

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
(State or other jurisdiction of
incorporation or organization)

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

3240 Bayshore Blvd.
Brisbane, California 94005
(415) 657-5500
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

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

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period 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 Smaller reporting company Emerging growth company
(Do not check if a smaller reporting 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,” “target,” “will,” “would” or 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 Delaware 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.

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%.

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.

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.

- **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*	Gynecology
<i>CoolGlide</i>	<i>CV</i>	2000	(a)	x							
	<i>Excel</i>	2001	(a)	x	x						
<i>xeo</i>	<i>Vantage</i>	2002	(a)	x	x		x				
	<i>Nd:YAG</i>	2003	(a)	x	x		x				
	<i>ProWave 770</i>	2005	(b)	x							
	<i>AcuTip 500</i>	2005	(b)		x						
	<i>Titan V/XL</i>	2006	(c)								
	<i>LimeLight</i>	2006	(b)		x	x					
	<i>Pearl</i>	2007	(d)			x	x				
	<i>Pearl Fractional</i>	2008	(d)			x	x				
	<i>ProWave LX</i>	2013	(b)	x							
	<i>excel V</i>	2011	(e)	x	x	x	x				
<i>myQ</i>	2011	(e)						x			
<i>truSculpt</i>	2012	(f)								x	
<i>excel HR</i>	2014	(g)	x	x	x						
<i>enlighten</i> (dual wavelength)	2014	(h)				x		x			
<i>enlighten III</i> (MLA)	2016	(i)				x		x			
<i>truSculpt 3D</i>	2017	(f)								x	
<i>Juliet</i>	2018	(j)				x	x				
<i>Secret RF</i>	2018	(k)					x				
<i>truSculpt iD</i>	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 abdomen 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.

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.

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.

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 Vigilância 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.

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.*

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
- <i>enlighten</i> picosecond and nanosecond 532/1064 nm for the treatment of benign pigmented lesions	August 2014
- <i>enlighten</i> picosecond and nanosecond 532/1064 nm for multi-colored tattoo removal	November 2014
- <i>enlighten III</i> picosecond and nanosecond 670 nm wavelength cleared for benign pigmented lesions	November 2016
- <i>enlighten</i> picosecond and nanosecond 532/1064 nm higher performance specifications for multi-colored tattoo removal and the treatment of benign pigmented lesions	April 2017
- <i>enlighten III</i> 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
- <i>enlighten</i> 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 <i>Titan</i> 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 <i>Titan</i> 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
<i>truSculpt</i> 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.	
- 16cm ² to 25cm ² hand pieces for smaller body parts	April 2008
- 16cm ² to 40cm ² hand pieces for larger body parts	November 2012
- Product labeling and technology updates for existing clearances	September 2014
- Temporary reduction in circumference of the abdomen	December 2016
- <i>truSculpt</i> 2.0: Hands-free treatment powering sequentially six 40 cm ² puck-style applicators	August 2017
- <i>truSculpt</i> iD: for non-surgical fat-reduction and circumferential reduction procedures	June 2018

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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 is 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 experiences 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.

Product liability suits could be brought against the Company due to a defective design, material or workmanship or misuse of its products and could result in expensive and time-consuming litigation, payment of substantial damages and an increase in its insurance rates.

If the Company's products are defectively designed, manufactured or labeled, contain defective components or are misused, the Company may become subject to substantial and costly litigation by our customers or their patients. Misusing our products or failing to adhere to operating guidelines could cause significant eye and skin damage, and underlying tissue damage. In addition, if its operating guidelines are found to be inadequate, the Company may be subject to liability. The Company has been involved, and may in the future be involved, in litigation related to the use of its products. Product liability claims could divert management's attention from its core business, be expensive to defend and result in sizable damage awards against the Company. The Company may not have sufficient insurance coverage for all future claims. The Company may not be able to obtain insurance in amounts or scope sufficient to provide the Company with adequate coverage against all potential liabilities. Any product liability claims brought against the Company, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, could harm its reputation in the industry and could reduce product sales. In addition, the Company historically experienced steep increases in its product liability insurance premiums as a percentage of revenue. If its premiums continue to rise, the Company may no longer be able to afford adequate insurance coverage.

The Company is currently involved in litigation that could adversely affect the Company's business and financial results, divert management's attention from our business, and subject the Company to significant liabilities.

As described under "Note 11- Commitments and Contingencies - Contingencies" in our consolidated financial statements included in this Annual Report on Form 10-K, the Company is involved in various litigation, which may adversely affect the Company's financial condition and may require us to devote significant resources to our defense of these claims.

Such litigation involves certain non-compete provisions of an agreement an employee of ours was a party to while employed by a competitor. The competitor alleges causes of action for breach of contract (against the employee) and intentional interference with contractual relations (Cutera). The Company believes the non-compete provisions are unenforceable. The competitor has also threatened to file a complaint against another current employee based in Arizona. As of March 14, 2019, the Company is involved in several lawsuits worldwide, with most of the claims in various federal or state courts throughout the U.S. The complaints generally seek damages and other relief based on theories of breach of express and implied warranties, fraudulent and negligent misrepresentation/concealment, unjust enrichment, and violations of various state consumer protection statutes.

Although the Company is defending these matters vigorously, the Company cannot predict with certainty the outcome or effect of any claim or other litigation matter, and there can be no assurance as to the ultimate outcome of any litigation or proceeding. Litigation may have a material adverse effect on the Company because of potential adverse outcomes, defense costs, the diversion of our management's resources, availability of insurance coverage and other factors.

If customers are not trained and/or our products are used by non-physicians, it could result in product misuse and adverse treatment outcomes, which could harm our reputation, result in product liability litigation, distract management and result in additional costs, all of which could harm our business.

Because the Company does not require training for users of its products, and sell its products at times to non-physicians, there exists an increased potential for misuse of our products, which could harm our reputation and our business. U.S. federal regulations allow us to sell our products to or on the order of "licensed practitioners." The definition of "licensed practitioners" varies from state to state. As a result, our products may be purchased or operated by physicians with varying levels of training, and in many states, by non-physicians, including nurse practitioners, chiropractors and technicians. Outside the U.S., many jurisdictions do not require specific qualifications or training for purchasers or operators of its products. The Company does not supervise the procedures performed with our products, nor does the Company require that direct medical supervision occur—that is determined by state law. The Company and its distributors generally offer but do not require product training to the purchasers or operators of our products. In addition, the Company sometimes sells its systems to companies that rent its systems to third parties and that provide a technician to perform the procedures. The lack of training and the purchase and use of its products by non-physicians may result in product misuse and adverse treatment outcomes, which could harm our reputation and its business, and, in the event these result in product liability litigation, distract management and subject us to liability, including legal expenses.

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

The primary objective of most of our investment activities is to preserve principal. To achieve this objective, the Company invests its excess cash primarily in money market funds and in highly liquid debt instruments of the U.S. government and its agencies and U.S. municipalities, in commercial paper and high grade corporate debt. As of December 31, 2018, our balance in marketable investments was \$9.5 million. The longer the duration of a security, the more susceptible it is to changes in market interest rates and bond yields. As yields increase, those securities with a lower yield-at-cost show a mark-to-market unrealized loss. For example, assuming a hypothetical increase in interest rates of one percentage point, there would not have any adverse impact the Company's earnings. As a result, changes in the market interest rates will affect its future net income (loss).

The Company's manufacturing operations are dependent upon third-party suppliers, making its vulnerable to supply shortages and price fluctuations, which could harm its business.

Many of the components and materials that comprise its products is currently manufactured by a limited number of suppliers. A supply interruption or an increase in demand beyond our current suppliers' capabilities could harm our ability to manufacture our products until a new source of supply is identified and qualified. The Company's reliance on these suppliers subjects us to a number of risks that could harm its business, including:

- interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's variation in a component;
- lack of long-term supply arrangements for key components with our suppliers;
- inability to obtain adequate supply in a timely manner, or on reasonable terms;
- inability to redesign one or more components in our systems in the event that a supplier discontinues manufacturing such components and the Company is unable to source it from other suppliers on reasonable terms;
- difficulty locating and qualifying alternative suppliers for our components in a timely manner;
- production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications; and
- delay in supplier deliveries.

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

Risks related to the reduction or interruption in supply and an inability to develop alternative sources for supply may adversely affect the Company's manufacturing operations and related product sales.

The Company maintains manufacturing operations at its facility in Brisbane, California, and purchase many of the components and raw materials used in manufacturing these products from numerous suppliers in various countries. Any problem affecting a supplier (whether due to external or internal causes) could have a negative impact on us.

In a few limited cases, specific components and raw materials are purchased from primary or main suppliers (or in some cases, a single supplier) for reasons related to quality assurance, cost-effectiveness ratio and availability. While the Company works closely with its suppliers to ensure supply continuity, the Company cannot guarantee that its efforts will always be successful. Moreover, due to strict standards and regulations governing the manufacture and marketing its products, it may not be able to quickly locate new supply sources in response to a supply reduction or interruption, with negative effects on its ability to manufacture its products effectively and in a timely fashion.

The Company's manufacturing is currently conducted at a single site, and the occurrence of a catastrophic disaster or other similar event could cause damage to its facilities and equipment, which might require the Company to cease or curtail operations.

The Company is vulnerable to damage from various types of disasters, including fires, earthquakes, terrorist acts, floods, power losses, communications failures and similar events. If any such disaster were to occur, the Company may not be able to operate our business at our facility in Brisbane, California. Our manufacturing facilities require FDA approval, which could result in significant delays before the Company could manufacture products from a replacement facility. The insurance the Company maintains may not be adequate to cover our losses resulting from disasters or other business interruptions. Therefore, any such catastrophe could seriously harm our business and consolidated results of operations.

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.

The Company relies on patent, copyright, trade secret and trademark laws and confidentiality agreements to protect our technology and products. At December 31, 2018, the Company had 32 issued U.S. patents and 5 pending U.S. patent applications. Some of our components, such as our laser module, electronic control system and high-voltage electronics, are not, and in the future may not be, protected by patents. Additionally, the Company's patent applications may not issue as patents or, if issued, may not issue in a form that will be advantageous to us. Any patents the Company obtains may be challenged, invalidated or legally circumvented by third parties. Consequently, competitors could market products and use manufacturing processes that are substantially similar to, or superior to, ours. The Company may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors, former employees or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and the Company does not know whether the steps it has taken to protect the Company's intellectual property will be effective. Moreover, the laws of many foreign countries will not protect the Company's intellectual property rights to the same extent as the laws of the U.S.

The absence of complete intellectual property protection exposes us to a greater risk of direct competition. Competitors could purchase one of the Company's products and attempt to replicate some or all of the competitive advantages the Company derives from our development efforts, design around our protected technology, or develop their own competitive technologies that fall outside of the Company's intellectual property rights. If the Company's intellectual property is not adequately protected against competitors' products and methods, the Company's competitive position and its business could be adversely affected.

The Company may be involved in future costly intellectual property litigation, which could impact its future business and financial performance.

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

The Company may become involved in litigation not only as a result of alleged infringement of a third party's intellectual property rights but also to protect our own intellectual property. For example, the Company has been involved in litigation to protect the trademark rights associated with its company name or the names of its products. Infringement and other intellectual property claims, with or without merit, can be expensive and time-consuming to litigate, and could divert management's attention from its core business.

The expense and potential unavailability of insurance coverage for the Company's customers could adversely affect its ability to sell its products, and therefore adversely affect its financial condition.

Some of the Company's customers and prospective customers have had difficulty procuring or maintaining liability insurance to cover their operation and use of its products. Medical malpractice carriers are withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, the Company's customers may discontinue using our products and potential customers may opt against purchasing laser-based products due to the cost or inability to procure insurance coverage. The unavailability of insurance coverage for our customers and prospects could adversely affect its ability to sell its products, and that could harm its financial condition.

From time to time the Company may become subject to income tax audits or similar proceedings, and as a result the Company may incur additional costs and expenses or owe additional taxes, interest and penalties that may negatively impact its operating results.

The Company is subject to income taxes in the U.S. and certain foreign jurisdictions where it operates through a subsidiary, including Australia, Belgium, Canada, France, Germany, Hong Kong, Japan, Spain, Switzerland, Italy and the United Kingdom. The Company's determination of its tax liability is subject to review by applicable domestic and foreign tax authorities.

The Company is currently under tax examination in Germany ("Cutera GmbH") for tax years ended December 31, 2011 through 2013 and are uncertain of the potential outcome of this examination. The Company underwent audits for our California sales and use tax returns for the period July 2013 through June 2016, and Canadian goods and services tax and harmonized sales tax returns for the period January 2013 to July 2015. Although these audits resulted in immaterial adjustments, the final timing and resolution of any future tax examinations are subject to significant uncertainty and could result in our having to pay amounts to the applicable tax authority in order to resolve examination of our tax positions. An increase or decrease of tax related to tax examination resolution could result in a change in the Company's income tax accrual and could negatively impact its financial position, results of operations or cash flows.

The Company may be adversely affected by changes in U.S. tax laws, importation taxes and other changes that may be imposed by the current administration.

The Company is subject to taxes in the U.S. and other jurisdictions. Tax rates in these jurisdictions may be subject to significant change due to economic and/or political conditions. A number of other factors may also impact our future effective tax rate including:

- the jurisdictions in which profits are determined to be earned and taxed;
- the resolution of issues arising from tax audits with various tax authorities
- changes in valuation of our deferred tax assets and liabilities;
- increases in expenses not deductible for tax purposes, including write-offs of acquired intangibles and impairment of goodwill in connection with acquisitions;
- changes in availability of tax credits, tax holidays, and tax deductions;
- changes in share-based compensation; and
- changes in tax laws or the interpretation of such tax laws and changes in generally accepted accounting principles.

In the U.S., the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the “Affordable Care Act”), for example, has the potential to significantly impact the pharmaceutical and medical device industries. The Affordable Care Act imposed, among other things, an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the U.S. Due to subsequent legislative amendments the excise tax has been suspended for the period January 1, 2016 to December 31, 2019, and, absent further legislative action, will be reinstated starting January 1, 2020, which may result in a material adverse effect on our financial condition or cash flows.

Any acquisitions that the Company makes could result in operating difficulties, dilution, and other consequences that may adversely impact our business and results of operations.

While the Company from time to time evaluates potential acquisitions of businesses, products and technologies, and anticipates continuing to make these evaluations, the Company has no present understandings, commitments or agreements with respect to any material acquisitions or collaborative projects. The Company may not be able to identify appropriate acquisition candidates or strategic partners, or successfully negotiate, finance or integrate any businesses, products or technologies that the Company acquire.

The Company has limited experience as a team with acquiring companies and products. Furthermore, the integration of any acquisition and management of any collaborative project may divert management’s time and resources from our core business and disrupt the Company’s operations and it may incur significant legal, accounting and banking fees in connection with such a transaction. Acquisitions could diminish our available cash balances for other uses, result in the incurrence of debt, contingent liabilities, or amortization expenses, and restructuring charges. Also, the anticipated benefits or value of its acquisitions or investments may not materialize and could result in an impairment of goodwill and/or purchased long-lived assets.

The Company failure to address these risks or other problems encountered in connection with our past or future acquisitions and investments could cause us to fail to realize the anticipated benefits of such acquisitions or investments, incur unanticipated liabilities, and harm our business and our financial condition or results.

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 its reputation and business operations.

The Company business is subject to regulation and oversight worldwide including:

- the FCPA, which prohibits corporations and individuals from paying, offering to pay or authorizing the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity;
- the UK Bribery Act, which prohibits both domestic and international bribery, as well as bribery across both public and private sectors; and bribery provisions contained in the German Criminal Code, which, pursuant to draft legislation being prepared by the German government, may make the corruption and corruptibility of physicians in private practice and other healthcare professionals a criminal offense;
- Health Insurance Portability and Accountability Act of 1996, as amended by The Health Information Technology for Economic and Clinical Health Act , which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and
- analogous state and foreign law equivalents of each of the above laws, such as state laws that require device companies to comply with the industry’s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The risk of being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of the Company's business activities, including our relationships with practitioners and thought leaders worldwide, some of whom recommend, purchase and/or use our devices, as well as the Company's sales agents and distributors, could be subject to challenge under one or more of such laws. The Company is also exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, independent sales agents and distributors may engage in fraudulent or other illegal activity. While the Company has policies and procedures in place prohibiting such activity, misconduct by these parties could include, among other infractions or violations, intentional, reckless and/or negligent conduct or unauthorized activity that violates FDA regulations, including those laws that require the reporting of true, complete and accurate information to the FDA, manufacturing standards, laws that require the true, complete and accurate reporting of financial information or data or other commercial or regulatory laws or requirements. It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions the Company takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting the Company from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

There are similar laws and regulations applicable to us outside the U.S., all of which are subject to evolving interpretations. Global enforcement of anti-corruption laws, including but not limited to the UK Bribery Act, the Brazil Clean Companies Act, and continued enforcement in the Europe, Middle East and Asia Pacific has increased substantially in recent years, with more frequent voluntary self-disclosures by companies, aggressive investigations and enforcement proceedings by governmental agencies, and assessment of significant fines and penalties against companies and individuals. The Company's operations create the risk of unauthorized payments or offers of payments by one of its employees, consultants, sales agents, or distributors because these parties are not always subject to its control. It is the Company's policy to implement safeguards to discourage these practices; however, its existing safeguards and any future improvements may prove to be less than effective, and its employees, consultants, sales agents, or distributors may engage in conduct for which the Company might be held responsible. Any alleged or actual violations of these regulations may subject us to government scrutiny, severe criminal or civil sanctions and other liabilities, and could negatively affect its business, reputation, operating results, and financial condition.

While the Company believes it has a strong culture of compliance and adequate systems of control, and it seeks continuously to improve its systems of internal controls and to remedy any weaknesses identified, there can be no assurance that the policies and procedures will be followed at all times or will effectively detect and prevent violations of the applicable laws by one or more of its employees, consultants, agents or partners and, as a result, the Company may be subject to penalties and material adverse consequences on its business, financial condition or results of operations.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

The Company occupies 66,000 square feet for its U.S. Corporate office in Brisbane, California, under a lease which extends through January 31, 2023. The original lease expired on December 31, 2017, and the Company entered into a Second Amendment on July 6, 2017 that extended the term of the lease from December 31, 2017 to January 31, 2023. Pursuant to the terms of the Second Amendment to the Lease Agreement, the Company has the option to extend the term of the lease by an additional 60 months. Additionally, the Company also has a one-time option to terminate the amended lease early effective as of December 31, 2020, in return for payment of a termination fee.

In addition, the Company has leased office facilities in certain countries as follows:

<u>Country</u>	<u>Square Footage</u>	<u>Lease termination or Expiration</u>
Japan	Approximately 5,896	Two leases, one of which was originally scheduled to expire in March 2018, but was extended for another three years from March 2018 to March 2021, and the other which expires in December 2019.
France	Approximately 2,239	One lease which expires in October 2021.
Spain	Approximately 3,584	One lease signed effective February 1, 2018, which expires in January 31, 2021.

The Company believes that these facilities are suitable and adequate for its current and future needs for at least the next twelve months.

ITEM 3. LEGAL PROCEEDINGS

From time to time, the Company may be involved in legal and administrative proceedings and claims of various types. For a description of material pending legal and regulatory proceedings and settlements as of December 31, 2018, please see Note 11 to the Company's consolidated financial statements entitled "Commitments and Contingencies," Item 8, included in this Annual Report on Form 10-K.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Stock Exchange Listing

The Company's common stock trades on The NASDAQ Global Select Market under the symbol "CUTR." As of March 1, 2019, the closing sale price of its common stock was \$17.72 per share.

Common Stockholders

The Company had 5 stockholders of record as of March 1, 2019. Since many stockholders choose to hold their shares under the name of their brokerage firm, the Company estimates that the actual number of stockholders was over 4,700 shareholders.

Issuer Purchases of Equity Securities

There were no repurchases of our common stock under the Company's Stock Repurchase Program in 2018.

Sales of Unregistered Securities

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

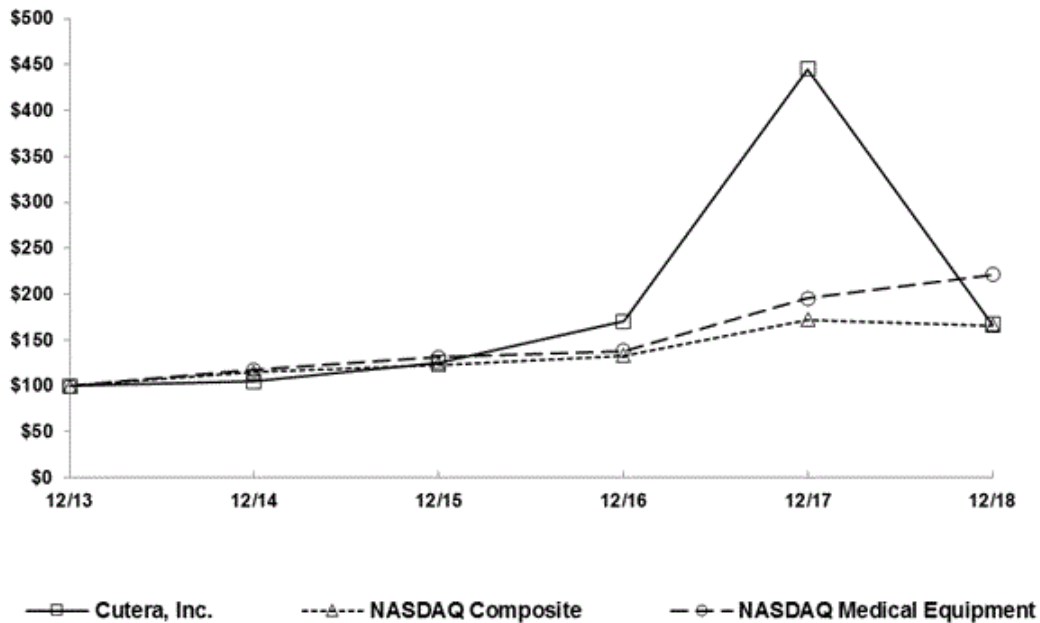
Securities Authorized for Issuance under Equity Compensation Plans

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

Performance Graph

The graph set forth below compares the cumulative total stockholder return on our common stock between December 31, 2013, and December 31, 2018, with the cumulative total return for (1) our common stock, (2) the NASDAQ Composite index and (3) the NASDAQ Medical Equipment Index over the same period. This graph assumes the investment of \$100.00 on December 31, 2013 in our common stock, the NASDAQ Composite Index, and the NASDAQ Medical Equipment Index,

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
Among Cutera, Inc., the NASDAQ Composite Index
and the NASDAQ Medical Equipment Index



*\$100 invested on 12/31/13 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

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

ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with our Consolidated Financial Statements and the accompanying Notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this report. The selected data in this section is not intended to replace the Consolidated Financial Statements.

	Year Ended December 31,				
Consolidated Statements of Operations Data (in thousands, except per share data):	2018	2017	2016	2015	2014
Net revenue	\$ 162,720	\$ 151,493	\$ 118,056	94,761	\$ 78,138
Cost of revenue	82,338	65,383	49,921	40,478	34,765
Gross profit	80,382	86,110	68,135	54,283	43,373
Operating expenses:					
Sales and marketing	58,420	52,070	41,563	35,942	32,246
Research and development	14,359	12,874	11,232	10,733	10,543
General and administrative	20,995	14,090	12,943	12,129	11,203
Lease termination income	--	(4,000)	--	--	--
Total operating expenses	93,774	75,034	65,738	58,804	53,992
Income (loss) from operations	(13,392)	11,076	2,397	(4,521)	(10,619)
Interest and other income, net	(123)	884	323	293	226
Income (loss) before income taxes	(13,515)	11,960	2,720	(4,228)	(10,393)
Income tax (benefit) provision	17,255	(18,033)	143	212	219
Net income (loss)	\$ (30,770)	\$ 29,993	\$ 2,557	\$ (4,440)	\$ (10,612)
Net income (loss) per share:					
Basic	\$ (2.23)	\$ 2.16	\$ 0.19	\$ (0.32)	\$ (0.74)
Diluted	\$ (2.23)	\$ 2.04	\$ 0.19	\$ (0.32)	\$ (0.74)
Weighted-average number of shares used in per share calculations:					
Basic	13,771	13,873	13,225	13,960	14,254
Diluted	13,771	14,728	13,753	13,960	14,254

	As of December 31,				
Consolidated Balance Sheet Data (in thousands):	2018	2017	2016	2015	2014
Cash, cash equivalents and marketable investments	\$ 35,575	\$ 35,912	\$ 54,074	\$ 48,407	\$ 81,146
Working capital (current assets less current liabilities)	39,578	45,063	59,460	49,398	81,900
Total assets	97,637	111,238	91,854	77,518	108,913
Retained earnings (accumulated deficit)	(24,010)	2,947	(27,046)	(29,672)	(25,232)
Total stockholders’ equity	46,386	64,893	61,010	50,034	80,508

* Financial results for year ended December 31, 2018, as compared to the years ended December 31, 2017, 2016, 2015, and 2014 reflect the effects of adopting ASU 2014-09, “Revenue from Contracts with Customers (Topic 606)” and the related amendments (ASC 606), which provided a new basis of accounting for our revenue arrangements during fiscal year 2018. The adoption of ASC 606 limits the comparability of revenue and certain expenses, including revenues and costs and operating expenses, presented in the results of operations for the year ended December 31, 2018 when compared to the years ended December 31, 2017, 2016, 2015, and 2014. For additional information regarding the impact from adoption of this accounting standard, see Note 1, “Revenue Recognition” to the Consolidated Financial Statements set forth in Item 8 of this Annual Report on Form 10-K.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our audited financial statements and notes thereto for the fiscal year ended December 31, 2018. This Annual Report on Form 10-K, including the following sections, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Throughout this Report, and particularly in this Item 7, the forward-looking statements are based upon our current expectations, estimates and projections and that reflect our beliefs and assumptions based upon information available to us at the date of this Report. In some cases, you can identify these statements by words such as "may," "might," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential" or "continue," and other similar terms. These forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties, and assumptions that are difficult to predict. The Company's actual results, performance or achievements could differ materially from those expressed or implied by the forward-looking statements. The forward-looking statements include, but are not limited to, statements relating to our future financial performance, the ability to grow our business, increase our revenue, manage expenses, generate additional cash, achieve and maintain profitability, develop and commercialize existing and new products and applications, improve the performance of our worldwide sales and distribution network, and to the outlook regarding long term prospects. The Company cautions you not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Annual Report on Form 10-K. The Company undertakes no obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Form 10-K.

Some of the important factors that could cause the Company's results to differ materially from those in our forward-looking statements, and a discussion of other risks and uncertainties, are discussed in Item 1A—Risk Factors. The Company encourages you to read that section carefully as well as other risks detailed from time to time in our filings with the SEC.

Introduction

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

- *Executive Summary.* This section provides a general description and history of our business, a brief discussion of our product lines and the opportunities, trends, challenges and risks the Company focuses on in the operation of our business.
- *Critical Accounting Policies and Estimates.* This section describes the key accounting policies that are affected by critical accounting estimates.
- *Recent Accounting Guidance.* This section describes the issuance and effect of new accounting pronouncements that are or may be applicable to us.
- *Results of Operations.* This section provides our analysis and outlook for the significant line items on our Consolidated Statements of Operations.
- *Liquidity and Capital Resources.* This section provides an analysis of our liquidity and cash flows, as well as a discussion of our commitments that existed as of December 31, 2018.

Executive Summary

Company Description

The Company is a leading medical device company specializing in the research, development, manufacture, marketing and servicing of light and other energy based aesthetics systems for practitioners worldwide. In addition to internal development of products, the Company distributes third party sourced products under our own brand names. The Company offers easy-to-use products which enable 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 intimate health. Our platforms are designed to be easily upgraded to add additional applications and hand pieces, which provide flexibility for our customers as they expand their practices. In addition to systems and upgrade revenue, the Company generates revenue from the sale of post warranty service contracts, providing services for products that are out of warranty, hand piece refills and other per procedure related revenue on select systems, and distribution of third-party manufactured skincare products.

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 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.

The Company's corporate headquarters and U.S. operations are located in Brisbane, California, where the Company conducts manufacturing, warehousing, research and development, regulatory, sales and marketing, service, and administrative activities. The Company markets, sells and services the Company's products through direct sales and service employees in North America (including Canada), Australia, Austria, Belgium, France, Germany, Hong Kong, Japan, Spain, Switzerland and the United Kingdom. Sales and Services outside of these direct markets are made through a worldwide distributor network in over 40 countries.

Products and Services

The Company derives revenue from the sale of Products and Services. Product revenue includes revenue from the sale of systems, hand pieces and upgrade of systems (collectively “Systems” revenue), replacement hand pieces, *truSculpt iD* cycle refills, as well as single use disposable tips applicable to *Juliet* and *Secret RF* (“Consumables” revenue), and the sale of skincare products (“Skincare” revenue). A system consists of a console that incorporates a universal graphic user interface, a laser and (or) other energy based module, control system software and high voltage electronics, as well as one or more hand pieces. However, depending on the application, the laser or other energy based module is sometimes contained in the hand piece such as with the Company’s *Pearl* and *Pearl Fractional* applications instead of within the console.

The Company offers customers the ability to select the system that best fits their practice at the time of purchase and then to cost-effectively add applications to their system as their practice grows. This provides customers the flexibility to upgrade their systems whenever they choose and provides us with a source of additional Systems revenue. The Company’s primary system platforms include: *excel*, *enlighten*, *Juliet*, *Secret RF*, *truSculpt* and *xeo*.

Skincare revenue relates to the distribution of ZO’s skincare products in Japan.

Service includes prepaid service contracts, training services, *enlighten* installation, direct billings for detachable hand piece replacements and revenue for parts, customer marketing support and labor on out-of-warranty products.

Significant Business Trends.

The Company believes that the ability to grow revenue will be primarily dependent on the following:

- continuing to expand the Company’s product offerings, both through internal development and sourcing from other vendors;
- ongoing investment in the Company’s global sales and marketing infrastructure;
- use of clinical results to support new aesthetic products and applications;
- enhanced luminary development and reference selling efforts (to develop a location where Company’s products can be displayed and used to assist in selling efforts);
- customer demand for the Company’s products;
- weakening against the U.S. dollar of key international currencies in which the Company transacts (e.g. Australian Dollar, Japanese Yen, Euro, Swiss Franc and British Pound);
- consumer demand for the application of the Company’s products;
- marketing to physicians in the core dermatology and plastic surgeon specialties, as well as outside those specialties; and
- generating recurring revenue from the Company’s growing installed base of customers through the sale of system upgrades, services, hand piece refills, *truSculpt* cycles, skincare products and replacement tips for *Juliet* and *Secret RF* products.

For a detailed discussion of the significant business trends impacting the Company’s business, please see the section titled “Results of Operations” below.

Factors that May Impact Future Performance

The Company’s industry is impacted by numerous competitive, regulatory and other significant factors. The Company’s industry is highly competitive and the Company’s future performance depends on the Company’s ability to compete successfully. Additionally, the Company’s future performance is dependent upon the ability to continue to expand the Company’s product offerings with innovative technologies, obtain regulatory clearances for the Company’s products, protect the proprietary technology of the products and manufacturing processes, manufacture the products cost-effectively, and successfully market and distribute the products in a profitable manner. If the Company fails to execute on the aforementioned initiatives, the Company’s business would be adversely affected.

On 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 rejuvenation” procedures using energy-based devices. The Company was not named in the announcement, and the Company has not received a letter from the agency, however the Company’s *Juliet* device is promoted and used by physicians in procedures that are the subject of the FDA’s public statement. The Company is not aware of any adverse events resulting from the use of *Juliet*, and believes that *Juliet*’s development and promotion is based on science and clinical evidence. Notwithstanding, the Company experienced a significant slowdown in the sale of *Juliet* systems 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.

A detailed discussion of these and other factors that could impact the Company's future performance are provided in (1) the Company's Annual Report on Form 10-K for the year ended December 31, 2017- Part I, Item 1A "Risk Factors." (2) the Company's reports and registration statements filed and furnished from time to time with the SEC, and (3) other announcements the Company makes from time to time.

Critical accounting policies, significant judgments and use of estimates

The preparation of the Company's Consolidated Financial Statements and related disclosures in conformity with generally accepted accounting principles in the U.S. ("GAAP") requires the Company to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses. These estimates, judgments and assumptions are based on historical experience and on various other factors that the Company believes are reasonable under the circumstances. The Company periodically reviews its estimates and make adjustments when facts and circumstances dictate. To the extent that there are material differences between these estimates and actual results, its financial condition or results of operations will be affected.

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

Revenue Recognition

Revenue is recognized upon transfer of control of promised products or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for promised goods or services. The Company's performance obligations are satisfied either over time or at a point in time.

The Company's system sale arrangements generally contain multiple products and services. For these bundled sale arrangements, the Company accounts for individual products and services as separate performance obligations if they are distinct. The Company's products and services are distinct if a customer can benefit from the product or service on its own or with other resources that are readily available to the customer, and if the Company's promise to transfer the products or service to the customer is separately identifiable from other promises in the contract. The Company's system sale arrangements include a combination of the following performance obligations: the system and software license (considered as one performance obligation), system accessories (hand pieces), training, other accessories, extended service contracts and marketing services.

For the Company's system sale arrangements that include an extended service contract, the period of service commences at the expiration of the Company's standard warranty offered at the time of the system sale. The Company considers the extended service contracts terms in the arrangements that are legally enforceable to be performance obligations. Other than extended service contracts and marketing services (which are satisfied over time), the Company generally satisfies all of the performance obligations at a point in time. Systems, system accessories (hand pieces), training, time and materials services are also sold on a stand-alone basis, and related performance obligations are satisfied at a point in time. For contracts with multiple performance obligations, the Company allocates the transaction price of the contract to each performance obligation on a relative standalone selling price basis.

Nature of Products and Services

Systems

System revenue represents the sale of a system or an upgrade of an existing system. A system consists of a console that incorporates a universal graphic user interface, a laser or other energy based module, control system software and high voltage electronics, as well as one or more hand pieces. However, depending on the application, the laser or other energy based module is sometimes contained in the hand piece such as with the Company's *Pearl* and *Pearl Fractional* applications instead of within the console.

The Company offers customers the ability to select the system that best fits their practice at the time of purchase and then to cost-effectively add applications to their system as their practice grows. This provides customers the flexibility to upgrade their systems whenever they choose and provides the Company with a source of additional Systems revenue.

The Company concludes that the system or upgrade and the right to use the embedded software represent a single performance obligation as the software license is integral to the functionality of the system or upgrade.

The Company does not identify calibration and installation services for systems other than *enlighten* as performance obligations because such services are immaterial in the context of the contract. The related costs to complete calibration and installation for systems other than *enlighten* are immaterial. Calibration and installation services for *enlighten* systems are identified as separate performance obligations.

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For systems sold directly to end-customers that are credit approved, revenue is recognized when the Company transfers control to the end-customer, which occurs when the product is shipped to the customer or when the customer receives the product, depending on the nature of the arrangement. The Company recognizes revenue on a cash basis for system sales to international direct end-customer sales that have not been credit approved, as the performance obligations in the contract are satisfied. For systems sold through credit approved distributors, revenue is recognized at the time of shipment.

The Company's system arrangements generally do not provide a right of return. The Company provides a standard one-year warranty coverage for all systems sold to end-customers to cover parts and service, and extended service plans that vary by the type of product and the level of service desired.

The Company typically receives payment for its system consoles and other accessories within 30 days of shipment. Certain international distributor arrangements allow for longer payment terms.

Skincare products

The Company sells third-party manufactured skincare products in Japan. The third-party skincare products are purchased from the third-party manufacturers and sold to licensed physicians. The Company acts as the principal in this arrangement, as it determines the price to charge customers for the skincare products, and controls the products before they are transferred to the customer. Skincare products are typically sold in contracts in which the skincare products represent the sole performance obligations. The Company recognizes revenue for skincare products at a point in time, generally upon shipment.

Consumables (Other accessories)

The Company treats its customers' purchases of replacement *Titan*, *truSculpt 3D* and *truSculpt iD* hand pieces as Consumable revenue, which provides the Company with a source of recurring revenue from existing customers. The Company's recently launched *Juliet* and *Secret RF* products have single use disposable tips which must be replaced after every treatment. Sales of these consumable tips further enhance the Company's recurring revenue. Hand piece refills of the Company's legacy *truSculpt* product are accounted for in accordance with the Company's standard warranty and service contract policies.

Extended contract services

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. These post-warranty services serve as additional sources of recurring revenue from the Company's installed product base. Service contract revenue is recognized over time, using a time based measure of progress, as the customers benefit from the service throughout the service period. Revenue related to services performed on a time-and-materials basis is recognized when performed.

Training

Sales of systems to customers include training on the system to be provided within 90 to 180 days of purchase. The Company considers training as a separate performance obligation as customers can immediately benefit from the training due to the fact that the customer already has the system. Training is also sold separately from systems. The Company recognizes revenue for training when the training is provided. Training is not required for customers to use the systems.

Customer Marketing Support

In North America, the Company offers marketing and consulting phone support to its customers who purchase its *truSculpt 3D* and *truSculpt iD* systems. These customer marketing support services include a practice development model and marketing training, performed remotely with ongoing phone consultations for six months from date of purchase. The Company considers customer marketing support a separate performance obligation, and recognizes revenue over the six-month term of the contracts.

Significant Judgments

More judgments and estimates are required under ASC Topic 606 than were required under the previous revenue recognition guidance, ASC Topic 605. Revenue recognition under ASC Topic 606 for the Company's arrangements may be dependent on contract-specific terms.

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Judgment is required to determine the standalone selling price ("SSP") for each distinct performance obligation. The Company estimates SSPs for each performance obligation as follows:

Systems: The SSPs for systems are based on directly observable sales in similar circumstances to similar customers. When SSP is not directly observable, the Company estimates SSP using the expected cost plus margin approach.

Training: SSP is based on observable price when sold on a standalone basis.

Extended warranty: SSP is based on observable price when sold on a standalone basis (by customer type).

Customer Marketing Support: SSP is estimated based on cost plus a margin.

The Company will combine two or more contracts entered into at or near the same time with the same customer (or related parties of the customer) and account for the contracts as a single contract. If a group of agreements are so closely related that they are, in effect, part of a single arrangement, such agreements are deemed to be one arrangement for revenue recognition purposes. The Company exercises significant judgment to evaluate the relevant facts and circumstances in determining whether the separate agreements should be accounted for separately or as, in substance, a single arrangement. The Company's judgments about whether a group of contracts comprise a single arrangement can affect the allocation of consideration to the distinct performance obligations, which could have an effect on results of operations for the periods involved.

The Company is required to estimate the total consideration expected to be received from contracts with customers. Generally, the Company has not experienced significant returns from or refunds to customers. These estimates require significant judgment and the change in these estimates could have an effect on the Company's results of operations during the periods involved.

Bill and Hold Arrangement

Under the ASC 605 in 2017, the Company segregated certain products for one order at the request of a customer for a limited period of time at a third-party storage facility ("bill -and -hold"). Revenue recognition for the bill-and-hold transaction requires consideration of, among other things, whether the customer has made a written fixed commitment to purchase the product; the existence of a substantial business purpose for the arrangement; the bill-and-hold arrangement is at the request of the customer; the scheduled delivery date must be reasonable and consistent with the buyer's business purpose; title and risk of ownership must pass to the customer and no additional performance obligations exist by the Company, at the time of the bill-and-hold the product is complete and ready for shipment and the product has been segregated from the Company's inventory. The Company recognized revenue of \$938,000 for that bill-and-hold transaction in 2017.

The Company recognized revenue of \$0 and \$938,000 for a bill-and-hold transaction in 2018 and 2017 respectively. There were no such transactions in 2016.

Loyalty Program

The Company launched a customer loyalty program during the third quarter of 2018 for qualified customers located in the U.S. and Canada. Under the program, customers accumulate points based on the customers purchasing or purchasing levels. Once a loyalty program member achieves a certain tier level, the member earns a reward. A customer's account has to be in good standing in order to receive the benefits of the rewards program. Rewards are given on a quarterly basis and must be used in the following quarter. Customers receive a notification regarding their rewards tier by the fifth (5th) day of the following quarter. All unused rewards are forfeited.

The fair value of the reward earned by loyalty program members is included in accrued liabilities and recorded as a reduction of net sales at the time the reward is earned.

Deferred Sales Commissions

Incremental costs of obtaining a contract, including sales commissions, are capitalized and amortized on a straight-line basis over the expected customer relationship period if the Company expects to recover those costs. The Company uses the portfolio method to recognize the amortization expense related to these capitalized costs related to initial contracts and such expense is recognized over a period associated with the revenue of the related portfolio, which is generally two to three years for the Company's product and service arrangements.

Total capitalized costs as of the year ended December 31, 2018 were \$5.2 million and are included in other long-term assets in the Company's consolidated balance sheet. Amortization of this asset was \$1.8 million during the year ended December 31, 2018 and is included in sales and marketing expense in the Company's consolidated statements of operations.

Valuation of Inventories

The Company states its inventories at the lower of cost and net realizable value, computed on a standard cost basis, which approximates actual cost on a first-in, first-out basis. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable cost of completion, disposal, and transportation. Standard costs are monitored and updated quarterly or as necessary, to reflect changes in raw material costs, labor to manufacture the product and overhead rates. The Company provides for excess and obsolete inventories when conditions indicate that the inventory cost is not recoverable due to physical deterioration, usage, obsolescence, reductions in estimated future demand and reductions in selling prices. Inventory provisions are measured as the difference between the cost of inventory and net realizable value to establish a lower cost basis for the inventories. The Company balances the need to maintain strategic inventory levels with the risk of obsolescence due to changing technology, timing of new product introductions and customer demand levels. Unfavorable changes in market conditions may result in a need for additional inventory provisions that could adversely impact our gross margins. Conversely, favorable changes in demand could result in higher gross margins when product that had previously been written down is sold.

Stock-based Compensation Expense

The Company accounts for stock-based compensation costs in accordance with the accounting standards for share-based compensation, which require that all share based payments to employees and non-employees be recognized in the consolidated statements of operations based on their fair values. The Company grants stock options, restricted stock units ("RSUs") and performance stock units ("PSUs") equity awards and employee stock purchase plan ("ESPP").

Stock Options

The Company accounts for stock-based compensation in accordance with the fair value recognition provisions of U.S. GAAP. To value options, the Company uses the Black-Scholes option-pricing model using the single-option approach, which requires the input of highly subjective and complex assumptions. The Company recognizes the expense associated with options using a single award approach over the requisite service period. The Company accounts for all stock options awarded to nonemployees at the fair value of the consideration received or the fair value of the equity instrument issued, as calculated using the Black-Scholes model. The Company subjects stock options granted to non-employees to periodic revaluation at each reporting date as the underlying equity instruments vest.

The assumptions used in the Black-Scholes-option pricing model to determine the fair value of award include the following:

- **Expected term** – The expected term represents the weighted-average period that the recipient of the option will retain their vested stock options before exercising them. The expected term is based on the observed and expected time to post-vesting exercise of options by employees. The Company use historical exercise patterns of previously granted options in relation to stock price movements to derive an employee behavioral pattern used to forecast expected exercise patterns. The expected term of groups of employees that have similar historical exercise patterns has been considered separately for valuation purposes.
- **Volatility** – The underlying stock price volatility of our stock. The Company estimates volatility based on a 50-50 blend of our historical volatility and the implied volatility of freely traded options of our stock in the open market
- **Expected risk-free interest rate and dividend rate over the expected term.** The risk-free interest rate is based on the U.S. treasury yield curve in effect at the time of grant for the expected term of the stock option.

Restricted Stock Units

The Company grants RSUs to our directors, officers and management employees and non-employees. The fair value of RSUs is based on the stock price on the grant date using a single-award approach. The RSUs are subject to a service vesting condition and are recognized on a straight-line basis over the requisite service period. For RSUs to non-employees, the Company recognizes expense on an accelerated attribution method and these equity awards are re-measured at fair value at the end of each reporting period, with the changes in fair value recorded to stock-based compensation expense in the period in which the change occurs. Shares are issued on the vesting dates, net of applicable tax withholding requirements to be paid by us on behalf of the recipient. As a result, the actual number of shares issued will be fewer than the actual number of RSUs outstanding. Furthermore, the Company records the obligation for withholding amounts to be paid by us as a reduction to additional paid-in capital.

Performance Stock Units

Performance stock units are granted to our officers and management employees and non-employees. PSU's with operational measurement goals are measured at the market price of our stock on the date of grant, whereas PSUs with market-based measurement goals are measured using a Monte-Carlo simulation option-pricing model. The Monte-Carlo simulation option-pricing model uses the same input assumptions as the Black-Scholes model; however, it also further incorporates into the fair-value determination the possibility that the market condition may not be satisfied. The final number of shares of common stock issuable at the end of the performance measurement period, subject to the recipient's continued service through that date, is determined based on the expected degree of achievement of the performance goals. For PSUs to non-employees, the Company recognizes expense on an accelerated attribution method and these equity awards are re-measured at fair value at the end of each reporting period, with the changes in fair value recorded to stock-based compensation expense in the period in which the change occurs. Stock-based compensation expense for PSUs is recognized based on the expected degree of achievement of the performance goals over the vesting period. However, stock-based compensation expense for market-based PSU awards are recognized regardless of whether the market condition is satisfied, provided that the requisite service has been provided. On the vesting date of PSU awards, the Company issues fully-paid up common stock, net of the minimum statutory tax withholding requirements to be paid by us and records the obligation for withholding amounts as a reduction to additional paid-in capital.

Forfeiture Rates

The Company recognizes share-based compensation expense for the portion of the equity award that is expected to vest over the requisite service period and develops an estimate of the number of share-based awards which will ultimately vest, primarily based on historical experience within separate groups of employees. The forfeiture rates used in 2018 ranged from 0% to 17%. The estimated forfeiture rate is reassessed periodically throughout the requisite service period. Such estimates are revised if they differ materially from actual forfeitures. As required, the forfeiture estimates will be adjusted to reflect actual forfeitures when an award vests. For the award types discussed above, if the employee or non-employee terminates employment prior to being vested in an award, then the award is forfeited.

Provision for Income Taxes

The Company is subject to taxes on earnings in both the U.S. and various foreign jurisdictions. As a global taxpayer, significant judgments and estimates are required in evaluating our uncertain tax positions and determining our provision for income taxes on earnings. The Company recognizes tax benefits from uncertain tax positions only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such positions are then measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement.

The Company's effective tax rates have differed from the statutory rate primarily due to changes in the valuation allowance, foreign operations, research and development tax credits, state taxes, and certain benefits realized related to stock option activity. The Company's current effective tax rate does not assume U.S. taxes on undistributed profits of foreign subsidiaries. These earnings could become subject to incremental foreign withholding or U.S. federal and state taxes, should they either be deemed or actually remitted to the U.S. The Company's future effective tax rates could be adversely affected by earnings being lower in countries where the Company has lower statutory rates and being higher in countries where the Company has higher statutory rates, or by changes in tax laws, accounting principles, interpretations thereof, net operating loss carryback, research and development tax credits, and due to changes in the valuation allowance of its U.S. deferred tax assets. In addition, the Company is subject to the examination of our income tax returns by the Internal Revenue Service and other tax authorities. The Company regularly assesses the likelihood of adverse outcomes resulting from these examinations to determine the adequacy of our provision for income taxes.

Undistributed earnings of the Company's foreign subsidiaries at December 31, 2018 are considered to be indefinitely reinvested and, accordingly, no provision for federal and state income taxes has been provided thereon. Due to the Transition Tax and Global Intangible Low-Tax Income ("GILTI") regimes as enacted by the 2017 Tax Act, those foreign earnings will not be subject to federal income taxes when actually distributed in the form of a dividend or otherwise. The Company, however, could still be subject to state income taxes and withholding taxes payable to various foreign countries. The amounts of taxes which the Company could be subject to are not material to the accompanying financial statements.

In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act ("SAB 118"), which allows companies to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. Since the 2017 Tax Act was passed late in the fourth quarter of 2017, and ongoing guidance and accounting interpretation was yet to be issued, the Company's accounting of the transition tax and deferred tax re-measurements was incomplete as of December 31, 2017. The Company filed its 2017 Federal corporate income tax return in the fourth quarter of 2018. The Company's final analysis and impact of the 2017 Tax Act is reflected in the tax provision and related tax disclosures for the year ended December 31, 2018. There was a net increase of approximately \$0.3 million to the originally estimated \$7.3 million remeasurement of deferred tax assets. The Company considers the \$0.3 million true-up to be an immaterial change in estimate which has been reflected within the measurement period in accordance with SAB 118.

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In January 2018, the FASB released guidance on the accounting for tax on the GILTI provisions of the 2017 Tax Act. The GILTI provisions impose a tax on foreign income in excess of a deemed return on tangible assets of foreign corporations. The guidance indicates that either accounting for deferred taxes related to GILTI inclusions or treating any taxes on GILTI inclusions as a period cost are both acceptable methods subject to an accounting policy election. The Company has elected to treat any taxes on GILTI inclusions as a period cost.

The Company has included in our Consolidated Balance Sheet a long-term income tax liability for unrecognized tax benefits and accrued interest of \$394,000 as of December 31, 2018. At this time, the Company is unable to make a reasonably reliable estimate of the timing of payments in individual years beyond 12 months due to uncertainties in the timing of tax audit outcomes. As a result, this amount is not included in the contractual obligations table above.

Litigation

The Company has been, and may in the future become subject to a number of legal proceedings involving securities litigation, product liability, intellectual property, contractual disputes, trademark and copyright, and other matters. The Company records a liability and related charge to earnings in its consolidated financial statements for legal contingencies when the loss is considered probable and the amount can be reasonably estimated. Our assessment is reevaluated each accounting period and is based on all available information, including discussion with any outside legal counsel that represents us. If a reasonable estimate of a known or probable loss cannot be made, but a range of probable losses can be estimated, the low-end of the range of losses is recognized if no amount within the range is a better estimate than any other. If a loss is reasonably possible, but not probable and can be reasonably estimated, the estimated loss or range of loss is disclosed in the notes to the consolidated financial statements.

Off-Balance Sheet Arrangements

The Company does not participate in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance, variable interest or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As of December 31, 2018, the Company was not involved in any unconsolidated transactions.

Recent Accounting Guidance

For a full description of recent accounting pronouncements, including the respective effective dates of adoption and effects on results of operations and financial condition see Note 1 — “Summary of Significant Accounting Pronouncements” in the Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K.

Results of Operations

The following table sets forth selected consolidated financial data expressed as a percentage of net revenue.

	Year Ended December 31,		
	2018	2017	2016
Net revenue	100%	100%	100%
Cost of revenue	51%	43%	42%
Gross profit	49%	57%	58%
Operating expenses:			
Sales and marketing	36%	34%	35%
Research and development	9%	8%	10%
General and administrative	13%	9%	11%
Lease termination income	—	(2)%	—
Total operating expenses	58%	50%	56%
Income (loss) from operations	(8)%	7%	2%
Interest and other income, net	—%	1%	—%
Income (loss) before income taxes	(8)%	8%	2%
Income tax (benefit) provision	11%	(12)%	—%
Net income (loss)	(19)%	20%	2%

Net Revenue

The following table sets forth selected consolidated revenue by major geographic area and product category with changes thereof.

(Dollars in thousands)	Year Ended December 31,				
	2018	% Change	2017	% Change	2016
Revenue mix by geography:					
United States	\$ 101,862	8%	\$ 94,581	44%	\$ 65,513
International	\$ 60,858	7%	\$ 56,912	8%	\$ 52,543
Consolidated total revenue	\$ 162,720	7%	\$ 151,493	28%	\$ 118,056
<i>United States as a percentage of total revenue</i>	63%		62%		55%
<i>International as a percentage of total revenue</i>	37%		38%		45%
Revenue mix by product category:					
Systems					
– North America	\$ 93,977	6%	\$ 88,338	51%	\$ 58,595
– Rest of World	38,618	3%	37,544	10%	34,126
<i>Total Systems</i>	132,595	5%	125,882	36%	92,721
Consumables	4,162	71%	2,436	(2)%	2,498
Skincare	5,778	33%	4,342	14%	3,809
<i>Total Products</i>	142,535	7%	132,660		99,028
Service	20,185	7%	18,833	(1)%	19,028
<i>Total Net revenue</i>	\$ 162,720	7%	\$ 151,493	28%	\$ 118,056

Total Net Revenue

The Company's revenue increased by 7% for the year ended December 31, 2018, compared to 2017, due primarily to strong demand for the Company's new products - the *truSculpt* portfolio of products and *Secret RF* systems, primarily offset by softness in the overall women's health market, competitive trends affecting certain legacy system pricing, and greater than expected turnover in our North American salesforce in the fourth quarter on 2018.

Revenue by Geography

The Company's U.S. revenue increased 8% for the year ended December 31, 2018, compared to 2017. This increase was due primarily to the introduction of *Secret RF* and *Juliet* during January 2018, and *truSculpt iD* in July 2018.

The Company's U.S. revenue increased 44% in 2017, compared to 2016. The increase in U.S. revenue was primarily a result of revenue generated from the launch of *truSculpt 3D*, as well as continued growth of our *enlighten III*, *excel HR* and *xeo* products, partially offset by decline in sales of some of our legacy systems.

The Company's international revenue increased 7% for the year ended December 31, 2018, compared to 2017. The increase was due to growth in the Company's business in the Middle East and Asia (excluding Japan).

The Company's international revenue increased 8% in 2017, compared to 2016. The increase in international revenue was primarily a result of increases in the Company's direct business in Japan, Australia, as well as increases in our distributor business in the Middle East, Europe and Asia, partially offset by a decline in revenue from our direct business in Europe and our Latin America distributors.

Revenue by Product Type

Systems Revenue

Systems revenue in North America increased 5%, for the year ended December 31, 2018, compared to 2017, due to sales in the U.S. and the introduction of *Secret RF* and *Juliet* during January 2018, and *truSculpt iD* in July 2018. The Rest of the World systems revenue increased 3%, for the year ended December 31, 2018, compared to 2017. The increase in Rest of the World revenue was primarily a result of an increase in the Company's direct business in Asia, excluding Japan, as well as increases in the Company's distributor business in the Middle East and Europe, partially offset by decreases in the Company's direct business in Australia and Europe.

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The Company's Systems revenue increased by 36% in 2017, compared to 2016. This increase in Systems revenue was primarily attributable to revenue generated by the launch of *truSculpt 3D* and *enlighten III*.

Consumables Revenue

Consumables revenue increased 71%, for the year ended December 31, 2018, compared to 2017. The increase in consumables revenue was due to the introduction of *Secret RF* and *Juliet* during January 2018, and *truSculpt iD* in July 2018, each of which have consumable elements.

The Company's consumables revenue decreased 2% in 2017 compared to 2016. This decrease was due primarily to declines in *Titan* consumables revenue caused by reduced utilization, partially offset by an increase in *truSculpt 3D* consumables revenue.

Skincare Revenue

The Company's revenue from Skincare products in Japan increased 33%, for the year ended December 31, 2018, compared to 2017. This increase was due primarily to increased marketing and promotional activities.

The Company's skincare revenue increased 14% in 2017, compared to 2016. This increase was primarily due to expanded product offerings of this distributed product, as well as an increase in the value of the Japanese Yen versus the U.S Dollar by approximately 4% and 10% in 2017 and 2016, respectively, when compared to prior periods.

Service Revenue

The Company's Service revenue increased 7%, for the year ended December 31, 2018, compared to 2017. This increase was due primarily to increased sales of service contracts, time and material to the Company's network of international distributors.

The Company's Service revenue decreased 1% in 2017, compared to 2016.

Gross Profit

(Dollars in thousands)	Year Ended December 31,				
	2018	% Change	2017	% Change	2016
Gross Profit	\$ 80,382	(7)%	\$ 86,110	26%	\$ 68,135
<i>As a percentage of total revenue</i>	49%		57%		58%

The Company's cost of revenue consists primarily of material, personnel expenses, product warranty costs, and manufacturing overhead expenses. The Company also continues to make investments in its international direct service support, as well as operational improvement activities.

Gross margin for the year ended December 31, 2018 declined 8%, compared to the same period in 2017. The reduced gross margins during 2018 was due primarily to:

- Lower average system pricing across the legacy portfolio, including continued pricing pressure on the *enlighten* system; and
- \$5.0 million product remediation charge related to one of the Company's legacy systems, of which \$1.1 million was utilized in the fourth quarter.

The gross margin for the year ended December 31, 2017 declined 1%, compared to the same period in 2016, due primarily to increased warranty costs, as well as higher Service personnel costs due to investments in additional headcount to fuel future growth.

Sales and Marketing

(Dollars in thousands)	Year Ended December 31,				
	2018	% Change	2017	% Change	2016
Sales and marketing	\$ 58,420	12%	\$ 52,070	25%	\$ 41,563
<i>As a percentage of total revenue</i>	36%		34%		35%

Sales and marketing expenses consist primarily of personnel expenses, expenses associated with customer-attended workshops and trade shows, post-marketing studies, advertising and training.

The \$6.4 million increase in sales and marketing expenses for the year ended December 31, 2018 compared to 2017 was due primarily to:

- \$2.9 million of higher promotional and product demonstration expenses, primarily in North America;
- \$1.7 million of higher travel related expenses in North America resulting from increased headcount;
- \$0.8 million increase in software user license fees and other expenses;
- \$0.6 million increase in consulting and outside professional fees;
- \$0.4 million increase in stock-based compensation due to increased headcount; and
- \$0.1 million of higher facility expenses due to the increase in our Brisbane headquarters rental cost.

The \$10.5 million increase in sales and marketing expenses for the year ended December 31, 2017 compared to 2016 was due primarily to:

- \$7.2 million increase in personnel related expenses, due primarily to higher commissions as a result of North America revenue growth and other higher personnel costs resulting primarily from an increased headcount;
- \$1.4 million increase in promotional spending driven by graphic design, workshops and advertising as we continue to invest in growth;
- \$0.9 million increase in consultant fees and commissions related to the revenue increase in North America; and
- \$0.4 million increased travel expenses associated with the increased activity and headcount.

Research and Development (“R&D”)

(Dollars in thousands)	Year Ended December 31,				
	2018	% Change	2017	% Change	2016
Research and development	\$ 14,359	12%	\$ 12,874	2%	\$ 11,232
<i>As a percentage of total revenue</i>	9%		8%		10%

R&D expenses consist primarily of personnel expenses, clinical research, regulatory and material costs. R&D expenses increased by \$1.5 million or 12%, and represented 9% of total net revenue during the year ended December 31, 2018, compared to 8% of total net revenue in 2017. This increase in expense was due primarily to increase in material cost related to ongoing research and development efforts.

R&D expenses increased by \$1.6 million or 13%, and represented 10% of total net revenue during the year ended December 31, 2017, compared to 11% of total net revenue in 2016. This increase in expense was due primarily to \$0.9 million of higher personnel expenses driven primarily by an increase in headcount and \$0.5 million increase in consulting expenses.

General and Administrative (“G&A”)

(Dollars in thousands)	Year Ended December 31,				
	2018	% Change	2017	% Change	2016
General and administrative	\$ 20,995	49%	\$ 14,090	9%	\$ 12,943
<i>As a percentage of total revenue</i>	13%		9%		11%

G&A expenses consist primarily of personnel expenses, legal, accounting, audit and tax consulting fees, as well as other general and administrative expenses. G&A expenses increased by \$6.9 million, or 49%, and represented 13% of total net revenue during the year ended December 31, 2018, compared to 9% of total net revenue in 2017, due primarily to:

- \$2.8 million of increased personnel related expenses, including stock-based compensation, driven by increased headcount;
- \$2.1 million of increased fees related to professional fees and consulting services, primarily related to accounting, legal, audit and tax fees;
- \$1.3 million of increase in allowance for doubtful accounts;
- \$0.5 million of increase in other administrative expense including travel; and
- \$0.2 million of increase in insurance expense.

General and Administrative expenses increased \$1.1 million in 2017, compared to 2016, primarily due to:

- \$1.3 million increase in personnel costs due to increased headcount, contract employees and stock-based compensation expenses to support growth in our business.
- \$0.6 million of higher accounting, tax and audit fees;
- \$0.3 million of higher project consulting costs; offset by
- \$1.2 million expense reduction attributable to a litigation settlement and legal fees associated with a matter settled in 2016.

Interest and Other Income (expense), Net

Interest and other income, net, consists of the following:

(Dollars in thousands)	Year Ended December 31,				
	2018	% Change	2017	% Change	2016
Total interest and other income (expense), net	\$ (123)	(114)%	\$ 884	174%	\$ 323
As a percentage of total net revenue	(0.1)%		0.6%		0.3%

Net interest and other income, decreased \$1.0 million or (114%) for the year ended December 31, 2018, compared to 2017. This decrease was due primarily to an increase in interest expense related to significant financing components included in our multi-year post-warranty service contracts for customers who make payment more than one year in advance of receiving the service under the new revenue standard effective January 1, 2018, an increase in net foreign exchange losses, as well as a decrease in interest income from the Company's marketable investments resulting from a decrease in the investment balance. The Company adopted the new revenue standard under modified retrospective method and so there was no equivalent expense last year.

Income Tax Provision

(Dollars in thousands)	Year Ended December 31,				
	2018	\$ Change	2017	\$ Change	2016
Income (loss) before income taxes	\$ (13,515)	\$ 25,475	\$ 11,960	\$ 9,240	\$ 2,720
Income tax (benefit) provision	17,255	35,288	(18,033)	(18,176)	143

During the year ended December 31, 2018, the Company applied a valuation allowance of \$16.9 million against certain U.S. federal and state deferred tax assets. In 2017, the Company recorded an income tax benefit of \$18.0 million. This tax benefit was primarily related to a (\$26.3) million release of our valuation allowance against certain U.S. deferred tax assets, which was partially offset by \$7.3 million for the revised measurement of our U.S. deferred tax assets resulting from the 2017 US Tax Act, \$0.7 million current tax expense and \$0.3 million of other deferred tax expense.

Liquidity and Capital Resources

Sources and Uses of Cash

The Company's principal source of liquidity is cash from maturity and sales of marketable investments and cash generated from the issuance of common stock through exercise of stock options and the Company's employee stock purchasing program. The Company actively manages its cash usage and investment of liquid cash to ensure the maintenance of sufficient funds to meet its daily needs. The majority of the Company's cash and investments are held in U.S. banks and its foreign subsidiaries maintain a limited amount of cash in their local banks to cover their short-term operating expenses.

As of December 31, 2018 and December 31, 2017, the Company had \$39.6 million and \$45.1 million of working capital, respectively. Cash and cash equivalents plus marketable investments decreased by \$0.3 million to \$35.6 million as of December 31, 2018, from \$35.9 million as of December 31, 2017, primarily as a result of the decline in the Company's stock price that impacted cash provided by the exercise of stock options and the Company's employee stock purchasing program, increased inventory purchases related to the increasing demand of our products, and an increase in investments in sales, service and other management headcount to facilitate continued revenue expansion. Cash and cash equivalents plus marketable investments decreased by \$18.2 million to \$35.9 million as of December 31, 2017, from \$54.1 million as of December 31, 2016, primarily as a result of the Company's share buyback program in 2017, increased inventory purchases related to the increasing demand of our products, and an increase in investments in sales, service and other management headcount to facilitate continued revenue expansion.

Cash, Cash Equivalents and Marketable Investments

The following table summarizes our cash and cash equivalents and marketable investments (in thousands):

(Dollars in thousands)	Year ended December 31,		
	2018	2017	Change
Cash, cash equivalents and marketable securities:			
Cash and cash equivalents	\$ 26,052	\$ 14,184	\$ 11,868
Marketable investments	9,523	21,728	(12,205)
Total	<u>\$ 35,575</u>	<u>\$ 35,912</u>	<u>\$ (337)</u>

Consolidated Cash Flow Data

In summary, our cash flows were as follows:

(Dollars in thousands)	Year ended December 31,		
	2018	2017	2016
Cash flows provided by (used in):			
Operating activities	\$ 307	\$ 14,287	\$ 1,992
Investing activities	10,773	17,694	(3,392)
Financing activities	788	(31,572)	4,307
Net increase (decrease) increase in cash and cash equivalents	<u>\$ 11,868</u>	<u>\$ 409</u>	<u>\$ 2,907</u>

Cash Flows from Operating Activities

Net cash provided by operating activities was \$0.3 million during 2018, which was due primarily to:

- \$30.8 million net loss as adjusted for non-cash related items consisting primarily of valuation allowance against certain U.S. deferred tax assets of \$17.4 million (excluding the \$1.2 million tax effect of the ASC 606 Adoption), stock-based compensation expense of \$7.2 million, \$1.3 million provision for doubtful accounts receivable, and \$3.0 million depreciation and amortization expenses;
- \$4.3 million generated from an increase in accounts payable due primarily to increased inventory related purchases;
- \$3.8 million cash used to settle accrued liabilities;
- \$3.8 million cash used to increase pre-paid expenses and other long term assets;
- \$2.5 million generated due to decrease in inventories;
- \$0.1 million used as a result of increased accounts receivables; and
- \$0.1 million generated as a result of increased deferred revenue.

The Company generated net cash of \$14.3 million in operating activities during 2017, which was primarily attributable to:

- \$17.4 million provided by operations based on a net income of \$30.0 million after adjusting for \$5.1 million non-cash stock-based compensation expense, \$1.0 million of depreciation and amortization expense, and \$18.7 million net change in deferred tax assets;
- \$15.3 million generated from a \$9.3 million increase in accrued liabilities primarily associated with personnel costs, \$4.4 million increase in accounts payable, and a \$1.6 million increase in deferred revenue due to higher extended service contracts sold; which was offset by
- \$13.8 million of cash used to increase inventories due primarily to higher raw materials required for future product revenue growth; and
- \$4.2 million used to increase in accounts receivable.

Cash Flows from Investing Activities

Net cash provided by investing activities was \$10.8 million during 2018, which was attributable primarily to:

- \$23.1 million in net proceeds from the sales and maturities of marketable investments; partially offset by
- \$10.9 million of cash used to purchase marketable investments; and
- \$1.5 million of cash used to purchase property, equipment and software.

Net cash provided net cash of \$17.7 million from investing activities in 2017, primarily attributable to:

- \$18.5 million net proceeds from the maturities and sales of marketable investments; offset by
- \$0.9 million used to purchase property and equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities was \$0.8 million during 2018, which was primarily due to:

- \$4.4 million proceeds from exercise of stock options and employee stock purchase plan, offset by
- \$3.1 million of cash used for taxes paid related to net share settlement of equity awards; and
- \$0.5 million of cash used to pay capital lease obligations.

Net cash used in financing activities in 2017 was \$31.6 million, which was primarily due to:

- \$35.2 million used to repurchase our common stock;
- \$1.5 million used for taxes paid related to net share settlement of equity awards; offset partially by
- \$5.4 million net proceeds from the issuance of common stock due to employees exercising their stock options and purchasing stock through the Employee Stock Purchase Plan ("ESPP") program.

Adequacy of Cash Resources to Meet Future Needs

The Company had cash, cash equivalents, and marketable investments of \$35.6 million as of December 31, 2018. The Company's principal source of liquidity in the year ended December 31, 2018 is cash from maturity and sales of marketable investments and cash generated from the issuance of common stock through exercise of stock options and the Company's employee stock purchasing program. The Company believes that the existing cash resources are sufficient to meet the Company's anticipated cash needs for working capital and capital expenditures for at least the next several years.

Loan and Security Agreement

On May 30, 2018, the Company and Wells Fargo Bank, N.A. ("Wells Fargo") entered into a Loan and Security Agreement (the "Original Revolving Line of Credit") in the original principal amount of \$25 million. The Original Revolving Line of Credit terminates on May 30, 2021. As of December 31, 2018, there were no borrowings under the Original Revolving Line of Credit.

Covenants

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. A violation of any of the covenants could result in a default under the Original Revolving Line of Credit that would permit the lenders to restrict the Company's ability to further access the revolving line of credit for loans and letters of credit and require the immediate repayment of any outstanding loans under the Loan and Security Agreement.

During the third quarter of 2018 the Company was notified that it was in violation of certain financial covenants in the Original Revolving Line of Credit. Upon receipt of this notice, the Company entered into discussions with Wells Fargo to amend and revise certain terms of the Original Revolving Line of Credit. Following the end of our third quarter, on or about November 2, 2018, the Company 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 Revised Revolving Line of Credit.

Similar to the Original Revolving Line of Credit, the First Amended Revolving Line of Credit contained revised financial and other covenants as well as the maintenance of a leverage ratio not to exceed 2.0 to 1.0 and a graduated scale of TTM adjusted EBITDA of not less than \$1 million as of the last day of the 2018 third fiscal quarter; \$2.5 million as of the last day of the 2018 fourth fiscal quarter; \$4 million as of the last day of the 2019 first and second fiscal quarters; \$6.5 million as of the last day of the 2019 third fiscal quarter; and \$10 million as of the last day of each fiscal quarter.

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. The Company 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. The Company may draw down on the line of credit at the time it reaches and maintains TTM adjusted EBITDA of not less than \$10 million, and a leverage ratio not to exceed 2.5 to 1.0.

Contractual Obligations

The following are our contractual obligations, consisting of future minimum lease commitments related to facility and vehicle leases as of December 31, 2018:

Contractual Obligations	Payments Due by Period (\$'000's)				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Operating leases	\$ 11,223	\$ 3,011	\$ 5,503	\$ 2,709	\$ —
Capital leases	1,015	576	287	152	—
Total leases	12,238	3,587	5,790	2,861	\$ —

Purchase Commitments

The Company maintains certain open inventory purchase commitments with our suppliers to ensure a smooth and continuous supply for key components. The Company's liability in these purchase commitments is generally restricted to a forecasted time-horizon as agreed between the parties. These forecasted time-horizons can vary among different suppliers. The Company's open inventory purchase commitments as of December 31, 2018 were \$1.7 million and \$7.2 million respectively for 2019 and 2020.

Other

In the normal course of business, we enter into agreements that contain a variety of representations, warranties, and indemnification obligations. For example, the Company has entered into indemnification agreements with each of our directors and executive officers. Our exposure under the various indemnification obligations is unknown and not reasonably estimable as they involve future claims that may be made against us. As such, the Company has not accrued any amounts for such obligations.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate and Market Risk

The primary objective of the Company's investment activities is to preserve principal while at the same time maximizing the income the Company receives from investments without significantly increasing risk. To achieve this objective, the Company maintains its portfolio of cash equivalents and short- and long-term investments in a variety of high quality securities, including U.S. treasuries, U.S. government agencies, corporate debt, cash deposits, money market funds, commercial paper, non-U.S. government agency securities, and municipal bonds. The securities are classified as available-for-sale and consequently are recorded at fair value with unrealized gains or losses reported as a separate component of accumulated other comprehensive loss. The weighted average maturity of the Company's portfolio as of December 31, 2018 was approximately 0.3 years. If interest rates rise, the market value of our investments may decline, which could result in a realized loss if we are forced to sell an investment before its scheduled maturity. A hypothetical increase in interest rate by one percentage point would have resulted in no impact on the Company's total investment portfolio.

The uncertain financial markets have resulted in a tightening in the credit markets, a reduced level of liquidity in many financial markets, and extreme volatility in fixed income and credit markets. The credit ratings of the securities we have invested in could further deteriorate and may have an adverse impact on the carrying value of these investments.

As of December 31, 2018, the Company had not drawn on the Revolving Line of Credit. 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. The Company 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. Overall interest rate sensitivity is primarily influenced by any amount borrowed on the line of credit and the prevailing interest rate on the line of credit facility. The effective interest rate on the line of credit facility is based on a floating per annum rate equal to the LIBOR rate. The LIBOR rate was 2.52% as of December 31, 2018, and accordingly the Company may incur additional expenses if the Company has an outstanding balance on the line of credit and the LIBOR rate increases in future periods.

Inflation

The Company does not believe that inflation has had a material effect on the Company's business, financial condition, or results of operations. If the Company's costs were to become subject to significant inflationary pressures, the Company may not be able to fully offset such higher costs through price increases. The Company's inability or failure to do so could harm the Company's business, financial condition, and results of operations.

Foreign Exchange Fluctuations

The Company generates revenue in Japanese Yen, Euros, Australian Dollars, Canadian Dollars, British Pounds and Swiss Francs. Additionally, a portion of the Company's operating expenses and assets and liabilities are denominated in each of these currencies. Therefore, fluctuations in these currencies against the U.S. dollar could materially and adversely affect the Company's results of operations upon translation of the Company's revenue denominated in these currencies, as well as the remeasurement of the Company's international subsidiaries' financial statements into U.S. dollars.

The Company has historically not engaged in hedging activities relating to the Company's foreign currency denominated transactions, given the Company has a natural hedge resulting from the Company's foreign cash receipts being utilized to fund the respective local currency expenses.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

CUTERA, INC. AND SUBSIDIARY COMPANIES

ANNUAL REPORT ON FORM 10-K

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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

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Reports of Independent Registered Public Accounting Firm	57
Consolidated Balance Sheets	59
Consolidated Statements of Operations	60
Consolidated Statements of Comprehensive Income (Loss)	61
Consolidated Statements of Stockholders' Equity	62
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Schedule II - Valuation and Qualifying Accounts	91

All other required schedules are omitted because of the absence of conditions under which they are required or because the required information is given in the Consolidated Financial Statements or the Notes thereto.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

**Cutera, Inc.
Brisbane, California**

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Cutera, Inc. (the “Company”) and subsidiaries as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive income (loss), stockholders’ equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and schedule listed in the accompanying index (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company and subsidiaries at December 31, 2018 and 2017, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the Company’s internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) and our report dated March 18, 2019 expressed an unqualified opinion thereon.

Change in Accounting Principle

As discussed in Notes 1 to the consolidated financial statements, the Company has changed its accounting method for recognizing revenue from contracts with customers in fiscal year 2018 due to the adoption of Topic 606: Revenue from Contracts with Customers.”

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company’s auditor since 2014.

San Jose, California

March 18, 2019

The Board of Directors and Stockholders of Cutera, Inc.:

Opinion on Internal Control over Financial Reporting

We have audited Cutera, Inc.'s (the "Company's") internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of the Company and subsidiaries as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and financial statement schedule listed in the accompanying index and our report dated March 18, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit of internal control over financial reporting in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ BDO USA, LLP
San Jose, California
March 18, 2019

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

	December 31,	
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 26,052	\$ 14,184
Marketable investments	9,523	21,728
Accounts receivable, net of allowance for doubtful accounts of \$1,257 and \$9, respectively	19,637	20,777
Inventories	28,014	28,782
Other current assets and prepaid expenses	3,972	2,903
Total current assets	<u>87,198</u>	<u>88,374</u>
Property and equipment, net	2,672	2,096
Deferred tax assets	457	19,055
Goodwill	1,339	1,339
Other long-term assets	5,971	374
Total assets	<u>\$ 97,637</u>	<u>\$ 111,238</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 11,279	\$ 7,002
Accrued liabilities	23,300	26,848
Extended warranty liabilities	3,159	—
Deferred revenue	9,882	9,461
Total current liabilities	<u>47,620</u>	<u>43,311</u>
Deferred revenue, net of current portion	2,684	2,195
Income tax liability	394	379
Other long-term liabilities	553	460
Total liabilities	<u>51,251</u>	<u>46,345</u>
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock, \$0.001 par value: Authorized: 50,000,000 shares; Issued and outstanding: 13,968,852 and 13,477,973 shares at December 31, 2018 and 2017, respectively	14	13
Additional paid-in capital	70,451	62,025
Retained earnings (accumulated deficit)	(24,010)	2,947
Accumulated other comprehensive loss	(69)	(92)
Total stockholders' equity	<u>46,386</u>	<u>64,893</u>
Total liabilities and stockholders' equity	<u>\$ 97,637</u>	<u>\$ 111,238</u>

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

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

	Year Ended December 31,		
	2018	2017	2016
Net revenue:			
Products	\$ 142,535	\$ 132,660	\$ 99,028
Service	20,185	18,833	19,028
Total net revenue	<u>162,720</u>	<u>151,493</u>	<u>118,056</u>
Cost of revenue:			
Products	66,843	56,363	40,149
Service	15,495	9,020	9,772
Total cost of revenue	<u>82,338</u>	<u>65,383</u>	<u>49,921</u>
Gross profit	<u>80,382</u>	<u>86,110</u>	<u>68,135</u>
Operating expenses:			
Sales and marketing	58,420	52,070	41,563
Research and development	14,359	12,874	11,232
General and administrative	20,995	14,090	12,943
Lease termination income	—	(4,000)	—
Total operating expenses	<u>93,774</u>	<u>75,034</u>	<u>65,738</u>
Income (loss) from operations	(13,392)	11,076	2,397
Interest and other income(expense), net	(123)	884	323
Income (loss) before income taxes	(13,515)	11,960	2,720
Income tax (benefit) provision	17,255	(18,033)	143
Net income (loss)	<u>\$ (30,770)</u>	<u>\$ 29,993</u>	<u>\$ 2,577</u>
Net loss per share:			
Basic	<u>\$ (2.23)</u>	<u>\$ 2.16</u>	<u>\$ 0.19</u>
Diluted	<u>\$ (2.23)</u>	<u>\$ 2.04</u>	<u>\$ 0.19</u>
Weighted-average number of shares used in per share calculations:			
Basic	<u>13,771</u>	<u>13,873</u>	<u>13,225</u>
Diluted	<u>13,771</u>	<u>14,728</u>	<u>13,753</u>

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

CUTERA, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(in thousands)

	Year Ended December 31,		
	2018	2017	2016
Net income (loss)	\$ (30,770)	\$ 29,993	\$ 2,577
Other comprehensive income (loss):			
Available-for-sale investments			
Net change in unrealized gain (loss) on available-for-sale investments	14	(15)	30
Less: Reclassification adjustment for net gains on investments recognized during the year	9	(5)	(3)
Net change in unrealized gain (loss) on available-for-sale investments	23	(20)	27
Tax provision		—	10
Other comprehensive income (loss), net of tax	23	(20)	17
Comprehensive income (loss)	<u>\$ (30,747)</u>	<u>\$ 29,973</u>	<u>\$ 2,594</u>

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

CUTERA, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Retained Earnings (Accumulated Deficit)	Accumulated Other Comprehensive Income (loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2015	12,980,807	\$ 13	\$ 79,782	\$ (29,672)	\$ (89)	\$ 50,034
Deferred tax relating to adoption of ASU 2016-09	—	—	—	49	—	49
Issuance of common stock for employee purchase plan	79,922	—	768	—	—	768
Exercise of stock options	1,051,138	1	9,342	—	—	9,342
Issuance of common stock in settlement of restricted and performance stock units, net of shares withheld for employee taxes, and stock awards	116,833	—	(618)	—	—	(618)
Repurchase of common stock	(455,311)	—	(4,873)	—	—	(4,873)
Stock-based compensation expense	—	—	3,713	—	—	3,713
Net income	—	—	—	2,577	—	2,577
Net change in unrealized loss on available-for-sale investments	—	—	—	—	17	17
Balance at December 31, 2016	13,773,389	\$ 14	\$ 88,114	\$ (27,046)	\$ (72)	\$ 61,010
Issuance of common stock for employee purchase plan	78,479	—	1,059	—	—	1,059
Exercise of stock options	488,398	—	4,376	—	—	4,376
Issuance of common stock in settlement of restricted and performance stock units, net of shares withheld for employee taxes, and stock awards	160,309	—	(1,469)	—	—	(1,469)
Repurchase of common stock	(1,022,602)	(1)	(35,165)	—	—	(35,166)
Stock-based compensation expense	—	—	5,110	—	—	5,110
Net income	—	—	—	29,993	—	29,993
Net change in unrealized loss on available-for-sale investments	—	—	—	—	(20)	(20)
Balance at December 31, 2017	13,477,973	\$ 13	\$ 62,025	\$ 2,947	\$ (92)	\$ 64,893
Adjustment to opening balance for ASC 606 adoption	—	—	—	3,813	—	3,813
Issuance of common stock for employee purchase plan	64,511	1	1,680	—	—	1,680
Exercise of stock options	271,902	—	2,718	—	—	2,718
Issuance of common stock in settlement of restricted and performance stock units, net of shares withheld for employee taxes, and stock awards	154,466	—	(3,128)	—	—	(3,128)
Stock-based compensation expense	—	—	7,157	—	—	7,157
Net loss	—	—	—	(30,770)	—	(30,770)
Net change in unrealized loss on available-for-sale investments	—	—	—	—	23	23
Balance at December 31, 2018	13,968,852	\$ 14	\$ 70,451	\$ (24,010)	\$ (69)	\$ 46,386

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

CUTERA, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2018	2017	2016
Cash flows from operating activities:			
Net income (loss)	\$ (30,770)	\$ 29,993	\$ 2,577
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Stock-based compensation	7,157	5,110	3,713
Depreciation and amortization	1,209	1,016	982
Amortization of contract acquisition costs	1,834	—	—
Change in deferred tax assets	17,438	(18,678)	22
Provision for doubtful accounts receivable	1,257	(1)	—
Other	241	(51)	(7)
Changes in assets and liabilities:			
Accounts receivable	(117)	(4,229)	(4,899)
Inventories	768	(13,805)	(2,899)
Other current assets and prepaid expenses	(1,070)	(591)	(432)
Other long-term assets	(2,754)	6	4
Accounts payable	4,277	4,404	639
Accrued liabilities	(3,781)	9,345	3,461
Extended warranty liabilities	3,159	—	—
Other long-term liabilities	140	—	(329)
Deferred revenue	1,305	1,557	(826)
Income tax liability	15	211	(14)
Net cash provided by operating activities	<u>308</u>	<u>14,287</u>	<u>1,992</u>
Cash flows from investing activities:			
Acquisition of property, equipment and software*	(1,488)	(855)	(537)
Disposal of property and equipment	41	53	20
Proceeds from sales of marketable investments	13,044	33,640	9,008
Proceeds from maturities of marketable investments	10,050	45,812	25,810
Purchase of marketable investments	(10,874)	(60,956)	(37,693)
Net cash provided by (used in) investing activities	<u>10,773</u>	<u>17,694</u>	<u>(3,392)</u>
Cash flows from financing activities:			
Repurchase of common stock	—	(35,167)	(4,873)
Proceeds from exercise of stock options and employee stock purchase plan	4,399	5,435	10,111
Taxes paid related to net share settlement of equity awards	(3,129)	(1,469)	(618)
Payments on capital lease obligation	(483)	(371)	(313)
Net cash provided by (used in) financing activities	<u>787</u>	<u>(31,572)</u>	<u>4,307</u>
Net increase (decrease) in cash and cash equivalents	11,868	409	2,907
Cash and cash equivalents at beginning of year	14,184	13,775	10,868
Cash and cash equivalents at end of year	<u>\$ 26,052</u>	<u>\$ 14,184</u>	<u>\$ 13,775</u>
Supplemental cash flow information:			
Cash paid for interest	<u>\$ 85</u>	<u>\$ 70</u>	<u>\$ 43</u>
Cash paid for income taxes	<u>472</u>	<u>\$ 220</u>	<u>\$ 222</u>
Supplemental non-cash investing and financing activities:			
Assets acquired under capital lease	<u>\$ 610</u>	<u>\$ 365</u>	<u>\$ 801</u>

*Included in Acquisition of property, equipment and software investing activity balance is non-cash investing of \$143,576

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

CUTERA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES***Description of Operations and Principles of Consolidation***

Cutera, Inc. (“Cutera” or the “Company”) is a global provider of laser and 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, enabling them to offer safe and effective aesthetic treatments to their customers. The Company currently markets the following system platforms: *excel*, *enlighten*, *Juliet*, *Secret RF*, *truSculpt* and *xeo*. The Company’s systems offer multiple hand pieces and applications, allowing customers to upgrade their systems. The sales of (i) systems, system upgrades and hand pieces (“Systems” revenue); (ii) hand piece refills applicable to *Titan*, *truSculpt 3D* and *truSculpt iD*, as well as single use disposable tips applicable to *Juliet* and *Secret RF* (“Consumables” revenue); and (iii) the distribution of third party manufactured skincare products (“Skincare” revenue); are collectively classified as “Products” revenue. In addition to Products revenue, the Company generates revenue from the sale of 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.

Headquartered in Brisbane, California, the Company has wholly-owned subsidiaries that are currently operational in Australia, Belgium, Canada, France, Germany, Hong Kong, Japan, Spain, Switzerland and the United Kingdom. The Company’s wholly owned subsidiary in Italy is currently dormant. These active subsidiaries market, sell and service the Company’s products outside of the United States. The Consolidated Financial Statements include the accounts of the Company and its subsidiaries. All inter-company transactions and balances have been eliminated.

Use of Estimates

The preparation of Consolidated Financial Statements in conformity with Generally Accepted Accounting Principles (“GAAP”) requires the Company’s management to make estimates and assumptions that affect the amounts reported of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial Statements and the accompanying notes, and the reported amounts of revenue and expenses during the reported periods. Actual results could differ materially from those estimates.

On an ongoing basis, management evaluates its estimates, including those related to warranty obligations, sales commission, accounts receivable and sales allowances, valuation of inventories, fair values of goodwill, useful lives of property and equipment, assumptions regarding variables used in calculating the fair value of the Company’s equity awards, expected achievement of performance based vesting criteria, fair value of investments, the standalone selling price of the Company’s products and services, the customer life and period of benefit used to capitalize and amortize contracts acquisition costs, variable consideration, contingent liabilities, recoverability of deferred tax assets, and effective income tax rates, among others. Management bases estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities.

Risks and Uncertainties

The Company’s future results of operations involve a number of risks and uncertainties. Factors that could affect the Company’s future operating results and cause actual results to vary materially from expectations include, but are not limited to, rapid technological change, continued acceptance of the Company’s products, stability of world financial markets, cybersecurity breaches and other disruptions that could compromise the Company’s information or results, management of international activities, competition from substitute products and larger companies, ability to obtain and maintain regulatory approvals, government regulations and oversight, patent and other types of litigation, ability to protect proprietary technology from counterfeit versions of the Company’s products, strategic relationships and dependence on key individuals.

Comparability

The Company adopted the new revenue standard effective January 1, 2018, using the modified retrospective method. Prior period financial statements were not retrospectively restated. The consolidated balance sheet as of December 31, 2018 and results of operations for December 31, 2018 were prepared using an accounting standard that was different than that in effect for the year ended December 31, 2017. As a result the consolidated balance sheets as of December 31, 2018 and December 31, 2017 are not directly comparable, nor are the consolidated statement of operations for the years ended December 31, 2018 and December 31, 2017.

Recent Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, "Leases," (also known as ASC Topic 842) which will require, among other items, lease accounting to recognize most leases as assets and liabilities on the balance sheet. Qualitative and quantitative disclosures will be enhanced to better understand the amount, timing and uncertainty of cash flows arising from leases. In July 2018, the FASB issued ASU 2018 -11, "Targeted Improvements," which gives the option to apply the transition provisions of ASU 2016-02 at its adoption date instead of at the earliest comparative period presented in its financial statements. In addition, ASU 2018 2018 -11 provides a practical expedient that permits lessors to not separate nonlease components from the associated lease component if certain conditions are met. Also in July 2018, the FASB issued ASU 2018-10, "Codification Improvements to ASC Topic 842, Leases," which clarifies certain aspects of ASU 2016-02. The Company will adopt ASU 2016-02 on a modified retrospective basis on its adoption date of January 1, 2019 with practical expedients, instead of at the earliest comparative period presented in the Company's financial statements.

The Company will adopt ASC Topic 842 - Leases on January 1, 2019, applying the modified retrospective transition approach to all leases existing at the date of initial application. The new standard provides a number of optional practical expedients in transition. The Company elected the 'package of practical expedients', which permits the Company not to reassess under the new standard the Company's prior conclusions about lease identification, lease classification and initial direct costs. The Company did not elect the practical expedient to use hindsight in determining the lease term.

The Company expects that this standard will have a material effect on our financial statements. While the Company continues to assess all of the effects of adoption, the Company currently believes the most significant effects relate to the recognition of new right-of-use ("ROU") assets and lease liabilities on our balance sheet for our auto, office, and embedded leases; and the requirement to provide significant new disclosures about our leasing activities.

Upon the adoption of ASC Topic 842, the Company will recognize additional operating liabilities ranging from \$10.0 million to \$11.0 million, with corresponding ROU assets of the same amount based on the present value of the remaining minimum rental payments under current leasing standards for existing operating leases.

The new standard also provides practical expedients for an entity's ongoing accounting. The Company will elect the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, the Company will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. The Company also will not elect the practical expedient to not separate lease and non-lease components for all of our leases.

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, "Revenue from Contracts with Customers," amending revenue recognition guidance and requiring more detailed disclosures to enable users of financial statements to understand the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The amended guidance, herein referred to as ASC Topic 606, is effective for annual and interim reporting periods beginning after December 15, 2017, with early adoption permitted for public companies effective for annual and interim reporting periods beginning after December 15, 2016. The Company adopted the new revenue standard in the first quarter of fiscal year 2018 using the modified retrospective method. The Company recognized the cumulative effect of applying the new revenue standard as an adjustment to retained earnings. The comparative information has not been restated and continues to be reported under the accounting standards in effect for the periods presented.

See "Revenue Recognition," for additional accounting policy and transition disclosures.

On January 26, 2017, the FASB issued Accounting Standards Update No. 2017-04, Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment. The new guidance requires only a one-step quantitative impairment test, whereby a goodwill impairment loss will be measured as the excess of a reporting unit's carrying amount over its fair value (not to exceed the total goodwill allocated to that reporting unit). The new guidance eliminates Step 2 of the current two-step goodwill impairment test, and requires companies to perform the goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. Companies will continue to have the option of performing a qualitative assessment of goodwill impairment; however, if a company performs a qualitative assessment of its goodwill and fails, it must proceed with quantitative impairment testing (ASC 350-20-35-3A).

The amendment is effective for the Company for its fiscal years beginning after December 15, 2019. The amendment is required to be adopted prospectively. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017 (350-20-65-3). The Company early adopted ASU 2017-04—Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment, on October 1, 2018. There was no material impact upon adoption of the new standard to the financial statements.

See "Goodwill and Other Intangible Assets" in Note 3 – Balance Sheet Detail.

In June 2018, the FASB issued ASU No. 2018-07, "Compensation -Stock Compensation (Topic 718): Improvement to Nonemployee Share-Based Payment Accounting". The new guidance changes the accounting for nonemployee awards including: (1) equity-classified share-based payment awards issued to nonemployees will be measured on the grant date, instead of the previous requirement to remeasure the awards through the performance completion date, (2) for performance conditions, compensation cost associated with the award will be recognized when the achievement of the performance condition is probable, rather than upon achievement of the performance condition, and (3) the current requirement to reassess the classification (equity or liability) for nonemployee awards upon vesting will be eliminated, except for awards in the form of convertible instruments. The new guidance also clarifies that any share-based payment awards issued to customers should be evaluated under ASC Topic 606. The amendments in the new guidance are effective for annual and interim reporting periods beginning after December 15, 2018, with early adoption permitted for public companies, but no earlier than an entity's adoption date of ASC Topic 606. The Company will adopt the new standard effective January 1, 2019 and the Company does not expect to have a material impact upon adoption of the new standard to the financial statements.

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Revenue

The Company adopted ASC Topic 606, "Revenue from Contracts with Customers," on January 1, 2018, applying the modified retrospective method to all agreements that were not completed as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 are presented under ASC Topic 606, while prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior periods. A cumulative catch up adjustment was recorded to beginning retained earnings to reflect the impact of all existing arrangements under ASC Topic 606.

Upon adoption of ASC Topic 606, the Company recorded an increase to retained earnings, net of deferred tax liability, of \$3.8 million (Note 14) for contracts still in force as of January 1, 2018 for the following items in the first quarter of 2018:

- \$237,000 reduction in deferred revenue balances for the differences in the amount of revenue recognized for the Company's revenue streams as a result of allocation of revenue based on standalone selling prices to the Company's various performance obligations.
- \$151,000 increase in deferred revenue balances, related to the accretion of financing costs for multi-year post-warranty service contracts for customers who pay more than one year in advance of receiving the service. The Company estimated interest expense for such advance payments under the new revenue standard.
- \$210,000 decrease in accrued liabilities.
- \$4.7 million for the capitalization of the incremental contract acquisition costs, such as sales commissions paid in connection with system sales. These contract acquisition costs were capitalized and are being amortized over the period of anticipated support renewals which is estimated to be approximately 2.5 years. The Company expensed such costs when incurred under the prior guidance.
- \$1.2 million deferred tax liability related to the direct tax effect of the ASC Topic 606 adoption.

The following table summarizes the effects of adopting ASC Topic 606 on the Company's consolidated balance sheet as of December 31, 2018:

	As reported under ASC Topic 606	Adjustments (In thousands)	Balances under Prior GAAP
Other long-term assets	\$ 5,971	\$ (5,217)	\$ 754
Deferred revenue	12,566	(106)	12,460
Retained earnings (deficit)	(24,010)	4,610	(19,400)

The following table summarizes the effects of adopting ASC Topic 606 on Company's consolidated income statement for the year ended December 31, 2018:

	As reported under Topic 606	Adjustments (In thousands)	Balances under Prior GAAP
Products revenue	\$ 142,535	\$ 274	\$ 142,261
Service revenue	20,185	280	19,905
Sales and marketing	58,420	540	58,960
Interest and other income, net*	(123)	297	174

* Included in interest and other income, net, is the estimated interest expense for advance payment related to service contracts under the new revenue standard.

Adoption of the standard had no impact on total net cash from or used in operating, investing, or financing activities within the consolidated statements of cash flows.

As part of the Company's adoption of ASC Topic 606, the Company elected to use the following practical expedients: (i) not to adjust the promised amount of consideration for the effects of a significant financing component when the Company expects, at contract inception, that the period between the Company's transfer of a promised product or service to a customer and when the customer pays for that product or service will be one year or less; (ii) to expense costs as incurred for costs to obtain a contract when the amortization period would have been one year or less; (iii) not to recast revenue for contracts that begin and end in the same fiscal year; and (iv) not to assess whether promised goods or services are performance obligations if they are immaterial in the context of the contract with the customer.

Revenue recognition

Revenue recognition- Period before January 1, 2018 - ASC Topic 606 Adoption

The Company recognized revenue under ASC Topic 605 prior to the adoption of ASC Topic 606 effective January 1 2018. Under ASC 605, the Company recognized products revenue when title and risk of ownership was transferred, provided that:

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

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

Multiple-element Arrangements

A multiple-element arrangement includes the sale of one or more tangible product offerings with one or more associated services offerings, each of which are individually considered separate units of accounting. The Company determined that its multiple-element arrangements are generally comprised of the following elements that are recognized as separate units of accounting: Product, service contracts, training, and in some cases, marketing support and installation.

For multiple-element arrangements, judgments are required as to the allocation of the proceeds received from an arrangement to the multiple elements of the arrangement. For multiple element arrangements the Company allocates revenue to all deliverables based on their relative selling prices in accordance with the FASB Accounting Standards Codification (“ASC”) 605-25. Because the Company has neither vendor specific objective evidence (“VSOE”) nor third-party evidence of selling price for the Company’s systems, the allocation of revenue has been based on the Company’s best estimate of selling prices (“BESP”). The objective of BESP is to determine the price at which the Company would transact a sale if the product or service was sold on a stand-alone basis. The Company determines BESP for the Company’s deliverables by considering multiple factors including, but not limited to, features and functionality of the system, geographies, type of customer and market conditions

With respect to the sale of its earlier generation of the *truSculpt* product, the Company includes unlimited refills as part of the *truSculpt* standard warranty and the Company does not account for the *truSculpt* warranty as a separate deliverable under the multiple-element arrangement revenue guidance. Upon a *truSculpt* sale, the Company recognizes the estimated costs which will be incurred under the warranty obligation in Products cost of revenue. Revenue from the sale of refills is recorded as Product revenue in the period in which such sales are made.

Customer Marketing Arrangements

The Company has a customer marketing and incentive program called “Cutera Bucks” for its North America customers through which it offers various sales incentives and discounts and pays or reimburses customers for qualifying expenses associated with practice set-up, advertising procedures related to the system purchased, and other expenses. The Company records such incentives as a reduction of revenue at the time when the sale of the system is recorded.

Service Revenue

The Company also offers customers extended service contracts. Revenue under service contracts is recognized on a straight-line basis over the period of the applicable service contract. Revenue from services performed in the absence of a service contract, including installation and training revenue, is recognized when the related services are performed and collectability is reasonably assured. Service revenue billed on a time and material basis, from customers whose systems are not under a service contract, is recognized as the services are provided. Service revenue for the years ended December 31, 2017 and 2016 was \$18.8 million, and \$19.0 million.

Bill and Hold Arrangement

Under ASC 605 in 2017 the Company segregated certain products for one order at the request of a customer for a limited period of time at a third-party storage facility (“bill -and -hold”). Revenue recognition for the bill-and-hold transaction requires consideration of, among other things, whether the customer has made a written fixed commitment to purchase the product; the existence of a substantial business purpose for the arrangement; the bill-and-hold arrangement is at the request of the customer; the scheduled delivery date must be reasonable and consistent with the buyer’s business purpose; title and risk of ownership must pass to the customer and no additional performance obligations exist by the Company, at the time of the bill-and-hold the product is complete and ready for shipment and the product has been segregated from the Company’s inventory. The Company recognized revenue of \$938,000 for a bill-and-hold transaction in 2017. There were no such transactions in 2016.

Revenue recognition- Period after January 1, 2018 - ASC Topic 606 Adoption

Revenue is recognized upon transfer of control of promised products or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for promised goods or services. The Company’s performance obligations are satisfied either over time or at a point in time. Revenue from performance obligations that are transferred to customers over time accounted for approximately 12% of the Company’s total revenue for the twelve months ended December 31, 2018.

The Company has certain system sale arrangements that contain multiple products and services. For these bundled sale arrangements, the Company accounts for individual products and services as separate performance obligations if they are distinct. The Company’s products and services are distinct if a customer can benefit from the product or service on its own or with other resources that are readily available to the customer, and if the Company’s promise to transfer the products or service to the customer is separately identifiable from other promises in the contract. The Company’s system sale arrangements include a combination of the following performance obligations: the system and software license (considered as one performance obligation), system accessories (hand pieces), training, other accessories, extended service contracts and marketing services.

For the Company’s system sale arrangements that include an extended service contract, the period of service commences at the expiration of the Company’s standard warranty offered at the time of the system sale. The Company considers the extended service contracts terms in the arrangements that are legally enforceable to be performance obligations. Other than extended service contracts and marketing services (which are satisfied over time), the Company generally satisfies all of the performance obligations at a point in time. Systems, system accessories (hand pieces), training, time and materials services are also sold on a stand-alone basis, and related performance obligations are satisfied at a point in time. For contracts with multiple performance obligations, the Company allocates the transaction price of the contract to each performance obligation on a relative standalone selling price basis.

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Nature of Products and Services

Systems

System revenue represents the sale of a system or an upgrade of an existing system. A system consists of a console that incorporates a universal graphic user interface, a laser or other energy based module, control system software and high voltage electronics, as well as one or more hand pieces. However, depending on the application, the laser or other energy based module is sometimes contained in the hand piece such as with the Company's *Pearl* and *Pearl Fractional* applications instead of within the console.

The Company offers customers the ability to select the system that best fits their practice at the time of purchase and then to cost-effectively add applications to their system as their practice grows. This provides customers the flexibility to upgrade their systems whenever they choose and provides the Company with a source of additional Systems revenue.

The Company concludes that the system or upgrade and the right to use the embedded software represent a single performance obligation as the software license is integral to the functionality of the system or upgrade.

The Company does not identify calibration and installation services for systems other than *enlighten* as performance obligations because such services are immaterial in the context of the contract. The related costs to complete calibration and installation for systems other than *enlighten* are immaterial. Calibration and installation services for *enlighten* systems are identified as separate performance obligations.

For systems sold directly to end-customers that are credit approved, revenue is recognized when the Company transfers control to the end-customer, which occurs when the product is shipped to the customer or when the customer receives the product, depending on the nature of the arrangement. The Company recognizes revenue on a cash basis for system sales to international direct end-customer sales that have not been credit approved, as the performance obligations in the contract are satisfied. For systems sold through credit approved distributors, revenue is recognized at the time of shipment.

The Company typically receives payment for its system consoles and other accessories within 30 days of shipment. Certain international distributor arrangements allow for longer payment terms.

Skincare products

The Company sells third-party manufactured skincare products in Japan. The third-party skincare products are purchased from the third-party manufacturers and sold to licensed physicians. The Company acts as the principal in this arrangement, as it determines the price to charge customers for the skincare products, and controls the products before they are transferred to the customer. Skincare products are typically sold in contracts in which the skincare products represent the sole performance obligations. The Company recognizes revenue for skincare products at a point in time, upon shipment.

Consumables (Other accessories)

The Company treats its customers' purchases of replacement *Titan*, *truSculpt 3D* and *truSculpt iD* hand pieces as Consumable revenue, which provides the Company with a source of recurring revenue from existing customers. The Company's recently launched *Juliet* and *Secret RF* products have single use disposable tips which must be replaced after every treatment. Sales of these consumable tips further enhance the Company's recurring revenue. Hand piece refills of the Company's legacy *truSculpt* product are accounted for in accordance with the Company's standard warranty and service contract policies.

Extended contract services

The Company offers post-warranty services to its customers through extended service contracts that cover parts and labor for a term of one, two, or three years. Service contract revenue is recognized over time, using a time based measure of progress, as the customers benefit from the service throughout the service period. The Company also offers services on a time-and-materials basis for detachable hand piece replacements, parts and labor. Revenue related to services performed on a time-and-materials basis is recognized when performed. These post-warranty services serve as additional sources of recurring revenue from the Company's installed product base

Training

Sales of system to customers include training on the system to be provided within 180 days of purchase. The Company considers training as a separate performance obligation as customers can immediately benefit from the training together with the customer's system. Training is also sold separately from systems. The Company recognizes revenue for training when the training is provided. Training is not required for customers to use the systems.

Customer Marketing Support

In North America, the Company offers marketing and consulting phone support to its customers who purchase *truSculpt 3D* and *truSculpt iD* systems. These customer marketing support services include a practice development model and marketing training, performed remotely with ongoing phone consultations for six months from date of purchase. The Company considers customer marketing support a separate performance obligation, and recognizes revenue over the six-month term of the contracts.

Significant Judgments

The Company combines two or more contracts entered into at or near the same time with the same customer and accounts for the contracts as a single contract. The contracts are negotiated as a package with a single commercial objective. The Company exercises significant judgment to evaluate the relevant facts and circumstances in determining whether the separate contracts of contracts comprise a single contract can affect the allocation of consideration to the distinct performance obligations, which could have an effect on results of operations for the periods involved.

The Company is required to estimate the total consideration expected to be received from contracts with customers. In limited circumstances, the consideration expected to be received is variable based on the specific terms of the contract. The Company has not experienced significant returns or refunds to customers. Estimating consideration expected to be received from contracts with customers requires significant judgment and the change in these estimates could have an effect on its results of operations during the periods involved.

The Company determines standalone selling price ("SSP") for each performance obligation as follows:

Systems: The SSPs for systems are based on directly observable sales in similar circumstances to similar customers. When SSP is not directly observable, the Company estimates SSP using the expected cost plus margin approach.

Training: SSP is based on observable price when sold on a standalone basis.

Extended warranty/Service contracts: SSP is based on observable price when sold on a standalone basis (by customer type).

Customer Marketing Support: SSP is estimated based on cost plus a margin.

Set-up /Installation: Set-up or installation for all other systems (excluding the enlighten system) is immaterial in the context of the contract as the set-up or installation for systems other than enlighten. The related costs to complete set-up or installation are immaterial.

The calibration and installation service of the enlighten system are treated as separate performance obligations because the Company regularly sells enlighten systems without the calibration and installation service.

Loyalty Program

The Company launched a customer loyalty program during the third quarter of 2018 for qualified customers located in the U.S. and Canada. Under the programs, customers accumulate points based on their purchasing levels. Once a loyalty program member achieves a certain tier level, the member earns a reward. A customer's account has to be in good standing in order to receive the benefits of the rewards program. Rewards are given on a quarterly basis and must be used in the following quarter. Customers receive a notification regarding their rewards tier by the fifth (5th) day of the following quarter. All unused rewards are forfeited.

The fair value of the reward earned by loyalty program members is included in accrued liabilities and recorded as a reduction of net sales at the time the reward is earned.

Cash Equivalents, and Marketable Investments

The Company invests its cash primarily in money market funds and in highly liquid debt instruments of U.S. federal and municipal governments and their agencies, commercial paper and corporate debt securities. All highly liquid investments with stated maturities of three months or less from date of purchase are classified as cash equivalents; all highly liquid investments with stated maturities of greater than three months are classified as marketable investments. The majority of the Company's cash and investments are held in U.S. banks and the Company's foreign subsidiaries maintain a limited amount of cash in their local banks to cover their short term operating expenses.

The Company determines the appropriate classification of its investments in marketable securities at the time of purchase and re-evaluates such designation at each balance sheet date. The Company's marketable securities have been classified and accounted for as available-for-sale securities. Investments with remaining maturities of more than one year are viewed by the Company as available to support current operations, and are classified as current assets under the caption marketable investments in the accompanying consolidated balance sheets. Investments in marketable securities are carried at fair value, with the unrealized gains and losses reported as a component of stockholders' equity. Any realized gains or losses on the sale of marketable securities are determined on a specific identification method, and such gains and losses are reflected as a component of interest and other income, net.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value. The Company's financial instruments include cash equivalents, accounts receivable, accounts payable and accrued liabilities. Carrying amounts of the Company's financial instruments, approximate their fair values as of the balance sheet dates given their generally short maturities. The fair value hierarchy distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy are described below in accordance with ASC 820:

- Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities.
- Level 2: Directly or indirectly observable inputs as of the reporting date through correlation with market data, including quoted prices for similar assets and liabilities in active markets and quoted prices in markets that are not active. Level 2 also includes assets and liabilities that are valued using models or other pricing methodologies that do not require significant judgment since the input assumptions used in the models, such as interest rates and volatility factors, are corroborated by readily observable data from actively quoted markets for substantially the full term of the financial instrument.
- Level 3: Unobservable inputs that are supported by little or no market activity and reflect the use of significant management judgment. These values are generally determined using pricing models for which the assumptions utilize management's estimates of market participant assumptions.

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

Impairment of Marketable Investments

After determining the fair value of available-for-sales debt instruments, gains or losses on these securities are recorded to other comprehensive income, until either the security is sold or the Company determines that the decline in value is other-than-temporary. The primary differentiating factors that the Company considers in classifying impairments as either temporary or other-than-temporary impairments are the Company's intent and ability to retain the investment in the issuer for a period of time sufficient to allow for any anticipated recovery in market value or the maturity of the investment, the length of the time and the extent to which the market value of the investment has been less than cost and the financial condition and near-term prospects of the issuer. There were no other-than-temporary impairments in the years ended December 31, 2018, 2017, and 2016.

Allowance for Sales Returns and Doubtful Accounts

The allowance for sales returns is based on the Company's estimates of potential future product returns and other allowances related to current period product revenue. The Company analyzes historical returns, current economic trends and changes in customer demand and acceptance of the Company's products.

In cases where the Company is aware of circumstances that may impair a specific customer's ability to meet its obligations to the Company, the Company records a specific allowance against amounts due from the customer, and thereby reduces the net recognized receivable to the amounts it reasonably believes will be collected

Concentration of Credit Risk and Other Risks and Uncertainties

The Company operates in markets that are highly competitive and rapidly changing. Significant technological changes, shifting customer needs, the emergence of competitive products or services with new capabilities and other factors could negatively impact our operating results.

The Company is also subject to risks related to changes in the value of our significant balance of financial instruments. Financial instruments that potentially subject the Company to concentrations of risk consist principally of cash, cash equivalents, marketable investments and accounts receivable. The Company's cash and cash equivalents are primarily invested in deposits and money market accounts with three major financial institutions in the U.S. In addition, the Company has operating cash balances in banks in each of the international locations in which it operates. Deposits in these banks may exceed the amount of insurance provided on such deposits, if any. Management believes that these financial institutions are financially sound and, accordingly, believes that minimal credit risk exists. To date, the Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company invests in debt instruments, including bonds of the U.S. Government, its agencies and municipalities. The Company has also invested in other high grade investments such as commercial paper and corporate debt securities. The Company has established guidelines relative to credit ratings, diversification and maturities that seek to maintain safety and liquidity. By policy, the Company restricts its exposure to any single issuer by imposing concentration limits. To minimize the exposure due to adverse shifts in interest rates, the Company maintains investments at an average maturity of generally less than twelve months.

Accounts receivable are recorded net of an allowance for doubtful accounts, and are typically unsecured and are derived from revenue earned from worldwide customers. The Company controls credit risk through credit approvals, credit limits, and monitoring procedures. The Company performs credit evaluations of its customers and maintains reserves for potential credit losses. As of December 31, 2018 and 2017, there was one customer who represented 4.9% of the Company's net accounts receivable. During the years ended December 31, 2018, 2017, and 2016, domestic revenue accounted for 62%, 62%, and 55%, respectively, of total revenue, while international revenue accounted for 37%, 38%, and 45%, respectively, of total revenue. No single customer represented more than 10% of total revenue for any of the years ended December 31, 2018, 2017, and 2016.

Supplier concentration

The Company relies on third parties for the supply of components of its products, as well as third-party logistics providers. In instances where these parties fail to perform their obligations, the Company may be unable to find alternative suppliers or satisfactorily deliver its products to its customers.

Inventories

Inventories are stated at the lower of cost and net realizable value, cost being determined on a standard cost basis which approximates actual cost on a first-in, first-out basis. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The cost basis of the Company's inventory is reduced for any products that are considered excessive or obsolete based upon assumptions about future demand and market conditions.

The Company includes demonstration units within inventories. Demonstration units are carried at cost and amortized over an estimated economic life of two years. Amortization expense related to demonstration units is recorded in Products cost of revenue or in the respective operating expense line based on which function and purpose for which the demonstration units are being used. Proceeds from the sale of demonstration units are recorded as revenue and all costs incurred to refurbish the systems prior to sale are charged to cost of revenue.

As of December 31, 2018 and 2017, demonstration inventories, net of accumulated depreciation, included in finished goods inventory balance was \$2.9 million and \$1.9 million, respectively.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation expense recognized is on a straight-line basis over the estimated useful lives of the assets, generally as follows:

	Useful Lives
Leasehold improvements	Lesser of useful life or term of lease
Office equipment and furniture (in years)	3
Machinery and equipment (in years)	3

Upon sale or retirement of property and equipment, the costs and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is reflected in operating expenses. Maintenance and repairs are charged to operations as incurred.

Depreciation expense related to property and equipment for 2018, 2017 and 2016, was \$1.2 million, \$1.0 million and \$0.8 million respectively. Amortization expense for vehicles leased under capital leases is included in depreciation expense.

Goodwill and Intangible Assets

Goodwill and intangible assets with indefinite useful lives are not amortized, but are tested for impairment at least annually during the fourth fiscal quarter, or if circumstances indicate their value may no longer be recoverable. Goodwill represents the excess of the purchase price over the fair value of net identifiable assets and liabilities.

The Company continues to operate in one segment, which is considered to be the sole reporting unit and, therefore, goodwill was tested for impairment at the enterprise level. As of December 31, 2018, there has been no impairment of goodwill. All acquired intangible assets have been fully amortized as of December 31, 2018.

Warranty Obligations

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. For sales to distributors, the Company generally provides a 14 to 16 month warranty for parts only, with labor being provided to the end customer by the distributor.

The Company also offers services on a time-and-materials basis for detachable hand piece replacements, parts and labor. These post-warranty services serve as additional sources of recurring revenue from the Company's installed product base.

Deferred Sales Commissions

Incremental costs of obtaining a contract, including sales commissions, are capitalized and amortized on a straight-line basis over the expected customer relationship period. The Company uses the portfolio method to recognize the amortization expense related to these capitalized costs related to initial contracts and such expense is recognized over a period associated with the revenue of the related portfolio, which is generally two to three years for the Company's product and service arrangements.

Total capitalized costs for the year ended December 31, 2018 was \$5.2 million and are included in other long-term assets in the Company's consolidated balance sheet. Amortization of this asset was \$1.8 million during the year ended December 31, 2018 and is included in sales and marketing expense in the Company's consolidated statements of operations.

Cost of Revenue

Cost of revenue consists primarily of material, finished and semi-finished products purchased from third-party manufacturers, labor, stock-based compensation expenses, overhead involved in the Company's internal manufacturing processes, service contracts technology license amortization and royalties, costs associated with product warranties and any inventory write-downs.

The Company's system sales include a control console, universal graphic user interface, control system software, high voltage electronics and a combination of applications (referred to as hand pieces). Hand pieces are programmed to have a limited number of uses to ensure the safety of the device to patients. The Company sells refurbished hand pieces, or "refills," of its *Titan* and *truSculpt 3D* products and provides for the cost of refurbishment of these hand pieces as part of cost of revenue. When customers purchase a replacement hand piece or are provided a replacement hand piece under a warranty or service contract, the Company ships the customer a previously refurbished unit. Upon the receipt of the expended hand piece from the customer, the Company capitalizes the expended hand piece as inventory at the estimated fair value. Cost of revenue includes the costs incurred to refurbish hand pieces.

Research and Development Expenditures

Research and development costs are expensed as incurred and include costs related to research, design, development, testing of products, salaries, benefits and other headcount related costs, facilities, material, third party contractors, regulatory affairs, clinical and development costs.

Advertising Costs

Advertising costs are included as part of sales and marketing expense and are expensed as incurred. Advertising expenses for 2018, 2017 and 2016 were \$2.8 million, \$1.8 million and \$1.3 million, respectively.

Stock-based Compensation

The Company accounts for share-based employee compensation plans using the fair value recognition and measurement provisions under U.S. GAAP. The Company's share-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as expense on a straight-line basis over the requisite service period. The Company estimates expected forfeitures at the time of grant and revises, if necessary, in subsequent periods if actual forfeitures differ from those estimated.

Expected Term: The expected term represents the weighted-average period that the stock options are expected to be outstanding prior to being exercised. The Company determines expected term based on historical exercise patterns and its expectation of the time it will take for employees to exercise options still outstanding.

Expected Volatility: The underlying stock price volatility of our stock. The Company estimates volatility based on a 50-50 blend of our historical volatility and the implied volatility of freely traded options of our stock in the open market.

Risk-Free Interest Rate: The risk-free interest rate is based on the U.S. treasury yield curve in effect at the time of grant for the expected term of the stock option.

- The fair value of stock options ("options") on the grant date is estimated using the Black-Scholes option-pricing model using the single-option approach. The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions, including the option's expected term and the price volatility of the underlying stock, to determine the fair value of award. The Company recognizes the expense associated with options using a single award approach over the requisite service period. The Company accounts for all stock options awarded to non-employees at the fair value of the consideration received or the fair value of the equity instrument issued, as calculated using the Black-Scholes model.
- The fair value of restricted stock units is determined based on the closing quoted 50-day moving average price of the Company's common stock on the day of the grant.

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- The fair value of Performance Stock Units (“PSUs”) that have operational measurement goals, are measured at the 50-day moving average price of the Company’s stock on the date of grant. PSUs with market-based measurement goals are valued using the Monte-Carlo simulation option-pricing model. The Monte-Carlo simulation option-pricing model uses the same input assumptions as the Black-Scholes model, however, it further incorporates into the fair-value determination the possibility that the market condition may not be satisfied.

See Note 9 - Stockholders’ Equity, Stock Plans and Stock-Based Compensation Expense for a detailed discussion of the Company’s stock plans and share-based compensation expense.

Income Taxes

The Company is subject to taxes on earnings in both the U.S. and various foreign jurisdictions. As a global taxpayer, significant judgments and estimates are required in evaluating our uncertain tax positions and determining our provision for income taxes on earnings. The Company recognizes tax benefits from uncertain tax positions only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such positions are then measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement.

The Company’s effective tax rates have differed from the statutory rate primarily due to changes in the valuation allowance, foreign operations, research and development tax credits, state taxes, and certain benefits realized related to stock option activity. The Company’s current effective tax rate does not assume U.S. taxes on undistributed profits of foreign subsidiaries. These earnings could become subject to incremental foreign withholding or U.S. federal and state taxes, should they either be deemed or actually remitted to the U.S. The Company’s future effective tax rates could be adversely affected by earnings being lower in countries where the Company has lower statutory rates and being higher in countries where the Company has higher statutory rates, or by changes in tax laws, accounting principles, interpretations thereof, net operating loss carryback, research and development tax credits, and due to changes in the valuation allowance of its U.S. deferred tax assets. In addition, the Company is subject to the examination of our income tax returns by the Internal Revenue Service and other tax authorities. The Company regularly assesses the likelihood of adverse outcomes resulting from these examinations to determine the adequacy of our provision for income taxes.

Undistributed earnings of the Company’s foreign subsidiaries at December 31, 2018 are considered to be indefinitely reinvested and, accordingly, no provision for federal and state income taxes has been provided thereon. Due to the Transition Tax and Global Intangible Low-Tax Income (“GILTI”) regimes as enacted by the 2017 Tax Act, those foreign earnings will not be subject to federal income taxes when actually distributed in the form of a dividend or otherwise. The Company, however, could still be subject to state income taxes and withholding taxes payable to various foreign countries. The amounts of taxes which the Company could be subject to are not material to the accompanying financial statements.

In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (“SAB 118”), which allows companies to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. Since the 2017 Tax Act was passed late in the fourth quarter of 2017, and ongoing guidance and accounting interpretation was yet to be issued, the Company’s accounting of the transition tax and deferred tax re-measurements was incomplete as of December 31, 2017. The Company filed its 2017 Federal corporate income tax return in the fourth quarter of 2018. The Company’s final analysis and impact of the 2017 Tax Act is reflected in the tax provision and related tax disclosures for the year ended December 31, 2018. There was a net increase of approximately \$0.4 million to the originally estimated \$7.3 million remeasurement of deferred tax assets. The Company considers the \$0.4 million true-up to be an immaterial change in estimate which has been reflected within the measurement period in accordance with SAB 118.

In January 2018, the FASB released guidance on the accounting for tax on the GILTI provisions of the 2017 Tax Act. The GILTI provisions impose a tax on foreign income in excess of a deemed return on tangible assets of foreign corporations. The guidance indicates that either accounting for deferred taxes related to GILTI inclusions or treating any taxes on GILTI inclusions as a period cost are both acceptable methods subject to an accounting policy election. The Company has elected to treat any taxes on GILTI inclusions as a period cost.

Computation of Net Income (Loss) per Share

Basic net income per share is computed using the weighted average number of shares outstanding during the period. Diluted net income per share is computed using the weighted average number of the Company’s shares and dilutive potential shares outstanding during the period. Dilutive potential shares primarily consist of employee stock options, restricted stock units, and shares to be purchased by employees under the Company’s employee stock purchase plan.

GAAP requires that employee equity share options, non-vested shares, and similar equity instruments granted by the Company be treated as potential common shares outstanding in computing diluted earnings per share. Diluted shares outstanding include the dilutive effect of equity awards, which is calculated based on the average share price for each fiscal period using the treasury stock method. Under the treasury stock method, the amount the employee must pay for exercising stock options and the amount of compensation cost for future service that the Company has not yet recognized are assumed to be used to repurchase shares. Diluted earnings per share (“EPS”) is same as basic when the Company incurs a loss.

Comprehensive Income (Loss)

Comprehensive income (loss) includes all changes in stockholders’ equity except those resulting from investments or contributions by stockholders. For the periods presented, the accumulated other comprehensive income (loss) consisted solely of the unrealized gains or losses on the Company’s available for-sale investments, net of tax.

Foreign Currency

The U.S. Dollar is the functional currency of the Company’s subsidiaries. Monetary assets and liabilities are re-measured into U.S. Dollars at the applicable period end exchange rate. Sales and operating expenses are re-measured at average exchange rates in effect during each period. Gains or losses resulting from foreign currency transactions are included in net income (loss) and are insignificant for each of the three years ended December 31, 2017. The effect of exchange rate changes on cash and cash equivalents was insignificant for each of the three years presented in the period ended December 31, 2018.

Segments

The Company operates in one segment. Management uses one measurement of profitability and does not segregate its business for internal reporting. As of December 31, 2018, and 2017, 89% and 98% of long-lived assets were in the United States, respectively. Revenue is attributed to a geographic region based on the location of the end customer. See Note 13 – Segment Information and Revenue by Geography and Products for details relating to revenue by geography.

NOTE 2—INVESTMENT SECURITIES

The following tables summarize cash, cash equivalents and marketable securities (in thousands):

	December 31,	
	2018	2017
Cash and cash equivalents:		
Cash	\$ 21,969	\$ 14,058
Cash equivalents:		
Money market funds	4,083	126
Total cash and cash equivalents	<u>26,052</u>	<u>14,184</u>
Marketable securities:		
U.S. government notes	1,397	11,870
U.S. government agencies	2,677	—
Municipal securities	200	200
Commercial paper	2,433	1,833
Corporate debt securities	2,816	7,825
Total marketable securities	<u>9,523</u>	<u>21,728</u>
Total cash, cash equivalents and marketable securities	<u>\$ 35,575</u>	<u>\$ 35,912</u>

The following table summarizes unrealized gains and losses related to the Company's marketable investments (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
December 31, 2018				
Cash and cash equivalents	\$ 26,052	\$ —	\$ —	\$ 26,052
Marketable investments				
U.S. government notes	1,397	—	—	1,397
U.S. government agencies	2,677	—	—	2,677
Municipal securities	200	—	—	200
Commercial paper	2,433	—	—	2,433
Corporate debt securities	2,825	—	(9)	2,816
Total marketable securities	<u>9,532</u>	<u>—</u>	<u>(9)</u>	<u>9,523</u>
Total cash, cash equivalents and marketable securities	<u>\$ 35,584</u>	<u>\$ —</u>	<u>\$ (9)</u>	<u>\$ 35,575</u>
December 31, 2017				
Cash and cash equivalents	\$ 14,184	\$ —	\$ —	\$ 14,184
Marketable investments				
U.S. government notes	11,885	—	(15)	11,870
Municipal securities	201	—	(1)	200
Commercial paper	1,836	—	(3)	1,833
Corporate debt securities	7,838	2	(15)	7,825
Total marketable securities	<u>21,760</u>	<u>2</u>	<u>(34)</u>	<u>21,728</u>
Total cash, cash equivalents and marketable securities	<u>\$ 35,944</u>	<u>\$ 2</u>	<u>\$ (34)</u>	<u>\$ 35,912</u>

No investments were in a continuous unrealized loss position for longer than 12 months as of December 31, 2018 and 2017.

The unrealized losses on the available-for-sale investments are related to corporate securities and government securities. The Company determined these unrealized losses to be temporary. Factors considered in determining whether a loss is temporary included the length of time and extent to which the investment's fair value has been less than the cost basis; the financial condition and near-term prospects of the investee; extent of the loss related to credit of the issuer; the expected cash flows from the security; the Company's intent to sell the security; and whether or not the Company will be required to sell the security before the recovery of its amortized cost.

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The following table summarizes the estimated fair value of the Company's marketable investments classified by the contractual maturity date of the security as of December 31, 2018 (in thousands):

	Amount
Due in less than one year	\$ 9,121
Due in 1 to 3 years	402
Total marketable securities	<u>\$ 9,523</u>

Fair Value Measurements

The following table summarizes financial assets measured and recognized at fair value on a recurring basis and classified under the appropriate level of the fair value hierarchy as described above (in thousands):

December 31, 2018	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 4,083	\$ —	\$ —	\$ 4,083
Short term marketable investments:				
Available-for-sale securities	—	9,523	—	9,523
Total assets at fair value	<u>\$ 4,083</u>	<u>\$ 9,523</u>	<u>\$ —</u>	<u>\$ 13,606</u>

December 31, 2017	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 126	\$ —	\$ —	\$ 126
Commercial paper	—	—	—	—
Short term marketable investments:				
Available-for-sale securities	—	21,728	—	21,728
Total assets at fair value	<u>\$ 126</u>	<u>\$ 21,728</u>	<u>\$ —</u>	<u>\$ 21,854</u>

The Company's Level 1 financial assets are money market funds with fair values that are based on quoted market prices. The Company's Level 2 investments include U.S. government-backed securities and corporate securities that are valued based upon observable inputs that may include benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data including market research publications. The average remaining maturity of the Company's Level 2 investments as of December 31, 2018 is less than 12 months and all of these investments are rated by S&P and Moody's at A or better. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the years ended December 31, 2018 or 2017.

NOTE 3—BALANCE SHEET DETAIL

Inventories

Inventories consist of the following (in thousands):

	December 31,	
	2018	2017
Raw materials	\$ 16,991	\$ 19,160
Work in process	2,306	2,744
Finished goods	8,717	6,878
Total	<u>\$ 28,014</u>	<u>\$ 28,782</u>

Property and Equipment, net

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

	December 31,	
	2018	2017
Leasehold improvements	\$ 660	\$ 640
Office equipment and furniture	2,835	2,370
Machinery and equipment	7,304	6,277
	10,799	9,287
Less: Accumulated depreciation	(8,127)	(7,191)
Property and equipment, net	<u>\$ 2,672</u>	<u>\$ 2,096</u>

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Included in machinery and equipment are financed vehicles used by the Company's North American sales employees. As of December 31, 2018 and 2017, the gross capitalized value of the leased vehicles was \$1.9 million and \$1.6 million and the related accumulated depreciation was \$1.1 million and \$0.7 million, respectively. Included in Property and equipment is construction in progress of \$0.4 million that is yet to be depreciated.

Goodwill and Other Intangible Assets

Goodwill and other intangible assets comprise a patent sublicense acquired from Palomar in 2006, intangible assets and goodwill related to the acquisition of Iridex's aesthetic business unit, and, customer relationships in the Benelux countries acquired from a former distributor in 2013. The components of intangible assets at December 31, 2018 and 2017 were as follows (in thousands):

	Gross Carrying Amount	Accumulated Amortization & Impairment Amount	Net Amount
December 31, 2018			
Patent sublicense	\$ 1,218	\$ 1,218	\$ —
Customer relationship intangible related to acquisition	2,510	2,510	—
Other identified intangible assets related to acquisition	780	780	—
Other intangible	155	155	—
Goodwill	1,339	—	1,339
Total	<u>\$ 6,002</u>	<u>\$ 4,663</u>	<u>\$ 1,339</u>
December 31, 2017			
Patent sublicense	\$ 1,218	\$ 1,218	\$ —
Customer relationship intangible related to acquisition	2,510	2,510	—
Other identified intangible assets related to acquisition	780	780	—
Other intangible	155	155	—
Goodwill	1,339	—	1,339
Total	<u>\$ 6,002</u>	<u>\$ 4,663</u>	<u>\$ 1,339</u>

The Company did not incur any amortization expense for intangible assets in 2018. Amortization expense in the 2017 and 2016 fiscal years for intangible assets was \$2,000 and \$141,000, respectively. Intangible assets were fully amortized and there were no additions as of December 31, 2018.

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2018	2017
Accrued payroll and related expenses	\$ 9,377	\$ 12,567
Sales and marketing accruals	2,379	3,710
Accrued sales tax	2,935	2,920
Warranty liability	4,666	3,508
Other accrued liabilities	3,943	4,143
Total	<u>\$ 23,300</u>	<u>\$ 26,848</u>

Product Remediation Liability

During the fourth quarter of 2018, the Company recognized a liability for a product remediation plan related to one of its legacy systems. This was related to a voluntary action initiated by the Company to replace a component in one of the Company's legacy products. The developed remediation plan consists primarily of replacement of a component in the system. The accrued liability consisted of cost of materials and labor costs to replace the component in all units that are under the Company's standard warranty or are covered under the existing extended warranty contracts. The Company recorded approximately \$5.0 million related to this remediation, of which \$1.1 million was utilized in the fourth quarter. Approximately \$0.8 million out of the \$5.0 million is included in accrued liabilities and \$3.2 million is separately recorded as extended warranties.

NOTE 4— WARRANTY AND EXTENDED SERVICES CONTRACT

The Company has a direct field service organization in North America (including Canada). Internationally, the Company provides direct service support in Australia, Belgium, France, Germany, Hong Kong, Japan, and Switzerland, as well as through third-party service providers in Spain and the United Kingdom. In several other countries, where the Company does not have a direct presence, the Company provides service through a network of distributors and third-party service providers.

After the original warranty period, maintenance and support are offered on an extended service contract basis or on a time and materials basis. The Company provides for the estimated cost to repair or replace products under standard warranty at the time of sale. Costs incurred in connection with extended service contracts are recognized at the time when costs are incurred, except the one-time extended service contracts charge of \$3.2 million related to the cost to replace a component in one of the Company's legacy products.. The following table provides the changes in the product standard warranty accrual for the years ended December 31, 2018 and 2017 (in thousands):

	December 31,	
	2018	2017
Balance at beginning of year	\$ 3,508	\$ 2,461
Add: Accruals for warranties issued during the period	9,205	7,583
Less: Warranty related expenses during the period	(8,045)	(6,536)
Balance at end of year	<u>\$ 4,668</u>	<u>\$ 3,508</u>

NOTE 5— DEFERRED REVENUE

The Company records deferred revenue when revenue is to be recognized subsequent to invoicing. For extended service contracts, the Company generally invoices customers at the beginning of the extended service contract term. The Company's extended service contracts typically have one, two or three year terms. Deferred revenue also includes payments for installation, training and extended marketing support service. Approximately 79% of the Company's deferred revenue balance of \$12.6 million as of December 31, 2018 will be recognized over the next 12 months.

The following table provides changes in the deferred contract revenue balance for the years ended December 31, 2018 and 2017 (in thousands):

	December 31,	
	2018	2017
Balance at beginning of year	\$ 10,719	\$ 9,431
Add: Payments received	14,882	14,369
Less: Revenue recognized	(13,746)	(13,081)
Balance at end of year	<u>\$ 11,855</u>	<u>\$ 10,719</u>

Costs for extended service contracts in 2018, 2017 and 2016 were \$7.8 million, \$6.0 million and \$6.7 million, respectively. The \$7.8 million in 2018 includes a one-time extended service contract cost of \$3.2 million to replace a component in one of the Company's legacy products (See Note 3).

NOTE 6—STOCKHOLDERS' EQUITY, STOCK PLANS AND STOCK-BASED COMPENSATION EXPENSE

As of December 31, 2018, the Company had the following stock-based employee compensation plans:

2004 Equity Incentive Plan and 1998 Stock Plan

In 1998, the Company adopted the 1998 Stock Plan, or 1998 Plan, under which 4,650,000 shares of the Company's common stock were reserved for issuance to employees, directors and consultants.

On January 12, 2004, the Board of Directors adopted the 2004 Equity Incentive Plan. A total of 1,750,000 shares of common stock were originally reserved for issuance pursuant to the 2004 Equity Incentive Plan. In addition, the shares reserved for issuance under the 2004 Equity Incentive Plan included shares reserved but un-issued under the 1998 Plan and shares returned to the 1998 Plan as the result of termination of options or the repurchase of shares. In 2012 the stockholders approved a "fungible share" provision whereby each full-value award issued under the 2004 Equity Incentive Plan results in a requirement to subtract 2.12 shares from the shares reserved under the Plan.

Options granted under the 1998 Plan and 2004 Equity Incentive Plan may be incentive stock options or non-statutory stock options. Stock purchase rights may also be granted under the 2004 Equity Incentive Plan. Incentive stock options may only be granted to employees. The Board of Directors determines the period over which options become exercisable. Options granted under the Plan to employees generally vest over a four-year term from the vesting commencement date and become exercisable 25% on the first anniversary of the vesting commencement date and an additional 1/48th on the last day of each calendar month until all of the shares have become exercisable. During 2013 and 2012 the officers of the Company were granted options that vest over a three-year term at the rate of one-third on the one-year anniversary of the vesting commencement date and 1/36th thereafter. In 2014 the officers of the Company were granted RSUs and PSUs but were not granted any options. The contractual term of the options granted in 2013 and 2012 was seven years.

In accordance with the 2004 Equity Incentive Plan, prior to 2012, the Company's non-employee directors were granted \$60,000 of grant fair value (determined by dividing the award amount by the 50-day moving average stock price on the day of the award), fully vested, stock awards annually on the date of the Company's Annual Meeting of stockholders. Following Board of Directors action on October 31, 2017, the Company's nonemployee directors receive \$60,000 of RSUs granted annually that cliff-vest on the one-year anniversary of the grant date. In the years ended December 31, 2018, 2017 and 2016, the Company issued 13,392, 21,605 and 45,350 RSUs, respectively, to its non-employee directors. Included in the 2016 grants, was 6,500 RSUs granted to one of the Company's non-employee directors for consulting services to the Company, which vest over a period of four years from the grant date.

In the years ended December 31, 2018, 2017 and 2016 the Company's Board of Directors granted 210,532, 270,707 and 229,865 RSUs, respectively, to its executive officers and certain members of the Company's management. The RSUs granted to the employees vest at the rate of one-fourth on the one-year anniversary of the grant date, and one-fourth in each of the subsequent three years. The annual RSUs granted to the executive officers vests at the rate of one-third on the one-year anniversary of the grant date, and one-third in each of the subsequent two years. In addition, on December 15, 2017, the Company's Board granted 100,000 RSUs to the President and Chief Executive Officer, which vest according to the following schedule: 15%, 15%, 25% and 15% on the first, second, third and fourth anniversary of the grant date, respectively. The Company measured the fair market values of the underlying stock on the dates of grant and recognizes the stock-based compensation expense over the vesting period. On the vesting date, the Company issues fully paid up common stock, net of stock withheld to settle the recipient's minimum statutory tax liability.

In the years ended December 31, 2018, 2017 and 2016 the Company's Board of Directors granted its executive officers and certain senior management employees 47,824, 117,418 and 204,976 of PSUs, respectively. All PSUs vesting was subject to the recipient's continued service and achievement of pre-established goals that were operational (in 2018, 2017 and 2016). The operational PSU goals were related to revenue growth, operating income improvement and specific product releases. On the vest date of the PSUs, the Company issues fully-paid up common stock, based on the degree of achievement of the pre-established targets, net of the stock withheld to settle the recipient's minimum statutory tax liability. 50% of the U.S. domestic metric was achieved while international metric was not achieved in 2018.

2004 Employee Stock Purchase Plan

On January 12, 2004, the Board of Directors adopted the 2004 Employee Stock Purchase Plan. Under the 2004 Employee Stock Purchase Plan, or 2004 ESPP, eligible employees are permitted to purchase common stock at a discount through payroll deductions. The 2004 ESPP offering and purchase periods are for approximately six months. The 2004 ESPP has an evergreen provision based on which shares of common stock eligible for purchase are increased on the first day of each fiscal year by an amount equal to the lesser of:

- i. 600,000 shares;
- ii. 2.0% of the outstanding shares of common stock on such date; or
- iii. an amount as determined by the Board of Directors.

The Company's Board of Directors did not increase the shares available for future grant on January 1, 2019, 2018 and 2017. The price of the common stock purchased is the lower of 85% of the fair market value of the common stock at the beginning or end of a six month offering period. In the years ended December 31, 2018, 2017 and 2016, under the 2004 ESPP, the Company issued 64,511, 78,479 and 79,922 shares, respectively. At December 31, 2018, 627,073 shares remained available for future issuance.

Option Activity

Activity under the 1998 Plan and 2004 Equity Incentive Plan is summarized as follows:

	Options Outstanding				
	Shares Available For Grant	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in \$ millions) (1)
Balances as of December 31, 2015	1,263,425	2,148,797	\$ 9.31	3.4	\$ 7.9
Options granted	(162,000)	162,000	\$ 11.55		
Options exercised	—	(1,051,138)	\$ 8.89		
Options cancelled (expired or forfeited)	143,187	(143,187)	\$ 12.93		
Stock awards granted	(1,018,005)	—	—		
Stock awards cancelled (expired or forfeited)	495,050	—	—		
Balances as of December 31, 2016	<u>721,657</u>	<u>1,116,472</u>	<u>\$ 9.56</u>	<u>3.7</u>	<u>\$ 8.7</u>
Options granted	(278,250)	278,250	\$ 31.00		
Options exercised	—	(488,398)	\$ 8.96		
Options cancelled (expired or forfeited)	66,405	(66,405)	\$ 16.54		
Stock awards granted	(873,881)	—	—		
Stock awards cancelled (expired or forfeited)	258,935	—	—		
Additional shares reserved ⁽²⁾	1,600,000	—	—		
Balances as of December 31, 2017	<u>1,494,866</u>	<u>839,919</u>	<u>\$ 16.46</u>	<u>3.99</u>	<u>\$ 24.4</u>
Options granted	(21,010)	21,010	\$ 50.65		
Options exercised	—	(271,902)	\$ 9.99		
Options cancelled (expired or forfeited)	81,322	(81,322)	\$ 21.55		
Stock awards granted	(562,070)	—	—		
Stock awards cancelled (expired or forfeited)	148,197	—	—		
Balances as of December 31, 2018	<u>1,141,305</u>	<u>507,705</u>	<u>\$ 20.52</u>	<u>3.52</u>	<u>\$ 2.00</u>
Exercisable as of December 31, 2018		<u>335,348</u>	<u>\$ 14.68</u>	<u>2.73</u>	<u>\$ 1.87</u>
Vested and expected to vest, net of estimated forfeitures, as of December 31, 2018		<u>485,469</u>	<u>\$ 19.88</u>	<u>3.42</u>	<u>\$ 19.86</u>

(1) Based on the closing stock price of \$17.02 of the Company's stock on December 31, 2018, \$45.35 on December 30, 2017, \$17.35 on December 31 2016 and \$12.79 on December 31, 2015.

(2) Approved by the board of directors and stockholders in 2017..

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (the aggregate difference between the Company's closing stock price on the last trading day of the fiscal year and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 31, 2018. The aggregate intrinsic amount changes based on the fair market value of the Company's common stock. Total intrinsic value of options exercised in 2018, 2017 and 2016 was \$8.3 million, \$8.0 million, and \$3.6 million, respectively. The options outstanding and exercisable at December 31, 2018 were in the following exercise price ranges:

Exercise Prices	Number Outstanding	Contractual Life (in years)	Number Outstanding
\$6.88 – \$7.44	28,832	0.58	28,832
\$8.80	97,268	1.44	97,268
\$9.65 – \$10.79	54,564	3.01	49,544
\$10.80 – \$11.24	57,521	3.18	47,293
\$11.67 – \$17.90	72,583	2.44	48,855
\$18.55 – \$25.70	71,250	5.21	28,512
\$39.30	72,000	5.83	23,230
\$43.40	6,510	6.45	—
\$47.40	38,927	5.86	10,564
\$53.90	8,250	5.30	1,250

Stock Awards (RSU and PSU) Activity Table

Information with respect to RSUs and PSUs activity is as follows (in thousands):

	Number of Shares	Weighted- Average Grant- Date Fair Value	Aggregate Fair Value ⁽¹⁾ (in thousands)	Aggregate Intrinsic Value ⁽²⁾ (in thousands)
Outstanding at December 31, 2015	371,630	\$ 12.39		\$ 4,753
Granted	480,191	\$ 10.80		
Vested ⁽³⁾	(172,990)	\$ 12.56	\$ 1,906 ⁽⁵⁾	
Forfeited	(233,514)	\$ 11.36		
Outstanding at December 31, 2016	445,317	\$ 11.15		\$ 7,726
Granted	412,208	\$ 28.74		
Vested ⁽³⁾	(224,799)	\$ 10.91	\$ 5,168 ⁽⁶⁾	
Forfeited	(122,139)	\$ 13.56		
Outstanding at December 31, 2017	510,587	\$ 24.88		\$ 23,155
Granted	265,124	\$ 44.57		
Vested ⁽³⁾	(231,515)	\$ 21.10	\$ 9,483 ⁽⁶⁾	
Forfeited	(69,905)	\$ 20.01		
Outstanding at December 31, 2018	474,291	\$ 38.44		\$ 8,072

(1) Represents the value of the Company's stock on the date that the restricted stock units and performance stock units vest.

(2) Based on the closing stock price of the Company's stock of \$ 17.02 on December 31, 2018, \$45.35 on December 31, 2017, \$17.35 on December 31, 2016 and \$12.79 on December 30, 2015.

(3) The number of restricted stock units vested includes shares that the Company withheld on behalf of the employees to satisfy the statutory tax withholding requirements.

(4) On the grant date, the fair value for these vested awards was \$2.2 million.

(5) On the grant date, the fair value for these vested awards was \$2.5 million.

(6) On the grant date, the fair value for these vested awards was \$4.9 million.

Stock-Based Compensation

Stock-based compensation expense for the years ended December 31, 2018, 2017 and 2016 was as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Stock options	\$ 838	\$ 815	\$ 989
RSUs	4,648	1,813	1,508
PSUs	1,105	2,093	967
ESPP	566	389	249
Total stock-based compensation expense	\$ 7,157	\$ 5,110	\$ 3,713

As of December 31, 2018, the unrecognized compensation cost, net of expected forfeitures, was \$12.8 million for stock options and stock awards, which will be recognized over an estimated weighted-average remaining amortization period of 2.63 years. For the ESPP, the unrecognized compensation cost, net of expected forfeitures, was \$272,000, which will be recognized over an estimated weighted-average amortization period 0.33 years.

The Company issues new shares of common stock upon the exercise of stock options, vesting of RSUs and PSUs, and the issuance of ESPP shares. The amount of cash received from these issuances (excluding PSUs), net of taxes withheld and paid, in 2018, 2017 and 2016 was \$1.3 million, \$4.0 million and \$9.5 million.

Total stock-based compensation expense recognized during the year ended December 31, 2018, 2017 and 2016 was recorded in the Consolidated Statement of Operations as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Cost of revenue	\$ 743	\$ 660	\$ 341
Sales and marketing	2,105	1,642	1,179
Research and development	824	936	596
General and administrative	3,485	1,872	1,597
Total stock-based compensation expense	\$ 7,157	\$ 5,110	\$ 3,713

Valuation Assumptions and Fair Value of Stock Options and ESPP Grants

The Company uses the Black-Scholes option pricing model to estimate the fair value of options granted under its equity incentive plans and rights to acquire stock granted under its employee stock purchase plan. The Company based the weighted average estimated values of employee stock option grants and rights granted under the employee stock purchase plan, as well as the weighted average assumptions used in calculating these values, on estimates at the date of grant, as follows:

	Stock Options			Stock Purchase Plan		
	2018	2017	2016	2018	2017	2016
Expected term (in years) ⁽¹⁾	3.7	3.70	3.83	0.50	0.50	0.50
Risk-free interest rate ⁽²⁾	2.6%	1.73%	1.09%	2.34%	1.14%	0.46%
Volatility ⁽³⁾	44%	40%	40%	61%	42%	39%
Dividend yield ⁽⁴⁾	—%	—%	—%	—%	—%	—%
Weighted average estimated fair value at grant date	<u>\$ 18.0</u>	<u>\$ 9.98</u>	<u>\$ 3.72</u>	<u>\$ 9.6</u>	<u>\$ 8.21</u>	<u>\$ 3.22</u>

- (1) *The expected term represents the period during which the Company's stock-based awards are expected to be outstanding. The estimated term is based on historical experience of similar awards, giving consideration to the contractual terms of the awards, vesting requirements, and expectation of future employee behavior, including post-vesting terminations. The expected term of groups of employees that have similar historical exercise patterns has been considered separately for valuation purposes.*
- (2) *The risk-free interest rate is based on U.S. Treasury debt securities with maturities close to the expected term of the option as of the date of grant.*
- (3) *Estimated volatility is based on historical volatility. The Company also considers implied volatility when there is sufficient volume of freely traded options with comparable terms and exercise prices in the open market.*

The Company periodically estimates forfeiture rates based on its historical experience within separate groups of employees and adjusts the stock-based payment expense accordingly. The forfeiture rates used in 2018 ranged from 0% to 17%.

Non-Employee Stock-Based Compensation

Stock-based compensation expense related to stock options granted to non-employees is recognized based on the fair value of the stock options, determined using the Black-Scholes option pricing model, as they are earned. The awards generally vest over the time period the Company expects to receive services from the nonemployee. The Company revalues stock options granted to non-employees at each reporting date as the underlying equity instruments vest.

The Company granted 3,384 RSUs to non-employees during the year ended December 31, 2018, 7,745 stock options and 2,478 RSUs during the year ended 2017, and zero shares during the year ended 2016. The 7,745 stock options granted in 2017 vests over 4 years at 25% on the first anniversary of the grant date and 1/48th each month thereafter.

The 3,384 RSUs granted in 2018 vests over 4 years at 25% each anniversary of the grant date. These RSUs and stock options were granted in exchange for consulting services to be rendered and are measured and recognized as they are earned.

Stock Awards Withholdings

For Stock Awards granted to employees, the number of shares issued on the date the Stock Awards vest is net of the tax withholding requirements paid on behalf of the employees. In 2018, 2017 and 2016, the Company withheld 77,049, 64,490, and 56,157 shares of common stock, respectively, to satisfy its employees' tax obligations of \$3,130,360, \$1,469,000 and \$619,000, respectively. The Company paid this amount in cash to the appropriate taxing authorities. Although shares withheld are not issued, they are treated as common stock repurchases for accounting and disclosure purposes, as they reduce the number of shares that would have been issued upon vesting.

NOTE 7—INCOME TAXES

The Company files income tax returns in the U.S. federal and various state and local jurisdictions and foreign jurisdictions. The Company's income (loss) before provision for income taxes consisted of the following (in thousands):

	Year Ended December 31,		
	2018	2017	2016
U.S.	\$ (14,177)	\$ 11,203	\$ 2,207
Foreign	662	757	513
Income (loss) before income taxes	<u>\$ (13,515)</u>	<u>\$ 11,960</u>	<u>\$ 2,720</u>

The components of the provision (benefit) for income taxes are as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Current:			
Federal	\$ (15)	\$ 148	\$ —
State	123	71	16
Foreign	303	511	131
Total Current	<u>411</u>	<u>730</u>	<u>147</u>
Deferred:			
Federal	15,674	(17,393)	(24)
State	1,230	(1,348)	(2)
Foreign	(60)	(22)	22
Total Deferred	<u>16,844</u>	<u>(18,763)</u>	<u>(4)</u>
Tax provision	<u>\$ 17,255</u>	<u>\$ (18,033)</u>	<u>\$ 143</u>

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

	December 31,	
	2018	2017
Net operating loss carryforwards	\$ 11,227	\$ 8,604
Stock-based compensation	1,040	1,179
Other accruals and reserves	1,924	1,663
Credits	10,857	11,781
Foreign	457	399
Accrued warranty	1,863	847
Depreciation and amortization	2,024	1,592
Other	282	303
Deferred tax asset before valuation allowance	<u>29,674</u>	<u>26,368</u>
Valuation allowance	(27,865)	(7,242)
Deferred tax asset after valuation allowance	<u>1,809</u>	<u>19,126</u>
Deferred tax liability	(1,269)	—
Deferred tax liability on goodwill	(83)	(71)
Net deferred tax asset	<u>\$ 457</u>	<u>\$ 19,055</u>

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

	Year Ended December 31,		
	2018	2017*	2016*
U.S. federal statutory income tax rate	21.00%	34.00%	34.00%
State tax rate	(4.95)	(5.59)	(14.56)
Meals and entertainment	(2.66)	2.15	7.56
Stock-based compensation	13.66	(21.55)	14.36
SAB 118 Change in Estimate	(2.43)	—	
Foreign rate differential	0.11	(0.50)	(0.16)
Other	(1.21)	0.65	(2.15)
General business credit	4.31	(2.72)	(9.25)
Change in Federal Tax Rate	—	60.98	—
Valuation allowance	(155.49)	(218.17)	(24.57)
Effective tax rate	(127.66)%	(150.75)%	5.23%

* Other balance in 2017 and 2016 was reclassified for consistency with current year.

The Company assesses the ability to realize its net deferred tax assets by evaluating all available evidence, both positive and negative, including (1) cumulative results of operations in recent years, (2) sources of recent income (loss), (3) estimates of future taxable income and (4) the length of net operating loss and tax credit carryforward periods. Such assessment is required on a jurisdiction-by-jurisdiction basis. In making such assessment, significant weight is given to evidence that can be objectively verified.

The Company's deferred tax assets are primarily comprised of U.S. Net Operating Loss ("NOL"), tax credit and other deferred tax assets relating to book-to-tax temporary differences. The Company had recorded and maintained a full valuation allowance against those net deferred tax assets to reduce them to their estimated net realizable value through September 30, 2017. As of December 31, 2017, the Company determined that it is more likely than not that a portion of the net deferred tax assets would be realized for federal and U.S. states, except California, and therefore recorded a net valuation allowance release of \$26.3 million.

As of each reporting date, the Company's management considers new evidence, both positive and negative, that could impact management's view with regard to future realization of deferred tax assets. As of December 31, 2018, in part because in the current year, the Company achieved three years of cumulative pre-tax losses in the U.S. federal tax jurisdiction, management determined that sufficient negative evidence exists as of December 31, 2018, to conclude that it is more likely than not that certain of its net deferred taxes would not be realizable, and therefore, recorded a valuation allowance in the amount of \$16.9 million accordingly.

At December 31, 2018, the Company had approximately \$45.7 million and \$20.5 million of federal and state net operating loss carryforwards, respectively, available to offset future taxable income. The federal and state net operating loss carryforwards, if not utilized will generally begin to expire in 2029 through 2038. \$11.8 million of total federal net operating loss carryforwards were generated post December 31, 2017 and have no expiration. At December 31, 2018, the Company had research and development tax credits available to offset federal, California and Massachusetts tax liabilities in the amount of \$6.7 million, \$7.4 million and \$0.3 million, respectively. Federal credits will begin to expire in 2024, California state tax credits have no expiration, and Massachusetts tax credits begin to expire in 2021.

The utilization of NOL carryforwards and tax credits may be subject to a substantial annual limitation due to the ownership change limitations provided by Section 382 of the U.S. Internal Revenue Code ("IRC"), and similar state provisions. The annual limitation may result in the expiration of NOL carryforwards and tax credits before utilization. The Company completed an IRC Section 382 analysis through December 31, 2018 and determined that there were no significant limitations to the utilization of NOL or tax credit carryforwards. As such, the NOL and tax credit carryforwards presented are not expected to expire unutilized, unless there is a future ownership change as determined by Section 382 of the IRC.

Undistributed earnings of the Company's foreign subsidiaries at December 31, 2018 are considered to be indefinitely reinvested and, accordingly, no provision for federal and state income taxes has been provided thereon. Due to the Transition Tax and GILTI regimes as enacted by the 2017 Tax Act, those foreign earnings will not be subject to federal income taxes when actually distributed in the form of a dividend or otherwise. The Company, however, could still be subject to state income taxes and withholding taxes payable to various foreign countries. The amounts of taxes which the Company could be subject to are not material to the accompanying financial statements.

In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act ("SAB 118"), which allows companies to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. Since the 2017 Tax Act was passed late in the fourth quarter of 2017, and ongoing guidance and accounting interpretation was yet to be issued, the Company's accounting of the transition tax and deferred tax re-measurements was incomplete as of December 31, 2017. The Company filed its 2017 Federal corporate income tax return in the fourth quarter of 2018. The Company's final analysis and impact of the 2017 Tax Act is reflected in the tax provision and related tax disclosures for the year ended December 31, 2018. There was a net increase of approximately \$0.3 million to the originally estimated \$7.3 million remeasurement of deferred tax assets. The Company considers the \$0.3 million true-up to be an immaterial change in estimate which has been reflected within the measurement period in accordance with SAB 118.

In January 2018, the FASB released guidance on the accounting for tax on the GILTI provisions of the 2017 Tax Act. The GILTI provisions impose a tax on foreign income in excess of a deemed return on tangible assets of foreign corporations. The guidance indicates that either accounting for deferred taxes related to GILTI inclusions or treating any taxes on GILTI inclusions as a period cost are both acceptable methods subject to an accounting policy election. The Company has elected to treat any taxes on GILTI inclusions as a period cost.

Uncertain Tax Positions

The Company establishes reserves for uncertain tax positions based on the largest amount that is more-likely-than-not to be sustained. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. The Company performs a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement.

Although the Company believes it has adequately reserved for its uncertain tax positions, no assurance can be given that the final tax outcome of these matters will not be different. The Company adjusts these reserves in light of changing facts and circumstances, such as the closing of a tax audit or the refinement of an estimate. To the extent that the final tax outcome of these matters is different than the amounts recorded, such differences will impact the provision for income taxes in the period in which such determination is made. The provision for income taxes includes the impact of reserve provisions and changes to reserves that are considered appropriate, as well as the related net interest and penalties.

The Company files U.S., state, and foreign income tax returns in jurisdictions with varying statutes of limitations. The 2005 through 2018 tax years generally remain subject to examination by U.S. federal and California state tax authorities due to the Company's net operating loss and credit carryforwards. For significant foreign jurisdictions, the 2011 through 2017 tax years generally remain subject to examination by their respective tax authorities.

The following table summarizes the activity related to the Company's gross unrecognized tax benefits in December 31, 2016 to December 31, 2018 (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Balance at beginning of year	\$ 1,519	\$ 707	\$ 651
Decreases related to prior year tax positions	(70)	643	—
Increases related to current year tax positions	114	169	56
Balance at end of year	<u>\$ 1,563</u>	<u>\$ 1,519</u>	<u>\$ 707</u>

It is the Company's policy to recognize interest and penalties related to income tax matters in income tax expense. As of December 31, 2018, the Company had accrued interest and penalties of \$107,000 related to uncertain tax positions.

NOTE 8—NET LOSS PER SHARE

Basic net income (loss) per share is computed using the weighted-average number of shares outstanding during the period. In periods of net income, diluted shares outstanding include the dilutive effect of in-the-money equity awards (stock options, restricted stock units, performance stock units and employee stock purchase plan contributions), which is calculated based on the average share price for each fiscal period using the treasury stock method. In accordance with ASC 260, the assumed proceeds under the treasury stock method include the average unrecognized compensation expense of in-the-money stock options and restricted stock units. This results in the assumed buyback of additional shares, thereby reducing the dilutive impact of equity awards.

Diluted earnings per share is the same as basic earnings per share for the periods in which the Company had a net loss because the inclusion of outstanding common stock equivalents would be anti-dilutive.

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

	Year Ended December 31,		
	2018	2017	2016
Numerator:			
Net Income(loss)	\$ (30,770)	\$ 29,993	\$ 2,577
Denominator:			
Weighted average shares of common stock outstanding used in computing net income (loss) per share, basic	13,771	13,873	13,225
Dilutive effect of incremental shares and share equivalents	—	855	528
Weighted average shares of common stock outstanding used in computing net income (loss) per share, diluted	13,771	14,728	13,753
Net income(loss) per share:			
Net income (loss) per share, basic	\$ (2.23)	\$ 2.16	\$ 0.19
Net income (loss) per share, diluted	\$ (2.23)	\$ 2.04	\$ 0.19

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

	Year Ended December 31,		
	2018	2017	2016
Options to purchase common stock	664	42	220
Restricted stock units	432	9	24
Employee stock purchase plan shares	133	—	—
Performance stock units	43	—	—
Total	1,272	51	244

NOTE 9—DEFINED CONTRIBUTION PLAN

In the U.S., the Company has an employee savings plan (“401(k) Plan”) that qualifies as a deferred salary arrangement under Section 401(k) of the Internal Revenue Code. Eligible employees may make voluntary contributions to the 401(k) Plan up to 100% of their annual compensation, subject to statutory annual limitations. In 2018, 2017 and 2016, the Company made discretionary contributions under the 401(k) Plan of \$0.4 million, \$0.3 million and \$0.2 million, respectively.

For the Company’s Japanese subsidiary, a discretionary employee retirement plan has been established. In addition, for some of the Company’s other foreign subsidiaries, the Company deposits funds with insurance companies, third-party trustees, or into government-managed accounts consistent with the requirements of local laws. The Company has fully funded or accrued for its obligations as of December 31, 2018, and the related expense for each of the three years then ended was not significant.

NOTE 10—SEGMENT INFORMATION AND REVENUE BY GEOGRAPHY AND PRODUCTS

Segment reporting is based on the “management approach,” following the method that management organizes the Company’s reportable segments for which separate financial information is made available to, and evaluated regularly by, the chief operating decision maker in allocating resources and in assessing performance. The Company’s chief operating decision maker is its Chief Executive Officer (“CEO”), who makes decision on allocating resources and in assessing performance. The CEO reviews the Company’s consolidated results as one operating segment. In making operating decisions, the CEO primarily considers consolidated financial information, accompanied by disaggregated information about revenues by geography and product. All of the Company’s principal operations and decision-making functions are located in the U.S. The Company’s CEO views its operations, manages its business, and uses one measurement of profitability for the one operating segment - which sells aesthetic medical equipment and services, and distributes skincare products, to qualified medical practitioners. Substantially all of the Company’s long-lived assets are located in the U.S.

The following table presents a summary of revenue by geography for the year ended December 31, 2018 and 2017 (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Revenue mix by geography:			
United States	\$ 101,862	\$ 94,581	\$ 65,513
Japan	17,819	17,264	14,727
Asia, excluding Japan	15,467	13,719	13,445
Europe	8,875	8,317	7,539
Rest of the world	18,696	17,612	16,832
Total Consolidated revenue	\$ 162,720	\$ 151,493	\$ 118,056
Revenue mix by product category:			
Systems	\$ 132,594	\$ 125,883	\$ 92,721
Consumables	4,162	2,435	2,498
Skincare	5,778	4,342	3,809
Total product revenue	142,535	132,660	99,028
Service	20,185	18,833	19,028
Total Consolidated revenue	\$ 162,720	\$ 151,493	\$ 118,056

NOTE 11—COMMITMENTS AND CONTINGENCIES**OPERATING LEASES*****Facility Leases***

As of December 31, 2018, the Company was committed to minimum lease payments for facilities and other leased assets under long-term non-cancelable operating leases as follows (in thousands):

Year Ending December 31,	Amount
2019	\$ 3,011
2020	2,939
2021	2,564
2022	2,495
2023 and thereafter	214
Future minimum rental payments	<u>\$ 11,223</u>

Gross rent expense recognized in the years ended December 31, 2018, 2017 and 2016 was \$2.9 million, \$1.5 million and \$1.6 million, respectively.

Vehicle Leases

As of December 31, 2018, the Company was committed to minimum lease payments for vehicles leased under long-term non-cancelable capital leases as follows (in thousands):

Year Ending December 31,	Amount
2019	\$ 576
2020	287
2021	152
Future minimum lease payments	<u>\$ 1,015</u>

Purchase Commitments

The Company maintains certain open inventory purchase commitments with its suppliers to ensure a smooth and continuous supply for key components. The Company's liability in these purchase commitments is generally restricted to a forecasted time-horizon as agreed between the parties. These forecasted time-horizons can vary among different suppliers. Although open purchase orders are considered enforceable and legally binding, the terms generally allow the Company the option to cancel, reschedule, and adjust their requirements based on the Company's business needs prior to the delivery of goods or performance of services. The Company's open inventory purchase commitments with its suppliers as of December 31, 2018 were \$1.7 million and \$7.2 million respectively, for 2019 and 2020.

Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations, warranties, and indemnification obligations. For example, the Company has entered into indemnification agreements with each of its directors and executive officers and certain key employees. The Company's exposure under its various indemnification obligations is unknown and not reasonably estimable as they involve future claims that may be made against the Company. As such, the Company has not accrued any amounts for such obligations.

Contingencies

The Company is named from time to time as a party to other legal proceedings, product liability, commercial disputes, employee disputes, and contractual lawsuits in the ordinary course of business. These matters are subject to many uncertainties and outcomes that are not predictable and that may not be known for extended periods of time. A liability and related charge are recorded to earnings in the Company's consolidated financial statements for legal contingencies when the loss is considered probable and the amount can be reasonably estimated. The assessment is re-evaluated each accounting period and is based on all available information, including discussion with outside legal counsel. If a reasonable estimate of a known or probable loss cannot be made, but a range of probable losses can be estimated, the low-end of the range of losses is recognized if no amount within the range is a better estimate than any other. If a material loss is reasonably possible, but not probable and can be reasonably estimated, the estimated loss or range of loss is disclosed in the notes to the consolidated financial statements. The Company expenses legal fees as incurred.

As of December 31, 2018 and December 31, 2017, the Company had accrued \$171,000 and \$91,000, respectively related to various pending commercial and product liability lawsuits. The Company does not believe that a material loss in excess of accrued amounts is reasonably possible.

NOTE 12—DEBT

Loan and Security Agreement

On May 30, 2018, the Company and Wells Fargo Bank, N.A. ("Wells Fargo") entered into a Loan and Security Agreement (the "Original Revolving Line of Credit") in the original principal amount of \$25 million. The Original Revolving Line of Credit terminates on May 30, 2021. As of December 31, 2018, there were no borrowings under the Original Revolving Line of Credit.

Covenants

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 Trailing Twelve Month ("TTM") adjusted EBITDA of not less than \$10 million. A violation of any of the covenants could result in a default under the Original Revolving Line of Credit that would permit the lenders to restrict the Company's ability to further access the revolving line of credit for loans and letters of credit and require the immediate repayment of any outstanding loans under the Loan and Security Agreement.

During the third quarter of 2018, the Company was notified that it was in violation of certain financial covenants in the Original Revolving Line of Credit. Upon receipt of this notice, the Company 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, the Company 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 Revised Revolving Line of Credit.

Similar to the Original Revolving Line of Credit, the First Amended Revolving Line of Credit contained revised financial and other covenants as well as the maintenance of a leverage ratio not to exceed 2.0 to 1.0 and a graduated scale of TTM adjusted EBITDA of not less than \$1 million as of the last day of the 2018 third fiscal quarter; \$2.5 million as of the last day of the 2018 fourth fiscal quarter; \$4 million as of the last day of the 2019 first and second fiscal quarters; \$6.5 million as of the last day of the 2019 third fiscal quarter; and \$10 million as of the last day of each fiscal quarter.

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. The Company 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. The Company may draw down on the line of credit at the time it reaches and maintains TTM adjusted EBITDA of not less than \$10 million, and a leverage ratio not to exceed 2.5 to 1.0.

As of the date of this filing, there were no borrowings under either the Second Amended Revolving Line of Credit, First Amended Revolving Line of Credit, or the Original Revolving Line of Credit, and the Company is in compliance with all financial covenants of the Revised Revolving Line of Credit.

NOTE 13—RELATED PARTIES

In 2018 and 2017, the Company paid \$63,000 and \$196,000, respectively, to a former board member Mr. Dave Gollnick for product development, clinical sales and marketing support services. In addition, as of December 31, 2016, the Company granted Mr. Gollnick 6,500 RSUs with a grant-date fair value of \$87,100, that vest over three years at the rate of 33.33% per year on each of the three anniversaries from the vesting commencement date of October 28, 2016, subject to him continuing to provide consulting and/ or board services to the Company. The Company's Audit Committee approved the extension of Mr. Gollnick's consulting agreement through December 31, 2018 at the rate of \$200 per hour for a maximum of 40 hours per week.

The Company signed an agreement with a real estate firm, T3 Advisors, effective September 2017, to assist the Company in real estate related issues (including strategic planning and search for new facilities). One of T3 Advisors' Senior Vice President "Mr. Austin Barrett" is related to Greg Barrett – a member of the Company's board of directors. In 2018 and 2017, the Company incurred \$192,000 and \$38,000 respectively, related to T3 Advisors Real estate brokerage services.

NOTE 14—CORRECTION OF PRIOR PERIOD IMMATERIAL ERROR

During the three months ended June 30, 2018, management discovered that the Company had not recorded the tax effect of the adoption of ASC Topic 606 in the balance sheet of the unaudited condensed consolidated financial statements as of March 31, 2018. Upon adoption of ASC Topic 606, the Company recorded an increase to retained earnings of \$5.0 million for contracts still in force as of January 1, 2018. The tax effect of the ASC Topic 606 adoption was \$1.2 million.

The Company evaluated the impact of the error on prior periods and determined that the effect was not material to the financial statements as of and for the three months ended March 31, 2018 and six months ended June 30, 2018. The Company corrected the error in the unaudited condensed consolidated financial statements as of and for the six months ended June 30, 2018. The correction of the error increased the Company's deferred tax liability by \$1.2 million and decreased retained earnings by \$1.2 million (Note 1) as of January 1, 2018.

The Company's condensed consolidated statements of operations, comprehensive income (loss) and cash flows for the three months ended March 31, 2018, the three, six and nine months ended September 30, 2018, and the consolidated statements for the year ended December 31, 2018 were not affected by this correction of the error. Accordingly, the Company's loss per share for the three months ended March 31, 2018, the three, six and nine months ended September 30, 2018, and the year ended December 31, 2018 remains unchanged.

NOTE 15—SUBSEQUENT EVENTS

The Company evaluates events or transactions that occur after the balance sheet date through to the date which the financial statements are issued, for potential recognition or disclosure in its consolidated financial statements in accordance with Subsequent Events.

Effective January 4, 2019, James A. Reinstein resigned from his position as Chief Executive Officer and as a member of the Company's board of directors. Effective as of that same date, the board of directors appointed the Company's current Chief Operating Officer, R. Jason Richey to serve as Interim President and Chief Executive Officer of the Company while the board of directors conducts a search for the Company's next Chief Executive Officer.

In connection with Mr. Reinstein's resignation, the Company entered into a Separation Agreement and release with him. Pursuant to the Separation Agreement, Mr. Reinstein will serve as a consultant to the Company for six months to assist with transition matters. In accordance with the Separation Agreement and General Release filed as Exhibit 10.2 to Form 8-K filed on January 9, 2019, Mr. Reinstein will receive a cash payment of approximately \$0.6 million, equivalent to (i) twelve (12) months of his annual base salary as in effect on the Separation Date, and (ii) 100% of his actual bonus for the prior fiscal year, consistent with the 2018 MBP program payout, less applicable withholdings. The payment was made to Mr. Reinstein within thirty (30) days after the effective date. He will also vest in outstanding equity awards of 4,667 shares through April 4, 2019.

SUPPLEMENTARY FINANCIAL DATA (UNAUDITED)
(In thousands, except per share amounts)

Quarter ended:	Dec. 31, 2018	Sept. 30, 2018	June 30, 2018	March 31, 2018	Dec. 31, 2017	Sept. 30, 2017	June 30, 2017	March 31, 2017
Net revenue	\$ 45,469	\$ 40,573	\$ 42,553	\$ 34,125	\$ 47,632	\$ 38,173	\$ 36,389	\$ 29,299
Cost of revenue	26,683	18,688	20,176	16,791	20,299	15,963	15,343	13,778
Gross profit	18,786	21,885	22,377	17,334	27,333	22,210	21,046	15,521
Operating expenses:								
Sales and marketing	15,318	14,479	15,535	13,088	15,362	13,148	12,787	10,773
Research and development	3,464	3,244	4,095	3,556	3,481	3,467	2,981	2,945
General and administrative	5,494	5,160	4,902	5,439	3,947	3,379	3,548	3,216
Lease termination income	—	—	—	—	—	(4,000)	—	—
Total operating expenses	24,276	22,883	24,532	22,083	22,790	15,994	19,316	16,934
Income (loss) from operations	(5,490)	(998)	(2,155)	(4,749)	4,543	6,216	1,730	(1,413)
Interest and other income, net	(44)	(49)	(129)	98	138	197	276	273
Income (loss) before income taxes	(5,534)	(1,047)	(2,284)	(4,651)	4,681	6,413	2,006	(1,140)
Income tax provision	20,760	(174)	(712)	(2,619)	(18,199)	225	59	(118)
Net income (loss)	\$ (26,293)	\$ (873)	\$ (1,572)	\$ (2,032)	\$ 22,880	\$ 6,188	\$ 1,947	\$ (1,022)
Net income (loss) per share—basic	\$ (1.89)	\$ (0.06)	\$ (0.11)	\$ (0.15)	\$ 1.66	\$ 0.44	\$ 0.14	\$ (0.07)
Net income (loss) per share—diluted	\$ (1.89)	\$ (0.06)	\$ (0.11)	\$ (0.15)	\$ 1.57	\$ 0.42	\$ 0.13	\$ (0.07)
Weighted average number of shares used in per share calculations:								
Basic	13,932	13,851	13,709	13,587	13,744	13,973	13,935	13,840
Diluted	13,932	13,851	13,709	13,587	14,569	14,767	14,629	13,840

SCHEDULE II

CUTERA, INC.

VALUATION AND QUALIFYING ACCOUNTS
(in thousands)
For the Years Ended December 31, 2018, 2017 and 2016

	Balance at Beginning of Year	Additions	Deductions	Balance at End of Year
Deferred tax assets valuation allowance				
Year ended December 31, 2018	\$ 7,242	\$ 22,770	\$ 2,147	\$ 27,865
Year ended December 31, 2017	\$ 31,751	\$ 617	\$ 25,126	\$ 7,242
Year ended December 31, 2016	\$ 27,616	\$ 6,755	\$ 2,620	\$ 31,751

	Balance at Beginning of Year	Additions	Deductions	Balance at End of Year
Allowance for doubtful accounts receivable				
Year ended December 31, 2018	\$ 9	\$ 1,880	\$ 632	\$ 1,257
Year ended December 31, 2017	\$ 21	\$ 14	\$ 26	\$ 9
Year ended December 31, 2016	\$ 4	\$ 21	\$ 4	\$ 21

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

The Company maintains disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

As required by SEC Rule 13a-15(b), the Company carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based on the foregoing, the Company's Interim Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), concluded that the Company's disclosure controls and procedures were effective at the reasonable assurance level.

Attached as exhibits to this Annual Report are certifications of the Company's CEO and CFO, which are required in accordance with Rule 13a-14 of the Securities Exchange Act of 1934, as amended (Exchange Act). This Controls and Procedures section includes the information concerning the controls evaluation referred to in the certifications, and it should be read in conjunction with the certifications for a more complete understanding of the topics presented.

Inherent Limitations Over Internal Controls

Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Management, including the Company's CEO and CFO, does not expect that our internal controls will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of internal controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Also, any evaluation of the effectiveness of controls in future periods are subject to the risk that those internal controls may become inadequate because of changes in business conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management's Report on Internal Control Over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in the Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including Company's CEO and CFO, the Company conducted an assessment of the effectiveness of our internal control over financial reporting based on the framework in Internal Control Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the results of our assessment under the framework in the Internal Control-Integrated Framework (2013), the Company's management concluded that the Company's internal control over financial reporting was effective as of December 31, 2018.

The effectiveness of our internal control over financial reporting as of December 31, 2018, has been audited by an independent registered public accounting firm, as stated in their attestation report, which is included in their annual report under "Item 8. Financial Statements and Supplementary Data" of this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There were no changes in the Company's internal control over financial reporting that occurred during the quarter ended December 31, 2018, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None

PART III

Certain information required by Part III is omitted from this report on Form 10-K and is incorporated herein by reference to our definitive Proxy Statement for our next Annual Meeting of Stockholders (the "Proxy Statement"), which we intend to file pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, within 120 days after December 31, 2018.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item concerning our directors and corporate governance is incorporated by reference to the information set forth in the section titled "Directors and Corporate Governance" in the Company's Proxy Statement. Information required by this item concerning the Company's executive officers is incorporated by reference to the information set forth in the section entitled "Executive Officers of the Company" in the Company's Proxy Statement. Information regarding our Section 16 reporting compliance and code of business conduct and ethics is incorporated by reference to the information set forth in the section entitled "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" in the Company's Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item regarding executive compensation is incorporated by reference to the information set forth in the sections titled "Executive Compensation" and "Compensation for Directors" in the Company's Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item regarding security ownership of certain beneficial owners and management is incorporated by reference to the information set forth in the section titled "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" in the Company's Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item regarding certain relationships and related transactions and director independence is incorporated by reference to the information set forth in the sections titled "Certain Relationships and Related Transactions" and "Directors and Corporate Governance" in the Company's Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item regarding principal accountant fees and services is incorporated by reference to the information set forth in the section titled "Principal Accountant Fees and Services" in the Company's Proxy Statement.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this Annual Report on Form 10-K

- (1) Financial Statements-See Index to Consolidated Financial Statements at Item 8 of this Annual Report on Form 10-K.
- (2) The following financial statement schedule of the Company is filed as part of this report and should be read in conjunction with the financial statements of the Company:

Schedule II: Valuation and Qualifying Accounts.

- (3) Exhibits.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (filed as Exhibit 3.5 to our Quarterly Report on Form 10-Q filed on November 7, 2017 and incorporated herein by reference)
3.2	Bylaws of the Registrant (filed as Exhibit 3.4 to our Current Report on Form 8-K filed on January 8, 2015 and incorporated herein by reference)
4.1	Specimen Common Stock certificate of the Registrant (filed as Exhibit 4.1 to our Annual Report on Form 10-K filed on March 25, 2005 and incorporated herein by reference)
10.1*	Form of Indemnification Agreement for directors and executive officers (filed as Exhibit 10.1 to our Current Report on Form 8-K filed on February 21, 2019 and incorporated herein by reference)
10.2*	1998 Stock Plan (filed as Exhibit 10.2 to our registration statement on Form S-1 filed on January 15, 2004 and incorporated herein by reference)
10.3*	2004 Employee Stock Purchase Plan (filed as Exhibit 10.4 to our Annual Report on Form 10-K filed on March 16, 2007 and incorporated herein by reference)
10.4	Brisbane Technology Park Lease dated August 5, 2003 by and between the Registrant and Gal-Brisbane, L.P. for office space located at 3240 Bayshore Boulevard, Brisbane, California (filed as Exhibit 10.6 to our registration statement on Form S-1 filed on January 15, 2004 and incorporated herein by reference)
10.5	Settlement Agreement between the Registrant and Palomar Medical Technologies, Inc. dated June 2, 2006 (filed as Exhibit 99.1 to our Current Report on Form 8-K filed on June 6, 2006 and incorporated herein by reference)
10.6	Non-Exclusive Patent License between the Registrant and Palomar Medical Technologies, Inc. dated June 2, 2006 (filed as Exhibit 99.2 to our Current Report on Form 8-K filed on June 6, 2006 and incorporated herein by reference)
10.7*	Form of Performance Unit Award Agreement (filed as Exhibit 10.11 to our Quarterly Report on Form 10-Q filed on November 14, 2005 and incorporated herein by reference)
10.8*	Amended and Restated 2004 Equity Incentive Plan (filed as Appendix B to our definitive proxy statement on Form 14A filed on May 1, 2017 and incorporated herein by reference)
10.9	First Amendment to Brisbane Technology Park Lease dated August 11, 2010 by and between the Company and BMR-Bayshore Boulevard LLC, as successor-in-interest to Gal-Brisbane, L.P., the original landlord, for office space located at 3240 Bayshore Boulevard (filed as Exhibit 10.19 to our Quarterly Report on Form 10-Q filed on November 1, 2010 and incorporated herein by reference)
10.10*	Change of Control and Severance Agreement between Kevin P. Connors and the Registrant (filed as Exhibit 10.20 to our Quarterly Report on Form 10-Q filed on August 1, 2016 and incorporated herein by reference)
10.11*	Change of Control and Severance Agreement between Ronald J. Santilli and the Registrant (filed as Exhibit 10.21 to our Quarterly Report on Form 10-Q filed on August 1, 2016 and incorporated herein by reference)
10.12*	Form of Performance Stock Unit Award Agreement (filed as Exhibit 10.22 to our Quarterly Report on Form 10-Q filed on August 1, 2016 and incorporated herein by reference)
10.13*	Change of Control and Severance Agreement between James Reinstein and the Registrant (filed as Exhibit 10.23 to our Current Report on Form 8-K filed on January 11, 2017 and incorporated herein by reference)
10.14	Lease Termination Agreement dated July 6, 2017 by and between the Registrant and SI 28, LLC (filed as Exhibit 10.26 to our Quarterly Report on Form 10-Q filed on August 7, 2017 and incorporated herein by reference)
10.15	Second Amendment to Lease dated July 6, 2017 by and between the Company and BMR-Bayshore Boulevard LP (filed as Exhibit 10.27 to our Quarterly Report on Form 10-Q filed on August 7, 2017 and incorporated herein by reference)
10.16	Transition Agreement dated July 12, 2017 by and between the Company and Ronald J. Santilli (filed as Exhibit 10.28 to our Quarterly Report on Form 10-Q filed on November 7, 2017 and incorporated herein by reference)
10.17*	Chief Financial Officer Consulting Agreement dated July 12, 2017 by and between the Company and Sandra A. Gardiner (filed as Exhibit 10.29 to our Quarterly Report on Form 10-Q filed on November 7, 2017 and incorporated herein by reference)

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10.18	<u>Loan and Security Agreement dated May 30, 2018 by and between the Company and Wells Fargo Bank, N.A. (filed as Exhibit 10.1 to our Current Report on Form 8-K filed on June 5, 2018 and incorporated herein by reference).</u>
10.19	<u>Separation Agreement dated January 4, 2019 by and between the Company and James Reinstein (filed as Exhibit 10.2 to our Current Report on Form 8-K on January 9, 2019 and incorporated herein by reference).</u>
23.1	<u>Consent of Independent Registered Public Accounting Firm</u>
24.1	<u>Power of Attorney</u>
31.1	<u>Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
31.2	<u>Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
32.1	<u>Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
	* Management contract or compensatory plan

ITEM 16. SUMMARY OF 10K

None

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Cutera, Inc.
Brisbane, California

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-114149, 333-123495, 333-132583, 333-141376, 333-149703, 333-158160, 333-187502, 333-206864, and 333-221542) of Cutera, Inc. of our reports dated March 18, 2019, relating to the consolidated financial statements and financial statement schedule, and the effectiveness of Cutera, Inc.'s internal control over financial reporting, which appear in this Form 10-K.

/s/ BDO USA, LLP
San Jose, California
March 18, 2019

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO 15 U.S.C. SECTION 7241, AS
ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Jason R. Richey, certify that:

1. I have reviewed this annual report on Form 10-K of Cutera, Inc.:
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 18, 2019

/s/ **JASON R. RICHEY**

Jason R. Richey
Chief Operating Office and Interim Chief Executive
Officer
(Principal Executive Officer)

**CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO 15 U.S.C. SECTION 7241, AS
ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Sandra A. Gardiner, certify that:

1. I have reviewed this annual report on Form 10-K of Cutera, Inc.:
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 18, 2019

/s/ **SANDRA A.GARDINER**

Sandra A. Gardiner
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

**CERTIFICATION OF
CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the annual report on Form 10-K of Cutera, Inc. a Delaware corporation, for the period ended December 31, 2018, as filed with the Securities and Exchange Commission, each of the undersigned officers of Cutera, Inc. certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his respective knowledge:

- (1) the annual report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) the information contained in the annual report fairly presents, in all material respects, the financial condition and results of operations of Cutera, Inc. for the periods presented therein.

Date: March 18, 2019

/s/ JASON R. RICHEY

**Jason R. Richey
Chief Operating Office and Interim Chief Executive Officer
(Principal Executive Officer)**

Date: March 18, 2019

/s/ SANDRA A. GARDINER

**Sandra A. Gardiner
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)**