% of our total revenue in 2018 compared to 38% of our total revenue in 2017. The Company depends on third-party distributors and a direct sales force to sell its products internationally, and the Company may be unable to increase or maintain its level of international revenue.

The Company has experienced significant turnover of our international sales team in the past. For instance, the Company announced on February 9, 2018, that Miguel Pardos resigned his position as Executive Vice President, International Sales of Cutera, effective on February 28, 2018. Cutera reassigned Mr. Pardos' duties among existing members of the International team. Though the departure did not have an adverse effect on the Company's international sales, it added additional pressure on the existing members. While the Company continues to have a direct sales and service organization in Australia, Japan, France, Belgium, Spain, Germany, Switzerland and the United Kingdom, a significant portion of its international revenue is generated through its network of distributors. Though the Company continues to evaluate and replace non-performing distributors, and has recently brought greater focus on collaborating with its distributor partners, there can be no assurance given that these initiatives will result in improved international revenue or profitability in the future.

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To grow the Company's business, it 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 the Company is not able to increase or maintain international revenue growth, our total revenue, profitability and stock price may be adversely impacted.

Economic and other risks associated with international sales and operations could adversely affect the Company's business.

In 2018, 37% of our total revenue was from customers outside of North America. The Company expects its sales from international operations and export sales to continue to be a significant portion of our revenue. The Company has placed a particular emphasis on increasing its growth and presence in international markets. The Company's international operations and sales are subject, in varying degrees, to risks inherent in doing business outside the U.S. These risks include:

changes in trade protection measures, including embargoes, tariffs and other trade barriers, and import and export regulations and licensing requirements;

instability and uncertainties arising from the global geopolitical environment, such as economic nationalism, populism, protectionism and anti-global sentiment;

changes in tax laws and potential negative consequences from the interpretation, application and enforcement by governmental tax authorities of tax laws and policies;

unanticipated changes in other laws and regulations or in how such provisions are interpreted or administered;

reduced protection for intellectual property rights in some countries and practical difficulties of enforcing intellectual property and contract rights abroad

possibility of unfavorable circumstances arising from host country laws or regulations, including those related to infrastructure and data transmission, security and privacy;

currency exchange rate fluctuations and restrictions on currency repatriation;

difficulties and expenses related to implementing internal control over financial reporting and disclosure controls and procedures;

disruption of sales from labor and political disturbances;

regional safety and security considerations;

increased costs and risks in developing, staffing and simultaneously managing global sales operations as a result of distance as well as language and cultural differences;

increased management, travel, infrastructure and legal compliance costs associated with having multiple international operations;

lengthy payment cycles and difficulty in collecting accounts receivable;

preference for locally-produced products, as well as protectionist laws and business practices that favor local companies; and

outbreak or escalation of insurrection, armed conflict, terrorism or war

Changes in the geopolitical or economic environments in the countries in which the Company operates could have a material adverse effect on our financial condition, results of operations or cash flows. For example, changes in U.S. policy regarding international trade, including import and export regulation and international trade agreements, could also negatively impact our business. In 2018, the U.S. imposed tariffs on certain goods imported from China and certain other countries, which has resulted in retaliatory tariffs by China and other countries. Additional tariffs imposed by the U.S. on a broader range of imports, or further retaliatory trade measures taken by China or other countries in response, could adversely impact our financial condition and results of operations.

The Company’s global operations are required to comply with the U.S. Foreign Corrupt Practices Act of 1977, as amended (“FCPA”), Chinese anti-corruption laws, U.K. Bribery Law, and similar anti-bribery laws in other jurisdictions, and with U.S. and foreign export control, trade embargo and customs laws. If the Company fails to comply with any of these laws, the Company could suffer civil and criminal sanctions.

Additionally, the Company continues to monitor Brexit and its potential impacts on our results of operations and financial condition. Volatility in foreign currencies is expected to continue as the United Kingdom executes its exit from the EU. If the United Kingdom's membership in the EU terminates without an agreement (referred to as a “hard Brexit”), there could be increased costs from re-imposition of tariffs on trade between the United Kingdom and EU, increased transportation costs, shipping delays because of the need for customs inspections and procedures and shortages of certain goods. The United Kingdom will also need to negotiate its own tax and trade treaties with countries all over the world, which could take years to complete and could result in a material impact to our consolidated revenue, earnings and cash flow.

In addition to the general risks that the Company faces outside the U.S., our operations in emerging markets could involve additional uncertainties for us, including risks that governments may impose withholding or other taxes on remittances and other payments to us, or the amount of any such taxes may increase; governments may seek to nationalize our assets; or governments may impose or increase investment barriers or other restrictions affecting our business. In addition, emerging markets pose other uncertainties, including the difficulty of enforcing agreements, challenges collecting receivables, protection of our intellectual property and other assets, pressure on the pricing of our products and services, higher business conduct risks, ability to hire and retain qualified talent and risks of political instability. The Company cannot predict the impact such events might have on our business, financial condition and

results of operations.

In addition, compliance with laws and regulations applicable to our international operations increases our cost of doing business in foreign jurisdictions. The Company may be unable to keep current with changes in foreign government requirements and laws as they change from time to time. Failure to comply with these regulations could have adverse effects on our business. In many foreign countries it is common for others to engage in business practices that are prohibited by our internal policies and procedures or U.S. regulations applicable to us. In addition, although the Company has implemented policies and procedures designed to ensure compliance with these laws and policies, there can be no assurance that all of our employees, contractors, distributors and agents will comply with these laws and policies. Violations of laws or key control policies by our employees, contractors, distributors or agents could result in delays in revenue recognition, financial reporting misstatements, fines, penalties, or the prohibition of the importation or exportation of our offerings and could have a material adverse effect on our business operations and financial results.

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To successfully market and sell third party products internationally, the Company must address many issues that are unique to the related distribution arrangements which could reduce our available cash reserves and negatively impact our profitability.

The Company has entered into distribution arrangements pursuant to which the Company utilizes its sales force and distributors to sell products manufactured by other companies. In Japan, the Company has a non-exclusive right to distribute a Q-switched laser product manufactured by a third party OEM. The Company also has an exclusive agreement with ZO to distribute certain of their proprietary skincare products in Japan. Each of these agreements requires us to purchase annual minimum dollar amounts of their products. Additionally, the Company has entered into distribution arrangements with other companies to promote and sell the *Secret RF* and *Juliet* products.

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Each of these distribution agreements presents its own unique risks and challenges. For example, to sell skincare products the Company needs to invest in creating a sales structure that is experienced in the sale of such products and not in capital equipment. The Company needs to commit resources to train our sales force, obtain regulatory licenses, and develop new marketing materials to promote the sale of these products. In addition, the minimum commitments and other costs of distributing products manufactured by these companies may exceed the incremental revenue that the Company derives from the sale of their products, thereby negatively impacting our profitability and reducing our available cash reserves.

If the Company does not make the minimum purchases required in the distribution contracts, or if the third party manufacturer revokes our distribution rights, the Company could lose the distribution rights of the products, which would adversely affect the Company's future revenue, results of operations, cash flows and its stock price.

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

The Company generally offers credit terms of 30 to 90 days to qualified customers. In addition, from time to time, it offers certain key international distributors, with whom the Company has had an extended period of relationship and payment history, payment terms that are significantly longer than the regular 30 to 90 day terms. This allows such international distributor partners to have its products in stock and provide its products to customers on a timely basis. As of December 31, 2018, one international distributor partner accounted for 3.4% of our outstanding accounts receivable balance.

While the Company believes it has an adequate basis to ensure that it collects its accounts receivable, the Company cannot provide any assurance that the financial position of customers to whom it has provided payment terms will not change adversely before the Company receives payment. In the event that there is a default by any of the customers to whom the Company has provided credit terms, the Company may recognize a bad debt charge in our general and administrative expenses. If this bad debt charge is material, it could negatively affect our future results of operations, cash flows and its stock price.

Additionally, in the event of deterioration of general business conditions or the availability of credit, the financial strength and stability of our customers and potential customers may deteriorate over time, which may cause them to cancel or delay their purchase of its products. In addition, the Company may be subject to increased risk of non-payment of its accounts receivables. The Company may also be adversely affected by bankruptcies or other business failures of our customers and potential customers. A significant delay in the collection of funds or a reduction of funds collected may impact our liquidity or result in bad debts.

The Company's ability to effectively compete and generate additional revenue from new and existing products depends upon the Company's ability to distinguish the Company and its products from the competitors and their products, and to develop and effectively market new and existing products. The Company's 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;
- product pricing;
- quality of customer support;
- development of successful distribution channels, both domestically and internationally; and
- intellectual property protection.

To compete effectively, the Company has to demonstrate that its new and existing products are attractive alternatives to other devices and treatments, by differentiating our products on the basis of such factors as innovation, performance, brand name, service, and price. This is difficult to do, especially in a crowded aesthetic market. Some of the Company's competitors have newer or different products and more established customer relationships than the Company does, which could inhibit our market penetration efforts. For example, the Company has encountered, and expect to continue to encounter, situations where, due to pre-existing relationships, potential customers decided to purchase additional products from our competitors. Potential customers also may need to recoup the cost of products that they have already purchased from our competitors and may decide not to purchase our products, or to delay such purchases. If the Company is unable to increase our market penetration or compete effectively, its revenue and profitability will be adversely impacted.

The Company competes against companies that offer alternative solutions to its products, or have greater resources, a larger installed base of customers and broader product offerings than ours. In addition, increased consolidation in the Company's industry may lead to increased competition. If the Company is not able to effectively compete with these companies, it may harm its business.

The medical technology and aesthetic product markets are highly competitive and dynamic and are characterized by rapid and substantial technology development and product innovations. The Company's products compete against conventional non-energy-based treatments, such as electrolysis, Botox and collagen injections, chemical peels, microdermabrasion and sclerotherapy. The Company's products also compete against laser and other energy-based products offered by public companies. Further, other companies could introduce new products that are in direct competition with our products. Competition with these companies could result in reduced selling prices, reduced profit

margins and loss of market share, any of which would harm our business, financial condition and results of operations.

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Recently, there has been consolidation in the aesthetic industry leading to companies combining their resources, which increases competition and could result in increased downward pressure on our product prices. For example, Allergan acquired Zeltiq in April 2017, Hologic acquired Cynosure in March 2017, XIO Group acquired Lumenis in September 2015, and Valeant acquired Solta in January 2014. These consolidations have created newly-combined entities with greater financial resources, deeper sales channels and greater pricing flexibility than the Company. Rumored or actual consolidation of our partners and competitors could cause uncertainty and disruption to our business and can cause our stock price to fluctuate.

The energy-based aesthetic market faces competition from non-energy-based medical products, such as Botox and collagen injections. Other alternatives to the use of our products include electrolysis, a procedure involving the application of electric current to eliminate hair follicles, and chemical peels. The Company may also face competition from manufacturers of pharmaceutical and other products that have not yet been developed.

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

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

consumer disposable income and access to consumer credit, which as a result of an unstable economy, maybe significantly impacted;

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

the success of the Company's sales and marketing efforts; and

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

If, as a result of these factors, there is not sufficient demand for the procedures performed with our products, practitioner demand for our products could be reduced, which could have a material adverse effect on our business, financial condition, revenue and result of operations.

If the Company fails to comply with applicable regulatory requirements, it could result in enforcement action by the U.S. Food and Drug Administration, federal and state agencies or international regulatory bodies and our commercial operations would be harmed.

The Company's products are medical devices that are subject to extensive regulation in the U.S. by the FDA for manufacturing, labeling, sale, promotion, distribution and shipping.The FDA, state authorities and international regulatory bodies have broad enforcement powers. If the Company fails to comply with any U.S. law or any of the applicable regulatory requirements of the FDA, or federal or state agencies, or one of the international regulatory bodies, it could result in enforcement action by the agencies, which may include any of the following sanctions:

warning letters, fines, injunctions, consent decrees and civil penalties;

repair, replacement, refund, 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.

Federal regulatory reforms and changes occurring at the FDA could adversely affect the Company's ability to sell its products profitably and financial condition.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the clearance or approval, manufacture and marketing of a device. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect the Company's business and our products. Changes in FDA regulations may lengthen the regulatory approval process for medical devices and require additional clinical data to support regulatory clearance for the sale and marketing of our new products. In addition, it may require additional safety monitoring, labeling changes, restrictions on product distribution or use, or other measures after the introduction of our products to market. Either of these changes lengthen the duration to market, increase our costs of doing business, adversely affect the future permitted uses of approved products, or otherwise adversely affect the market for its products.

For instance, on or about July 30, 2018, the FDA issued a public statement and sent letters to a number of companies in the medical aesthetics industry expressing concerns regarding "vaginal revitalization" procedures using energy-based

devices. The Company's *Juliet* device is promoted and used by physicians in procedures that are the subject of the FDA's public warning. However, neither the Company nor its distribution partner were named in the announcement, and neither the Company nor its distribution partner have received a letter from the agency as of the date of this filing. Working with our distribution partner and the FDA, the Company is assessing the potential parameters of an additional study regarding our *Juliet* device to address the concerns highlighted in the FDA's statement. However, there can be no assurances that we will reach an agreement with our distribution partner on the execution details of such a study, or that such a study will be successful in addressing the FDA's safety concerns with our *Juliet* device.

Notwithstanding, the Company saw a significant slowdown in the sales of *Juliet* in the third and fourth quarters of 2018. The Company believes this relates to the safety letter, given the timing. The Company supports any action that helps ensure patient safety going forward. The Company has a robust, multi-functional process that reviews its promotional claims and materials to ensure they are truthful, not misleading, fair and balanced, and supported by sound scientific evidence.

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

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

The FDA enforces the QSR and laser performance standards through periodic unannounced inspections. The Company has had multiple quality system audits by the FDA, our Notified Body, and other foreign regulatory agencies, with the most recent inspection by the FDA occurring in March, 2017. There were no significant findings or observations as a result of this audit. Failure to take satisfactory corrective action in response to an adverse QSR inspection or its failure to comply with applicable laser performance standards could result in enforcement actions, including a public warning letter, a shutdown of our manufacturing operations, a recall of its products, civil or criminal penalties, or other sanctions, such as those described in the preceding paragraph, which would cause its sales and business to suffer.

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The Company is a sponsor of Biomedical Research. As such, the Company is also subject to FDA regulations relating to the design and conduct of clinical trials. The Company are subject to unannounced BIMO audits, with the most recent inspection by FDA occurring over 5 days in August 2016. There were no significant findings and only two observations as a result of this audit. Our responses to these observations were accepted by the FDA. Failure to take satisfactory corrective action in response to an adverse BIMO inspection or our failure to comply with Good Clinical Practices could result in us no longer being able to sponsor Biomedical Research, the reversal of 510(k) clearances previously granted based on the results of clinical trials conducted to gain clinical data to support those 510(k) clearances, or enforcement actions, including a public warning letter, civil or criminal penalties, or other sanctions, such as those described in the preceding paragraph, which would cause our sales and business to suffer.

If the Company modifies one of its FDA-cleared devices, it may need to seek a new clearance, which, if not granted, would prevent the Company from selling its modified products or cause it to redesign its products.

Any modifications to an FDA-cleared device that would significantly affect its safety or effectiveness or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a pre-market approval. The Company may not be able to obtain additional 510(k) clearance or premarket approvals for new products or for modifications to, or additional indications for, its existing products in a timely fashion, or at all. Delays in obtaining future clearance would adversely affect its ability to introduce new or enhanced products in a timely manner, which in turn would harm its revenue and future profitability.

The Company has made modifications to its devices in the past and may make additional modifications in the future that it believes do not or will not require additional clearance or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, the Company may be required to recall and to stop marketing the modified devices, which could harm the Company’s operating results and require it to redesign its products.

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

Sales of the Company’s products outside the U.S. are subject to foreign regulatory requirements that vary widely from country to country. In addition, exports of medical devices from the U.S. are regulated by the FDA. Complying with international regulatory requirements can be an expensive and time-consuming process and approval is not certain. The time required for obtaining clearance or approvals, if required by other countries, may be longer than that required for FDA clearance or approvals, and requirements for such clearances or approvals may significantly differ from FDA requirements. The Company may be unable to obtain or maintain regulatory qualifications, clearances or approvals in other countries. The Company may also incur significant costs in attempting to obtain and in maintaining foreign regulatory approvals or qualifications. If the Company experience delays in receiving necessary qualifications, clearances or approvals to market its products outside the U.S., or if the Company fails to receive those qualifications, clearances or approvals, the Company may be unable to market its products or enhancements in international markets

effectively, or at all, which could have a material adverse effect on our business and growth strategy.

Any defects in the design, material or workmanship of its products may not be discovered prior to shipment to customers, which could materially increase its expenses, adversely impact profitability and harm its business.

The design of the Company's products is complex. To manufacture them successfully, the Company must procure quality components and employ individuals with a significant degree of technical expertise. If the Company's designs are defective, or the material components used in its products are subject to wearing out, or if suppliers fail to deliver components to specification, or if its employees fail to properly assemble, test and package its products, the reliability and performance of its products will be adversely impacted.

If the Company's products contain defects that cannot be repaired easily, inexpensively, or on a timely basis, the Company may experience:

damage to our brand reputation;

loss of customer orders and delay in order fulfillment;

increased costs due to product repair or replacement;

inability to attract new customers;

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

legal action.

The occurrence of any one or more of the foregoing could materially increase expenses, adversely impact profitability and harm our business.