Sientra, Inc.
Form 10-K
March 14, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2016

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 001-36709

SIENTRA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	20-5551000
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

420 South Fairview Avenue, Suite 200, Santa Barbara, California	93117
(Address of Principal Executive Offices)	(Zip Code)

(805) 562-3500

(Registrant's Telephone Number, Including Area Code)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of 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, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

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

The aggregate market value of registrant's common stock held by non-affiliates of the registrant, based upon the closing price of a share of the registrant's common stock on June 30, 2016 as reported by NASDAQ Global Select Market on such date was approximately $65,626,788. Shares of the registrant's common stock held by each executive officer, director and holder of 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 9, 2017, there were 18,833,933 shares of the registrant’s common stock, par value $0.01 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant’s definitive Proxy Statement relating to its 2017 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. Such Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

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Signatures

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SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10 K, or Annual Report contains forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or 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, “anticipate,” “believe,” “may,” “might,” “could,” “will,” “aim,” “estimate,” “continue,” “intend,” “expect,” “pla negative of those terms, and similar expressions that convey uncertainty of future events or outcomes to identify these forward looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Forward looking statements in this Annual Report on Form 10 K include, but are not limited to, statements about:

- the timing and availability of alternative manufacturing sources and our ability to supply our silicone gel breast implants, tissue expanders and other products to our customers;
- the success of our market reentry plan in light of limited inventory;
- our ability to achieve profitability;
- our ability to generate significant net sales through the sale of our silicone gel breast implants and other products;
- the ability of our products to achieve and maintain market acceptance;
- our ability to successfully commercialize our products;
- our ability to comply with the applicable governmental regulations to which our products and operations are subject;
- our ability to successfully integrate new products into our portfolio;
- our ability to retain a high percentage of our customer base;
- plans regarding the expansion of our sales force and marketing programs;
- the productivity of our sales representatives and ability to achieve expected growth;
- our assumptions about the breast implant market;
- our ability to protect our intellectual property;
- our ability to successfully defend against lawsuits filed against us and our officers; and
- our estimates regarding expenses, net sales, capital requirements and needs for additional financing.

These forward looking statements involve risks and uncertainties as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled “Risk Factors” included under Part I, Item 1A below. You should read these factors and the other cautionary statements made in this Annual Report as being applicable to all related forward-looking statements wherever they appear in this Annual Report. We caution you that the risks, uncertainties and other factors referenced above may not contain all of the risks, uncertainties and other factors that may impact the results and timing of certain events to differ materially from those expressed or implied in forward-looking statements. In addition, we cannot guarantee future results, level of activity, performance or achievements. Any forward looking statement made by us in this Annual Report speaks only as of the date of this Annual Report. Except as required by law, we undertake no obligation to update any forward looking statements, whether as a result of new information, future events or otherwise, after the date of such statements.

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PART I

Item 1. Business

Overview

Sientra, Inc. ("Sientra", the "Company," "we," "our" or "us") is a medical aesthetics company committed to making a differenc in patients' lives by enhancing their body image, growing their self esteem and restoring their confidence. We were founded to provide greater choices to board certified plastic surgeons and patients in need of medical aesthetics products. We have developed a broad portfolio of products with technologically differentiated characteristics, supported by independent laboratory testing and strong clinical trial outcomes. We sell our breast implants and breast tissue expanders, or Breast Products, exclusively to board certified and board admissible plastic surgeons and tailor our customer service offerings to their specific needs, which we believe helps secure their loyalty and confidence. We have recently expanded our product portfolio through two acquisitions. We began selling bioCorneum®, an advanced silicone scar treatment directly to physicians after we acquired bioCorneum® from Enaltus LLC, or Enaltus, in March 2016. Additionally, we began selling the AlloX2®, and Dermaspan™ lines of breast tissue expanders, as well as the Softspan™ line of general tissue expanders, after we acquired these product lines from Specialty Surgical Products, Inc., or SSP, in November 2016.

Our primary products are silicone gel breast implants for use in breast augmentation and breast reconstruction procedures, which we offer in approximately 400 variations of shapes, sizes, fill volumes and textures. Our breast implants are primarily used in elective procedures that are generally performed on a cash pay basis. Many of our proprietary breast implants incorporate one or more technologies that differentiate us from our competitors, including a High Strength Cohesive, or HSC, silicone gel and shell texturing. Our breast implants offer a desired balance between strength, shape retention and softness due to the integration of our silicone implant shell and High Strength Cohesive silicone gel used in our implants. The texturing on Sientra's implant shell is designed to reduce the incidence of malposition, rotation and capsular contracture.

Our breast implants were approved by the U.S. Food and Drug Administration, or FDA, in 2012, based on data we collected from our ongoing, long term clinical trial of our breast implants in 1,788 women across 36 investigational sites in the United States, which included 3,506 implants (approximately 53% of which were smooth and 47% of which were textured). Our clinical trial is the largest prospective, long term safety and effectiveness pivotal study of breast implants in the United States and includes the largest magnetic resonance imaging, or MRI, cohort with 571 patients. The MRI cohort is a subset of study patients that underwent regular MRI screenings in addition to the other aspects of the clinical trial protocol prior to FDA approval. Post-approval, all patients in the long-term clinical trial are subject to serial MRI screenings as part of the clinical protocol. The clinical data we collected over a nine year follow up period demonstrated rupture rates, capsular contracture rates and reoperation rates that were comparable to or better than those of our competitors, at similar time points. In addition to our pivotal study, our clinical data is supported by our Continued Access Study of 2,497 women in the United States. We have also commissioned a number of bench studies run by independent laboratories that we believe further demonstrate the advantages of our breast implants over those of our competitors.

We sell our Breast Products exclusively to board certified and board admissible plastic surgeons, as determined by the American Board of Plastic Surgery, who we refer to as Plastic Surgeons. These surgeons have completed the extensive multi year plastic surgery residency training required by the American Board of Plastic Surgery. While aesthetic procedures are performed by a wide range of medical professionals, including dermatologists, otolaryngologists, obstetricians, gynecologists, dentists and other specialists, the majority of aesthetic surgical procedures are performed by Plastic Surgeons. Plastic Surgeons are thought leaders in the medical aesthetics industry. According to the American Board of Plastic Surgery, there are approximately 6,500 board certified plastic surgeons in

the United States. We seek to provide Plastic Surgeons with differentiated services, including enhanced customer service offerings, a ten year limited warranty that we believe is the best in the industry based on: providing patients with the largest cash reimbursement for certain out of pocket costs related to revision surgeries in a covered event; a lifetime no charge implant replacement program for covered ruptures; and our industry first CapCon Care Program, or C3 Program, through which we offer no charge replacement implants to breast augmentation patients who experience capsular contracture within the first five years after implantation with our smooth or textured breast implants.

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We commenced sales of our breast implants in the United States in the second quarter of 2012. Our net sales were $20.7 million, $38.1 million and $44.7 million for the years ended December 31, 2016, 2015 and 2014, respectively. Our net loss was $40.2 million, $41.2 million and $5.8 million for the years ended December 31, 2016, 2015 and 2014, respectively.

Between October 9, 2015 and March 1, 2016, we voluntarily suspended the sale of all Sientra devices manufactured by Silimed Indústria de Implantes Ltda. (formerly, Silimed-Silicone e Instrumental Medico-Cirugio e Hospitalar Ltda.), or Silimed, due to the suspension of Silimed's CE and ISO 13485 certifications by TÜV SÜD, Silimed's notified body under EU regulations. This was followed by Brazilian regulatory inquiries of Silimed and a suspension by the Brazilian regulatory agency ANVISA and the Department of the Secretary of State of Rio de Janeiro of the manufacturing and shipment of all medical devices made by Silimed, and their recommendation that plastic surgeons discontinue implanting the devices until further notice. See Note 1(e) to our Financial Statements for more information on the history of these developments with Silimed.

After ongoing discussions with the FDA and our own review of the matter with the assistance of independent experts in quality management systems, current Good Manufacturing Practices, or cGMP, and data-based risk assessment, on March 1, 2016, we lifted the temporary hold on sales. We also informed our Plastic Surgeons of our controlled market re-entry plan designed to optimize our inventory supply, which continues to be limited as we finalize access to an alternative manufacturing source.

The events involving Silimed will likely continue to adversely impact our business, in particular due to the limitations on our existing inventory levels, the uncertainty of our customers' responsiveness to our controlled market re-entry plan, the fact that Silimed filed a lawsuit against us alleging, among other things, a material breach of the existing manufacturing contract, and the fact that the manufacturing contract with Silimed expires on its terms on April 1, 2017. See "Risk Factors — Risks Relating to Our Business and Our Industry" for further detail.

In response to these events and anticipated impacts on our business, we have increasingly focused our efforts on securing and qualifying an alternate manufacturing supplier.

On August 9, 2016, we announced our collaboration with Vesta Intermediate Funding, Inc., or Vesta, pursuant to which we are working with Vesta towards establishing a dedicated contract manufacturing facility for our breast implants. Vesta is a Lubrizol LifeSciences Company and leading medical device contract manufacturer of silicone products and other medical devices headquartered in Wisconsin. On March 14, 2017, we announced that we had executed a definitive manufacturing agreement with Vesta for the manufacture and supply of our breast implants. In addition, on March 14, 2017, we announced that we had submitted a pre market approval, or PMA, supplement to the FDA for the manufacturing of our PMA-approved breast implants by Vesta. For further details, see Item 9B — "Other Information."

We sell our products in the United States through a direct sales organization, which as of December 31, 2016, consisted of 43 employees, including 36 sales representatives and 7 sales managers.

Our Market

The overall market for medical aesthetic procedures is significant, and awareness and acceptance of these procedures is growing in the United States. According to the American Society for Aesthetic Plastic Surgery, or ASAPS, in 2015, consumers in the United States spent approximately $13.5 billion on aesthetic procedures overall, including both surgical and non invasive cosmetic treatments. Of this amount, more than $7.8 billion was spent on aesthetic surgical procedures.

Breast augmentation surgery remains the leading aesthetic surgical procedure by dollars and number of procedures in the United States. According to ASAPS, over 305,000 primary breast augmentation procedures were performed in the United States in 2015. These procedures provide cosmetic solutions generally to enhance breast size and shape, correct breast asymmetries or help restore fullness after breastfeeding. For breast reconstruction, American Society of Plastic Surgeons, or ASPS, estimates that approximately 106,000 procedures were performed in the United States in 2015. These procedures are a surgical solution generally used to restore a breast to near normal shape and appearance following a mastectomy and typically utilize a breast tissue expander prior to implantation of a breast implant. Based on the number of procedures reported by ASAPS and by ASPS, and our estimates of average selling price, implant mix and

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implants per procedure, we estimate that the U.S. market for breast implants and breast tissue expanders exceeded $635 million in 2015.

Our Opportunity

We believe a significant opportunity exists in the U.S. marketplace due to the high barriers to entry in the U.S. breast implant market and the historical lack of product and service innovation for Plastic Surgeons.

For more than 20 years prior to the FDA approval of our breast implants in 2012, only two companies manufactured and distributed breast implants in the United States. We believe that this market concentration is largely a result of the considerable costs and risks associated with the lengthy regulatory approval process required by the FDA, which has created a significant barrier to entry in the U.S. breast implant market. All new breast implants require PMA approval from the FDA before they may be marketed in the United States. The PMA application process is lengthy and uncertain, and it must be supported by valid scientific evidence, which typically requires long term follow up of a large number of enrolled patients, as well as extensive pre clinical, clinical and other product data to demonstrate safety and effectiveness. We believe that in the near term, it is likely that the companies currently providing silicone gel breast implants in the United States will continue to be the only companies servicing the U.S. silicone breast implant market.

We believe the rigorous FDA approval process and the existence of only two competitors in the U.S. market have historically contributed to a lack of technological innovation in the U.S. breast implant industry resulting in limited product choices. Until the FDA approval of our breast implants in 2012, surgeons in the United States were only able to purchase basic round breast implants from our two U.S. competitors, while surgeons outside of the United States were able to purchase technologically advanced round and anatomically shaped breast implants.

Our Competitive Strengths

We believe that we are well positioned to take advantage of opportunities afforded by current market dynamics. By focusing on products with technologically differentiated characteristics, demonstrating strong clinical data, offering more product choices and providing services tailored specifically to the needs of Plastic Surgeons, we believe we can enhance our position in the breast implant market. Our competitive strengths include:

Differentiated silicone gel and texturing technologies. We incorporate differentiated technologies into our proprietary breast implants to distinguish ourselves from our competitors, including our silicone shell, High Strength Cohesive silicone gel and a textured surface. Our breast implants offer a desired balance between strength, shape retention and softness due to the High-Strength Cohesive silicone gel used in our products. In addition, the texturing on Sientra's implant shell is designed to reduce the incidence of malposition, rotation and capsular contracture.

Strong clinical trial outcomes. Our clinical trial results demonstrate the safety and effectiveness of our breast implants. Our breast implants were approved by the FDA based on data we collected from our ongoing, long term clinical trial of our breast implants in 1,788 women across 36 investigational sites in the United States. The clinical data we collected over a nine-year follow-up period demonstrated rupture rates, capsular contracture rates and reoperation rates that were comparable to or better than those of our competitors, based on our competitors' published nine-year data.

Innovative services that deliver an improved customer experience. Our Breast Product customer service offerings are intended to accommodate and anticipate the needs of Plastic Surgeons so they can focus on providing better services to their patients. We provide a ten year limited warranty that we believe is the best in the industry based on: providing patients with the largest cash reimbursement for certain out of pocket costs related to revision surgeries in a covered event; a lifetime no charge implant replacement program for covered ruptures; and our industry first C3 Program

through which we offer no charge replacement implants to breast augmentation patients who experience capsular contracture within the first five years after implantation with our smooth or textured breast implants. We also offer specialized educational initiatives and a streamlined ordering, shipping and billing process.

Board certified plastic surgeon focus. We sell our Breast Products exclusively to board certified and board admissible plastic surgeons who are thought leaders in the medical aesthetics industry. We address the specific needs of Plastic Surgeons through continued product innovation, expansion of our product portfolio and enhanced customer service offerings. We believe that securing the loyalty and confidence of Plastic Surgeons is essential to our success and that our association with Plastic Surgeons enhances our credibility and aligns with our focus on making a difference in patients' lives.

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Proven and experienced leadership team. We have a highly experienced management team at both the corporate and operational levels with significant experience in the medical aesthetics industry. Members of our senior management team have extensive experience in the medical aesthetics industry.

Our Strategy

Our objective is to become a leading global provider of differentiated medical aesthetic products and services tailored to meet the needs of physicians, allowing us to deliver on our commitment to enhance and make a difference in patients' lives. We are mainly focused on the breast implant and breast tissue expander markets and our share of them in the United States, and intend to continue to leverage our capabilities into new or complementary aesthetic products or technologies and new geographic markets or market segments. To achieve our objective, we are pursuing the following business strategies:

Create awareness of our differentiated technologies, products and services with Plastic Surgeons and consumers. Since we commenced commercial operations, we have focused most of our marketing efforts on Plastic Surgeons to promote and create awareness of the benefits of our products. Among other marketing programs targeted at Plastic Surgeons, we offer educational initiatives exclusively to Plastic Surgeons through our Sientra Education Forums, and we have continued our consumer-directed efforts, including an exclusive collaboration with RealSelf.com. We believe that continuing to invest in expanding marketing initiatives will have a positive impact on our business.

Selectively pursue acquisitions and expand into new markets. We may continue to selectively pursue domestic and international acquisitions of businesses or technologies that may allow us to leverage our relationships with Plastic Surgeons and our existing commercial infrastructure to provide us with new or complementary products or technologies, and allow us to compete in new geographic markets or market segments or to increase our market share. For example, we began selling bioCorneum® directly to physicians after we acquired bioCorneum® from Enaltus in March 2016. We began selling the AlloX2® and Dermaspan™ lines of breast tissue expanders, and the Softspan™ line of general tissue expanders, after we acquired these product lines from SSP in November 2016.

Broaden our product portfolio and launch new products and services. We plan to continue to develop products that address the unmet needs of Plastic Surgeons and patients by leveraging our innovative technologies in combination with our regulatory and product development expertise. We have a number of new Breast Products under development with different characteristics and configurations. We believe these expanded product choices will allow Plastic Surgeons to potentially achieve better outcomes for their patients.

Enhance our sales capabilities and marketing programs to drive adoption of our products. We intend to increase our direct sales capabilities through the hiring of additional, experienced sales representatives and support staff. We believe that continued expansion of our sales team will allow us to broaden our market reach and educate a broader group of Plastic Surgeons on the benefits of our products.

Invest in clinical studies and peer reviewed articles with key opinion leaders. We intend to continue to invest in clinical studies in order to provide published peer reviewed articles that support the clinical benefits of our products and technologies over those of our competitors. We believe our relationship with Plastic Surgeons and our continued focus on providing differentiated products and services will allow us to leverage our existing capabilities to increase our share of the breast implant market specifically and the medical aesthetics market generally.

Our Products

Our portfolio of products has been specifically tailored to the needs of the physicians we serve. We believe that our broad portfolio of products with technologically differentiated characteristics enable Plastic Surgeons to deliver better

outcomes for their patients.

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Breast Augmentation and Breast Reconstruction Products

Our Breast Products are comprised of breast implants and breast tissue expanders.

Breast Implants. We offer the following breast implants:

- Anatomically shaped textured. A full line of textured, anatomically shaped HSC+ breast implants, all of which incorporate our High Strength Cohesive silicone gel and a textured surface. Our anatomically shaped implants are engineered for shape retention and feature a gradual upper pole slope and distributed volume that mimics the characteristics of a natural breast. They also provide a desired balance between strength, shape retention and softness and are designed to enhance tissue adherence to reduce malposition and capsular contracture. Due to the unique relationship between our implant gel and our implant shells, our anatomically shaped implants have enhanced ability to retain their shape without sacrificing the desired softness. We offer these anatomically shaped implants in three base configurations: Round Base, Classic Base and Oval Base. Our Round Base implants are available in one projection profile and eight volumes, our Classic Base implants are available in one projection profile and eight volumes and our Oval Base implants are available in three projection profiles and 25 volumes. Additionally, in the fourth quarter of 2016, we received FDA approval of 84 new anatomically-shaped devices, a 205% increase of our anatomically-shaped portfolio. Our Round Base implants were approved with an additional projection and 28 new sizes, our Classic Base implants were approved with an additional projection and 32 new sizes and our Oval Base implants were approved with an additional 24 sizes.
- Round textured. A full line of textured, round HSC breast implants, all of which incorporate our High Strength Cohesive silicone gel and textured surface technology. Our textured, round implants maintain softness and are designed to enhance tissue adherence that reduces malposition and capsular contracture. We offer these textured, round implants in three projection profiles: Low, Moderate Plus and High. Our Low projection implants are available in 15 volumes, our Moderate Plus projection implants are available in 22 volumes and our High projection implants are available in 16 volumes. Additionally, in the fourth quarter of 2016, we received approval of an additional projection and 52 more sizes.
- Round smooth. A full line of smooth, round HSC breast implants, all of which incorporate our High Strength Cohesive silicone gel. Our smooth, round implants are designed to deliver full upper pole aesthetic results without compromising softness. We offer these smooth, round implants in five projection profiles: Low, Moderate, Moderate Plus, Moderate High and High. Additionally, in the fourth quarter of 2016, we received FDA approval of 8 more sizes.
- Breast Tissue Expanders. We offer a full line of breast tissue expanders, marketed as AlloX2® and Dermaspan™ in 52 different shapes and sizes. Our AlloX2 is the first and only breast tissue expander with access to the periprosthetic space, with its patented technology, addressing fluid accumulation that can lead to postoperative complications. Our breast tissue expanders are temporary devices used in breast reconstruction and implanted during or after the completion of a mastectomy and intended to aid in the process of recreating tissue coverage to allow for the placement of the final implant to reconstruct the breast.

Scar Management Products

We offer bioCorneum®, the only advanced scar treatment with a patented crosslinking silicone technology, Silishield™, plus the protection of SPF 30. bioCorneum® acts as a quick drying, silicone gel that creates an invisible, breathable and flexible silicone sheet over scars. It is a clinically proven silicone scar technology that prevents and minimizes the formation of hypertrophic and keloid scars, decreases the appearance of old scars, and helps to restore the function of healthy skin. The SPF 30 provides protection from the sun to reduce the sun’s darkening effects on scars. The patented gel helps to safeguard against chemical, microbial, and physical detriments while improving the cosmetic appearance of scar tissue by binding with the stratum corneum (the outer layer of skin cells). bioCorneum® decreases transepidermal water loss and increases the production of fibroblast growth factor to heal skin and prevent abnormal scarring. Additionally, we offer bioCorneum® with Hydrocortisone to relieve itching.

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Other Products

We also offer a range of other aesthetic products that have received 510(k) clearance from the FDA, including:

- temporary, single use, saline filled breast implant sizers that can be used to help identify the correct style and size implant for an individual patient; and
- Softspan™ non breast tissue expanders, which are temporary devices intended to aid in the process of expanding tissue and skin surface area for burn care and other reconstructive use.

Our Technology

Our current portfolio of breast implants utilizes what we believe are the most advanced technologies currently available on the market. These technologies are supported by rigorous product testing, analytics and clinical data. The advanced technologies in our products include:

High Strength Cohesive silicone gel. Our HSC and HSC+ breast implants offer a desired balance between strength, shape retention and softness due to the High Strength Cohesive silicone gel used in our products. The use of High Strength Cohesive silicone gel in our HSC and HSC+ breast implants in conjunction with our silicone shell allows the breast implants to hold a controlled shape while maintaining a soft feel.

The silicone material used in our breast implants has been designed to provide the characteristics desired by Plastic Surgeons for breast implants. At present, we are the only company in the United States that has received FDA approval to use High Strength Cohesive silicone gel in breast implants.

We have completed a number of studies conducted by independent laboratories to demonstrate the competitive advantages of using High Strength Cohesive silicone gel in our breast implants. We believe this technology differentiates our breast implants for the following reasons:

- our implant gel is stronger, which is evidenced by its resistance to gel fracture;
- due to the unique relationship between our implant gel and our implant shells, our implants have an enhanced ability to retain their shape while preserving the shape of anatomically shaped implants without sacrificing the desired softness; and
- our shaped implants are softer and more elastic than our competitors' shaped implants.

We believe the beneficial properties of our implants arise from the characteristics of the gel, as well as the integration of the gel with our implant shell. Inside each of our implants, the gel adheres to the shell, creating additional structural strength and shape retention in the implant. This results in the ability to deliver strength and shaping capability without a stiffer gel or implant and without sacrificing the desired softness. We typically evaluate these characteristics using the following metrics:

- Peel force. Peel force is measured by the amount of force, measured in pound force, or lbf, necessary to separate the outer shell of the implant from the internal gel filling. A greater peel force measurement indicates greater gel shell integration. In the case of anatomically shaped implants, greater peel force can also be an indication of the ability of the implant to retain its shape, particularly the upper portions of the implant, also referred to as the upper pole. Upper pole stability is of particular importance in preserving the desired anatomical shape of an implant over time.
- Gel strength. Gel strength is measured by the amount of force, measured in lbf, required to cause permanent fractures in the gel. A larger value indicates greater strength.
- Gel elasticity and implant elasticity. Gel elasticity and implant elasticity can be measured by the level of resistance, measured in millimeters, or mm, to an applied constant force. A higher value represents greater softness and a lower deformation value represents greater firmness.

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Sientra's Implant Texture. We sell breast implants that are available with a smooth outer surface or a textured outer surface. We believe our textured breast implants offer us clinical advantages over our competitors' textured products, including:

- better tissue adherence to reduce the incidence of malposition and rotation; and
- reduction in the rate of capsular contracture, a complication in which the patient's body creates a scar tissue capsule around the implant that can tighten and squeeze the implant potentially causing discomfort, pain and even dislocation of the implant. While we have neither sought nor obtained FDA approval to state that our breast implants reduces the incidence of capsular contracture, we believe it may significantly reduce this risk, as evidenced by the lower rates of capsular contraction reported over a nine year follow up period in our ongoing clinical trial.

On a breast implant, the desired texture should have a proportionate amount of surface disruption, as overly aggressive texture can result in double capsule formation while not enough texturing can result in a lack of adherence resulting in malposition or rotation. We believe that our textured implants have the right combination of surface disruption without overly aggressive texturing.

By incorporating High Strength Cohesive silicone gel and our texturing into our breast implants, we believe we have a competitive advantage in marketing and differentiating our products to Plastic Surgeons.

Our Clinical Data

In 2012, our breast implants were approved by the FDA based on data we collected from our ongoing, long term clinical trial of our breast implants in 1,788 women across 36 investigational sites in the United States, which included 3,506 implants (approximately 53% of which were smooth and 47% of which were textured). Our clinical trial results demonstrate the safety and effectiveness of our breast implants and provide Plastic Surgeons and their patients the security and confidence to choose our products.

Our clinical trial is the largest prospective, long term safety and effectiveness pivotal study of breast implants in the United States and included the largest magnetic resonance imaging, or MRI, cohort with 571 patients. The MRI cohort is a subset of study patients that underwent regular MRI screenings in addition to the other aspects of the clinical trial protocol prior to FDA approval. Post-approval, all patients in the long-term clinical trial are subject to serial MRI screening as part of the clinical protocol. The clinical data we collected over a nine year follow up period demonstrated rupture rates, capsular contracture rates and reoperation rates that were comparable to or better than those of our competitors, at similar time points. In addition to our pivotal study, our clinical data is supported by our Continued Access Study of 2,497 women in the United States. We have also commissioned a number of bench trials run by independent laboratories that we believe further demonstrate the advantages of our breast implants over those of our competitors.

We and our two competitors were required to run independent ten year clinical studies to obtain PMA approval from the FDA. Our clinical study was not designed to facilitate head to head comparisons. However, our clinical data and our competitors' clinical data are publicly available to both surgeons and patients who are able to use such data to compare and contrast competing implants.

Our Services

Our services are designed to cater to the specific needs of Plastic Surgeons to enable them to maintain and grow their practices. We provide our Plastic Surgeons with superior warranty programs, enhanced customer service offerings and specialized educational initiatives. We believe that tailoring our customer service offerings to Plastic Surgeons helps secure their loyalty and confidence.

Industry Leading Product Programs and Warranties. Through our C3 Program, we provide no charge replacement implants to patients who experience capsular contracture in the first five years following primary breast augmentation. We provide this benefit to every patient implanted with our smooth or textured breast implants. We also provide a ten year limited warranty that we believe is the best in the industry, based on providing patients with the largest cash reimbursement for certain out of pocket costs related to revision surgeries in a covered event and a lifetime no charge implant replacement program for covered ruptures.

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Enhanced Customer Service. As we focus primarily on Plastic Surgeons and their patients, we believe we are able to tailor our customer service offerings to their specific needs. Our surgeon facing customer service policies include:

- simplified account setup through our sales representatives with pre qualification and pre approved credit terms;
- no charge shipping to and from accounts;
- six month pre approved returns of unused products with no charge return shipping and no restocking fees;
- end of month statement billing, rather than one invoice per shipment, and 30 day payment terms;
- individualized consignment inventory; and
- order acceptance by phone, fax, email or through our sales representatives.

Educational and Marketing Initiatives. We have implemented educational and marketing initiatives with a focus on both Plastic Surgeons and their patients considering breast augmentation or reconstruction.

Plastic Surgeons. In order to educate Plastic Surgeons about our product lines and, in particular, about the proper use of our anatomically shaped breast implants, we provide a variety of education programs for Plastic Surgeons under the banner of the Sientra Education Forum. To date:

- we have developed a tablet based mobile marketing tool for our sales representatives to use while calling on accounts that includes access to our patient and surgeon labeling, published clinical studies, marketing literature, details on our warranty and C3 programs, our educational iBooks and more.
- we host symposia with one or more key note speakers who speak on topics ranging from our corporate identity and customer service offerings to surgical tips and suggestions from thought leading Plastic Surgeons.
- we produce comprehensive guides for Plastic Surgeons via the Internet, referred to as iBooks, to provide them training and expertise on the implantation of anatomically shaped breast implants.
- we send a limited number of Plastic Surgeons to Europe to observe surgeries and train with world renowned surgeons who have been implanting anatomically shaped breast implants for decades and, upon return to the United States, we engage them as consultant educators to conduct training sessions for other U.S. based Plastic Surgeons.
- we periodically sponsor educational surgical preceptorships where a small group of Plastic Surgeons are able to observe a live surgery conducted by one of our trained preceptors and train with that preceptor.

Patients. We have been engaging directly with consumers who are considering breast augmentation or reconstruction. We initially focused our consumer educational and marketing activities on websites where consumers come to research their breast augmentation or reconstruction options, including:

- our own consumer website, branded with our “Feel So Good” campaign, that provides resources for consumers considering breast augmentation or reconstruction, including referrals and commentaries, product descriptions, patient planning guides and educational brochures and information regarding our rupture warranty and C3 programs; and
- our exclusive collaboration with RealSelf, the leading online community helping people make confident choices in elective cosmetic procedures. Together with RealSelf, we deliver fresh and meaningful content to the RealSelf community that answers common questions patients have regarding breast augmentation. This content is featured on a dedicated Sientra page on RealSelf’s website designed to build consumer engagement with the brand and open up the online conversation around breast augmentation directly with Plastic Surgeons.

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We believe that our innovative services, including industry leading product programs and warranties, enhanced customer service offerings and educational and marketing initiatives, deliver an improved customer experience to Plastic Surgeons and their patients.

Sales and Marketing

As of December 31, 2016, we had a sales organization of 43 employees, including 36 sales representatives and 7 sales managers. We assign sales territories based on the regions with the highest concentration of accounts. Our sales team is supported by customer and sales experience teams, which provide full time telephonic and email customer support to our sales representatives and customers.

In addition, our marketing team leads our efforts in brand development, trade show attendance, educational forums, product messaging, website development and advertising, among others.

Research and Development

We have incurred, and expect to continue to incur, significant research and development expenses. Our research and development expenses were approximately $9.7 million, $7.2 million and $4.7 million for the years ended December 31, 2016, 2015 and 2014, respectively. Our research and development is focused on enhancing and improving our Breast Products, increasing our breast implant portfolio, product development related activities and expanding into synergistic markets. We believe research and development is important to the success of the Company as we continue to develop and expand our product portfolio.

Manufacturing and Quality Assurance

We hold an FDA Medical Device Establishment Registration. All of our medical device products are listed under our Device Listing where it indicates we are the specification developer of our products, and except for our breast implant sizers, we are the owner of our products' FDA approvals and clearances. This means that we are primarily responsible for the design, manufacturing and quality assurance of our products. However, we do not manufacture our products ourselves. Instead, we rely on our third-party manufacturers to manufacture and package our silicone gel breast implants, tissue expanders and other products to our specifications. When we receive our products from our third-party manufacturers, we inspect a representative sample of packaging and labeling prior to shipping them to our customers. We typically maintain strategic levels of inventory at our storage facilities located in Santa Barbara, California. As a result of the events with Silimed, currently all of the remaining inventory we received from Silimed is located at this storage facility.

We, along with our third-party manufacturers are subject to the FDA's Quality System Regulation, or QSR, reporting requirements and current Good Manufacturing Practices, or cGMP, audits by the FDA. Under the QSR and cGMP requirements, manufacturers, including third-party manufacturers, must follow stringent design, testing, production, control, supplier and contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process. The FDA has regularly inspected both the Company and Silimed. The FDA has never found the Company or Silimed to be in violation of any part of the Federal Food, Drug and Cosmetic Act, or FDCA.

Historically, all of our silicone gel breast implants were manufactured by Silimed pursuant to an amended and restated exclusivity agreement with Silimed, which we refer to as the Silimed Agreement. Several events have occurred which have affected our supply of silicone gel breast implants. These events include the suspension of Silimed's CE and ISO 13485 certificate by TÜV SÜD followed by a suspension by the Brazilian regulatory agency ANVISA and the Department of the Secretary of State of Rio de Janeiro of the manufacturing and shipment of all medical devices made

by Silimed, including products manufactured for Sientra, and the Silimed manufacturing facility where Sientra breast implants were manufactured was damaged by a fire on October 22, 2015. As a result of the suspensions, between October 9, 2015 and March 1, 2016, we voluntarily placed a temporary hold on the sale of all Sientra devices manufactured by Silimed and recommended that plastic surgeons discontinue implanting the devices until further notice. On March 1, 2016, after ongoing discussions with the FDA and our own review of the matter with the assistance of independent experts in quality management systems, GMP and data-based risk assessment, we lifted this temporary hold on sale and informed our Plastic Surgeons of our controlled market re-entry plan designed to optimize our inventory supply, which continues to be limited. The events involving Silimed will likely continue to adversely impact our business, in particular due to the limitations on our existing inventory levels, the uncertainty of our customers' responsiveness to our controlled market re-entry plan, the fact that Silimed filed a lawsuit against us alleging, among other things, a material breach of the existing manufacturing

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contract, and the fact that the manufacturing contract with Silimed expires on its terms on April 1, 2017. See "Risk Factors — Risks Relating to Our Business and Our Industry" for further detail.

Pursuant to the Silimed Agreement, in the event Silimed fails to supply products ordered by us, we may, under certain circumstances, exercise manufacturing rights to manufacture the products directly or through a third-party manufacturer. Silimed also granted to us an exclusive, royalty free, non transferable license to use certain of its trademarks in the United States and Canada, which we refer to as the Territory, including in the event Silimed fails to supply the products to us and in connection with the marketing and sale of the products in the Territory. In addition, the Silimed Agreement addresses intellectual property rights, including that the parties will jointly own all developments, modifications, enhancements or alterations of products jointly created by the parties, subject to certain restrictions concerning the use of such improvements outside of the Territory. Each party is subject to certain limitations and other restrictions on the transfer of the other party's technology to third parties.

In response to these events and anticipated impacts on our business, we have increasingly focused our efforts on securing and qualifying an alternate manufacturing supplier. On August 9, 2016, we announced our collaboration with Vesta, pursuant to which we are working with Vesta towards establishing a dedicated contract manufacturing facility for our breast implants. On March 14, 2017, we announced that we had executed a definitive manufacturing agreement with Vesta for the manufacture and supply of our breast implants. In addition, on March 14, 2017, we announced that we had submitted a PMA supplement to the FDA for the manufacturing of our PMA-approved breast implants by Vesta.

Competition

The medical device industry is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products or other market activities of industry participants. We primarily compete with two companies that manufacture and sell breast implants in the United States: Johnson & Johnson through its wholly owned subsidiary, Mentor Worldwide, LLC, or Mentor, and Allergan plc, or Allergan.

Both of our U.S. competitors are either publicly traded companies or divisions or subsidiaries of publicly traded companies with significantly more market share and resources than we have. These companies have greater financial resources for sales, marketing and product development, broader established relationships with healthcare providers and third party payors, and larger and more established distribution networks. In some instances, our competitors also offer products that include features that we do not currently offer. For example, Allergan sells temporary gel sizers for silicone gel implants and we sell only temporary saline filled sizers. In addition, our competitors may offer pricing programs with discounts across their non breast aesthetic product portfolios.

We also face potential future competition from a number of companies, medical researchers and existing medical device companies that may be pursuing new implant technologies, new material technologies and new methods of enhancing and reconstructing the breast.

We believe the primary competitive factors in our markets include:

- breadth of portfolio;
- technological characteristics of products;
- clinical evidence;
- product price;
- customer service; and
- support by key opinion leaders.

Government Regulation

Our products are subject to extensive regulation by the FDA and other federal and state regulatory authorities, Health Canada and, if we commence international sales outside of the United States and Canada, other regulatory bodies in other countries.

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Regulation by the FDA. The Federal Food, Drug and Cosmetic Act, or FDCA, and the FDA's implementing regulations govern, among other things:

- product design and development;
- pre clinical and clinical testing;
- establishment registration and product listing;
- product manufacturing;
- product labeling and storage;
- pre market clearance or approval;
- post market studies;
- advertising and promotion;
- product sales and distribution;
- record-keeping and device tracking;
- complaint handling;
- recalls and field safety corrective actions; and
- post market surveillance and adverse event reporting, including reporting of deaths, serious injuries or device malfunctions.

Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States will require either a pre market notification to the FDA requesting permission for commercial distribution under Section 510(k) of the FDCA, also referred to as a 510(k) clearance, or approval from the FDA of a PMA application. Both the 510(k) clearance and PMA approval processes can be expensive, lengthy and require payment of significant user fees, unless an exemption is available.

The FDA classifies medical devices into one of three classes. Unless specifically exempted from certain requirements, all three classes of devices are subject to general controls such as labeling, pre market notification and adherence to the FDA's QSR, which cover manufacturers' methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of products. Devices deemed to pose low to moderate risk are placed in Class I or II, which, absent an exemption, requires the applicant to obtain a 510(k) clearance. Class II devices are subject to special controls such as performance standards, post market surveillance, FDA guidelines, or particularized labeling requirements, as well as general controls. Some low risk devices are exempted by regulation from the 510(k) clearance requirement, and/or the requirement of compliance with substantially all of the QSR. A PMA application is required for devices deemed by the FDA to pose the greatest risk, such as life sustaining, life supporting or certain implantable devices, including all breast implants, or devices that are "not substantially equivalent" either to a device previously cleared through the 510(k) process or to a "preamendment" Class III device in commercial distribution in the United states before May 28, 1976 for which a regulation requiring a PMA application has not been issued by the FDA.

Our tissue expanders and our body contouring, facial and nasal implants received FDA clearance as Class II devices at various dates prior to approval of our breast implants in March 2012. To obtain 510(k) clearance, we must submit a pre market notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or a preamendment device. The FDA's 510(k) clearance pathway usually takes from three to 12 months from the date the application is completed, but it can take significantly longer and clearance is never assured. Although many 510(k) pre market notifications are cleared without clinical data, in some cases, the FDA requires significant clinical

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data to support substantial equivalence. In reviewing a pre market notification, the FDA may request additional information, including clinical data, which may significantly prolong the review process. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination regarding whether a new pre market submission is required for the modification of an existing device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained. If the FDA requires us to seek 510(k) clearance or approval of a PMA application for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. In addition, in these circumstances, we may be subject to significant regulatory fines or penalties for failure to submit the requisite 510(k) clearance(s) or PMA application(s). In addition, the FDA is currently evaluating the 510(k) process and may make substantial changes to industry requirements.

Silicone gel breast implants are treated as Class III devices and a full PMA is required. A PMA for our breast implants was approved by the FDA in March 2012. The PMA application process is generally more costly and time consuming than the 510(k) process and requires proof of the safety and effectiveness of the device to the FDA's satisfaction. Accordingly, a PMA application must be supported by valid scientific evidence that typically includes, but is not limited to, extensive information regarding the product, including pre clinical, clinical, and other product data to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. After a PMA application is submitted and found to be sufficiently complete, the FDA begins an in depth review of the submitted information. By statute, the FDA has 180 days to review the "accepted application," although, generally, review of the application takes between one and three years, but may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA generally will conduct a pre approval inspection of the intended manufacturing facility to evaluate compliance with QSR, which requires manufacturers to implement and follow elaborate design, testing, control, documentation and other quality assurance procedures in the device design and manufacturing process.

The FDA may approve a PMA application with post approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution and collection of long term follow up data from patients in the clinical study that supported approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval. New PMA applications or PMA supplements are required for significant modifications to the manufacturing process, labeling and design of a device that could affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. PMA supplements often require submission of the same type of information as a PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

Clinical Trials. A clinical trial is almost always required to support a PMA application and may be required for a 510(k) pre market notification. In the United States, absent certain limited exceptions, human clinical trials intended to support product clearance or approval require an Investigational Device Exemption, or IDE, application. Some types of studies deemed to present "non significant risk" are deemed to have an approved IDE once certain requirements are addressed and institutional review board, or IRB, approval is obtained. If the device presents a "significant risk" to human health, as defined by the FDA, the Sponsor must submit an IDE application to the FDA and obtain IDE

approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to evaluate the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of subjects, unless the product is deemed a non significant risk device and eligible for more abbreviated IDE requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the responsible institutional review boards at the clinical trial sites. There can be no assurance that submission of an IDE will result in the ability to commence clinical trials. Additionally, after a trial begins, the FDA may place it on hold or terminate it if, among other reasons, it concludes that the clinical subjects are exposed to unacceptable health risks that outweigh the benefits of participation in the study. During a study, we are required to comply with the FDA's IDE requirements for investigator

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selection, clinical trial monitoring, reporting, record keeping and prohibitions on the promotion of investigational devices or making safety or efficacy claims for them. We are also responsible for the appropriate labeling and distribution of investigational devices. Our clinical trials must be conducted in accordance with FDA regulations and federal and state regulations concerning human subject protection, including informed consent and healthcare privacy. The investigators must also obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices and comply with all reporting and record-keeping requirements. The FDA's grant of permission to proceed with clinical testing does not constitute a binding commitment that the FDA will consider the study design adequate to support clearance or approval. In addition, there can be no assurance that the data generated during a clinical study will meet chosen safety and effectiveness endpoints or otherwise produce results that will lead the FDA to grant marketing clearance or approval.

Other Regulatory Requirements. Even though our breast implants have been approved and commercialized, numerous regulatory requirements apply after a device is placed on the market, regardless of its classification or pre market pathway. These include, but are not limited to:

- establishment registration and device listing with the FDA;
- QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, production, control, supplier and contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations that prohibit the promotion of products for uncleared or unapproved, or "off label," uses, and impose other restrictions on labeling, advertising and promotion;
- medical Device Reporting, or MDR, 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
- corrections and removals reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health. In addition, the FDA may order a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death.

The FDA requires us to conduct post market surveillance studies and to maintain a system for tracking our breast implants through the chain of distribution to the patient level. The FDA enforces regulatory requirements by conducting periodic, unannounced inspections and market surveillance. Inspections may include the manufacturing facilities of our subcontractors.

Failure by us or our manufacturer to comply with applicable regulatory requirements can result in enforcement actions by the FDA and other regulatory agencies. These may include, but may not be limited to, any of the following sanctions or consequences:

- warning letters or untitled letters that require corrective action;
- fines and civil penalties;
- unanticipated expenditures;
- delays in or refusal to grant requests for 510(k) clearance or pre market approval of new products or modified products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries;
- suspension or withdrawal of FDA clearance or approval;
- product recall, detention or seizure;

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- operating restrictions, partial suspension or total shutdown of production;
- injunctions and consent decrees; and
- criminal prosecution.

We and our contract manufacturers and some suppliers of components or device accessories also are required to manufacture our products in compliance with cGMP requirements set forth in the QSR. The QSR requires a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of marketed devices, and it includes extensive requirements with respect to quality management and organization, device design, buildings, equipment, purchase and handling of components or services, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing, and record keeping. The FDA evaluates compliance with the QSR through periodic, unannounced inspections that may include the manufacturing facilities of our subcontractors. If the FDA believes that we or any of our contract manufacturers or regulated suppliers are not in compliance with these requirements, it can shut down our manufacturing operations, require recall of our products, refuse to approve new marketing applications, institute legal proceedings to detain or seize products, enjoin future violations or assess civil and criminal penalties against us or our officers or other employees.

Healthcare Regulatory Laws. Our business activities, including but not limited to, research, sales, marketing, promotion, distribution, medical education and other activities are subject to regulation under additional healthcare laws by numerous regulatory and enforcement authorities in the United States, in addition to the FDA. These laws include, without limitation, state and federal anti kickback, false claims, physician sunshine, and patient data privacy and security laws and regulations, including but not limited to those described below.

Additionally, our relationships with healthcare providers and other third parties are subject to scrutiny under these laws. Non compliance with the laws described below may generally result in the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any actions for non compliance of such laws can be costly, time consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Federal Anti Kickback Law. The federal Anti Kickback Statute prohibits, among other things, knowingly or willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase, recommendation, order or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. The definition of “remuneration” has been broadly interpreted to include anything of value, including such items as improper payments, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, waiver of payments and providing anything at other than its fair market value. There are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case by case basis based on a cumulative review of all of its facts and circumstances.

The penalties for violating the federal Anti Kickback Statute include imprisonment for up to five years, fines of up to $25,000 per violation and possible exclusion from federal healthcare programs such as Medicare and Medicaid. Further, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to commit a violation. Rather, if “one purpose” of the remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. In addition, a claim including items or services resulting from a violation of the federal

Anti Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act, or FCA.

We have entered into consulting, speaker and other financial arrangements with physicians, including some who prescribe or recommend our products to patients. We engage such physicians as consultants, advisors and to educate other physicians. Noncompliance with the federal Anti Kickback Statute could result in the penalties set forth above.

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Federal Civil False Claims Act. The FCA prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim to the federal government. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. Manufacturers can be held liable under the FCA if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off label. Penalties for FCA violations include three times the actual damages sustained by the government, plus mandatory civil penalties of between $10,781.40 and $21,562.80 for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the federal FCA is a civil statute, FCA violations may also implicate various federal criminal statutes.

In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud, known as "qui tam", or whistleblower, lawsuits. Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government intervenes and is ultimately successful in obtaining redress in the matter, or if the plaintiff succeeds in obtaining redress without the government's involvement, then the plaintiff will receive a percentage of the recovery. Qui tam actions have increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a false claim action, pay fines or be excluded from Medicare, Medicaid or other federal or state healthcare programs as a result of an investigation arising out of such action.

Federal Criminal False Claims Laws. The federal criminal false claims laws prohibit, among other things, knowingly and willfully making, or causing to be made, a false statement or representation of a material fact for use in determining the right to any benefit or payment under a federal health care program. A violation of these laws may constitute a felony or misdemeanor and may result in fines or imprisonment.

Civil Monetary Penalties Law. The federal Civil Monetary Penalties Law prohibits, among other things, the offering or transferring of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of Medicare or Medicaid payable items or services. Noncompliance with such beneficiary inducement provision of the federal Civil Monetary Penalties Law can result in civil money penalties of up to $10,000 for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the federal healthcare programs.

Health Insurance Portability and Accountability Act of 1996. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, augmented two federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from governmental programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, including the Final HIPAA Omnibus Rule published on January 25, 2013, mandates, among other things, that certain types of entities and individuals adopts uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes certain of HIPAA's standards and requirements directly applicable to "business associates"—independent contractors or agents of covered entities that create, receive or obtain 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 and business associates, and gave state attorneys general new 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, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties.

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Physician Payments Sunshine Act. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, PPACA, imposed, among other things, new annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, for certain payments and "transfers of value" provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately, and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1 million per year for "knowing failures," for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission. We are required to report detailed payment data and submit legal attestation to the accuracy of such data by March 31st of each calendar year.

In addition, there has been a recent trend of increased federal and state regulation of payments and other transfers of value provided to healthcare professionals and entities. Similar to the federal law, certain states also have adopted marketing and/or transparency laws relevant to device manufacturers, some of which are broader in scope. Certain states, such as California and Connecticut, also mandate that device manufacturers implement compliance programs. Other states, such as Massachusetts and Vermont, impose restrictions on device manufacturer marketing practices and require tracking and reporting of gifts, compensation, and other remuneration to healthcare professionals and entities. The need to build and maintain a robust compliance program with different compliance and/or reporting requirements increases the possibility that a healthcare company may violate one or more of the requirements, resulting in fines and penalties

Additional State Healthcare Laws. Many states have also adopted some form of each of the aforementioned laws, some of which may be broader in scope and may apply regardless of payor. Nevertheless, a determination of liability under such laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions.

Additionally, as some of these laws are still evolving, we lack definitive guidance as to the application of certain key aspects of these laws as they relate to our arrangements with providers with respect to patient training. We cannot predict the final form that these regulations will take or the effect that the final regulations will have on us. As a result, our provider and training arrangements may ultimately be found to be not in compliance with applicable laws.

United States Foreign Corrupt Practices Act. The United States Foreign Corrupt Practices Act, or FCPA, prohibits United States corporations and their representatives from offering, promising, authorizing or making corrupt payments, gifts or transfers to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA would include interactions with certain healthcare professionals in many countries.

International Regulation. We may evaluate international expansion opportunities in the future. International sales of medical devices are subject to local government regulations, which may vary substantially from country to country. The time required to obtain approval in another country may be longer or shorter than that required for FDA approval, and the requirements may differ. There is a trend towards harmonization of quality system standards among the European Union, United States, Canada and various other industrialized countries.

The primary regulatory body in Europe is that of the European Union, which includes most of the major countries in Europe. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. The European Union has adopted numerous directives and 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 the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be

commercially distributed throughout Europe. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self assessment by the manufacturer and a third party assessment by a "Notified Body." This third party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's product. An assessment by a Notified Body of one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union. Additional local requirements may apply on a country by country basis. Outside of the European Union, regulatory approval would need to be sought on a country by country basis in order for us to market our products.

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Coverage and Reimbursement. Sales of our products depend, in part, on the extent to which the procedures using our products will be covered by third party payors, such as government health care programs, commercial insurance and managed healthcare organizations. Breast augmentation procedures are generally performed on a cash pay basis and are not covered by third party payors. In contrast, breast reconstruction procedures may be covered by third party payors, but such third party payors are increasingly limiting coverage and reducing reimbursements for medical products and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost containment programs, including price controls, restrictions on coverage and reimbursement. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical drug products and medical services, in addition to questioning their safety and efficacy. Adoption of price controls and cost containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net sales and results.

Moreover, the process for determining whether a third-party payor will provide coverage for a product or procedure may be separate from the process for establishing the reimbursement rate that such a payor will pay for the product or procedure. A payor's decision to provide coverage for a product or procedure does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product or procedure does not assure that other payors will also provide coverage for the product or procedure. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to ensure profitability.

Health Reform. The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our business. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access.

By way of example, in the United States, the PPACA is an example of a reform measure with the potential to substantially change healthcare financing and delivery by both governmental and private insurers, and significantly impact the pharmaceutical and medical device industries. The PPACA imposed, among other things, a new federal excise tax of 2.3% on certain entities that manufacture or import medical devices for sale in the United States and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. The medical device excise tax has been suspended by the Consolidated Appropriations Act of 2016, or the CAA, with respect to medical device sales during calendar years 2016 and 2017. Absent further Congressional action, this excise tax will be reinstated for medical device sales beginning January 1, 2018. The CAA also temporarily delays implementation of other taxes intended to help fund PPACA programs.

The full impact of the PPACA on our business remains unclear. There have been judicial and Congressional challenges to certain aspects of the PPACA, and we expect there will be additional challenges and amendments in the future. In January, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the PPACA. The Budget Resolution is not a law; however, it is widely viewed as the first step toward the passage of repeal legislation. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the PPACA that are repealed.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint

Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, following passage of the Bipartisan Budget Act of 2015, and will stay in effect through 2025 unless Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, further reduced Medicare payments to several providers, including hospitals.

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We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Intellectual Property and Proprietary Rights

We believe that in order to maintain a competitive advantage in the marketplace, we must develop and maintain protection of the proprietary aspects of our product lines. We rely on a combination of trademarks, trade secrets, confidential information, copyrights, patent rights and other intellectual property rights to protect our intellectual property. Our trademark portfolio consists of seven registered U.S. trademarks.

In addition, to protect our trade secrets, confidential information and other intellectual property rights, we have entered into confidentiality agreements with third parties, and confidential information and invention assignment agreements with employees, consultants and advisors.

There are risks related to our intellectual property rights. For further details on these risks, see Item 1A — “Risk Factors.”

Employees

As of December 31, 2016, we had 89 full time employees. None of our employees are represented by a collective bargaining agreement, and we have never experienced any work stoppage. We believe we have good relations with our employees.

Facilities

Our headquarters located in Santa Barbara, California is approximately 20,000 square feet. The term of the lease for our headquarters expires in February 2020. We also lease warehouse space located in Santa Barbara, California, which is approximately 10,000 square feet. The term of the lease for our warehouse expires in January 2019.

Legal Proceedings

From time to time, we are involved in legal proceedings and regulatory proceedings arising out of our operations. We establish reserves for specific liabilities in connection with legal actions that we deem to be probable and estimable. The ability to predict the ultimate outcome of such matters involves judgments, estimates, and inherent uncertainties. The actual outcome of such matters could differ materially from management’s estimates.

Class Action Shareholder Litigation

On September 25, 2015, a lawsuit styled as a class action of the Company’s stockholders was filed in the United States District Court for the Central District of California. The lawsuit names the Company and certain of our officers as defendants, or the Sientra Defendants, and alleges violations of Sections 10(b) and 20(a) of the Exchange Act in connection with allegedly false and misleading statements concerning the Company’s business, operations, and prospects. The plaintiff seeks damages and an award of reasonable costs and expenses, including attorneys’ fees. On November 24, 2015, three stockholders (or groups of stockholders) filed motions to appoint lead plaintiff(s) and to approve their selection of lead counsel. On December 10, 2015, the court entered an order appointing lead plaintiffs and approving their selection of lead counsel. On February 19, 2016, lead plaintiffs filed their consolidated amended complaint, which added claims under Sections 11, 12(a)(2), and 15 of the Securities Act and named as defendants the

underwriters associated with the Company's follow-on public offering that closed on September 23, 2015, or the Underwriter Defendants. On March 21, 2016, the Sientra Defendants and the Underwriter Defendants each filed a motion to dismiss, or the Motions to Dismiss, the consolidated amended complaints. On April 20, 2016, lead plaintiffs filed their opposition to the Motions to Dismiss, and the Sientra Defendants and Underwriter Defendants filed separate replies on May 5, 2016. On June 9, 2016, the court granted in part and denied in part the Motions to Dismiss. On July 14, 2016, the Sientra Defendants moved the court to reconsider its June 9, 2016 order and grant the Motions to Dismiss in full. On August 4, 2016, lead plaintiffs filed an opposition to the motion for reconsideration. On August 12, 2016, the court denied the motion for reconsideration, and the Sientra Defendants and the Underwriter Defendants each filed an answer to the consolidated amended complaint.

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On October 28, November 5, and November 19, 2015, three lawsuits styled as class actions of the Company's stockholders were filed in the Superior Court of California for the County of San Mateo. The lawsuits name the Company, certain of our officers and directors, and the underwriters associated with our follow-on public offering that closed on September 23, 2015 as defendants. The lawsuits allege violations of Sections 11, 12(a)(2), and 15 of the Securities Act in connection with allegedly false and misleading statements in our offering documents associated with the follow-on offering concerning our business, operations, and prospects. The plaintiffs seek damages and an award of reasonable costs and expenses, including attorneys' fees. On December 4, 2015, defendants removed all three lawsuits to the United States District Court for the Northern District of California. On December 15 and December 16, 2015, plaintiffs filed motions to remand the lawsuits back to San Mateo Superior Court, or Motions to Remand. On January 19, 2016, defendants filed their opposition to the Motions to Remand, and plaintiffs filed their reply in support of the Motions to Remand on January 26, 2016.

On May 20, 2016, the United States District Court for the Northern District of California granted plaintiffs' Motions to Remand, and the San Mateo Superior Court received the remanded cases on May 27, 2016. On July 19, 2016, the San Mateo Superior Court consolidated the three lawsuits. On August 2, 2016, plaintiffs filed their consolidated complaint. On August 5, 2016, defendants filed a motion to stay all proceedings in favor of the class action filed in the United States District Court for the Central District of California.

On September 13, 2016, the parties to the actions pending in the San Mateo Superior Court and the United States District Court for the Central District of California signed a memorandum of understanding that sets forth the material deal points of a settlement that covers both actions and includes class-wide relief. On September 13, 2016, and September 20, 2016, respectively, the parties filed notices of settlement in both courts. On September 22, 2016, the United States District Court for the Central District of California stayed that action pending the court's approval of a settlement. On September 23, 2016, the San Mateo Superior Court stayed that action as well as pending the court's approval of a settlement.

On December 20, 2016, the plaintiffs in the federal court action filed a motion for preliminary approval of the class action settlement. On January 23, 2017, the United States District Court for the Central District of California preliminarily approved the settlement. A final approval hearing in that court is scheduled for May 22, 2017. On January 5, 2017, the plaintiffs in the state court action also filed a motion for preliminary approval of the class action settlement. On February 7, 2017, the San Mateo Superior Court preliminarily approved the settlement. A final approval hearing in that court is scheduled for May 31, 2017. The settlement is contingent upon final approval by both the San Mateo Superior Court and the United States District Court for the Central District of California.

As a result of these developments, we have determined that a probable loss has been incurred and we have recognized a net charge to earnings of approximately $1.6 million within general and administrative expense, which is comprised of the loss contingency of approximately $10.9 million, net of expected insurance proceeds of approximately $9.4 million. We have classified the loss contingency as "legal settlement payable" and the expected insurance proceeds as "insurance recovery receivable" on the accompanying condensed balance sheets. While it is possible that we may incur a loss greater than the amounts recognized in the accompanying interim financial statements, we are unable to determine a range of possible losses greater than the amount recognized.

Silimed Litigation

On November 6, 2016, Silimed filed a lawsuit in the United States District Court for the Southern District of New York naming Sientra as the defendant and alleging breach of contract of the Silimed Agreement, unfair competition and misappropriation of trade secrets against us. In its complaint, Silimed alleges that our theft, misuse, and improper disclosure of Silimed's confidential, proprietary, and trade secret manufacturing information was done in order for us to develop our own manufacturing capability that we intend to use to manufacture our PMA-approved products.

Silimed is seeking a declaration that we are in material breach of the Silimed Agreement, a preliminary and permanent injunction to prevent our allegedly wrongful use and disclosure of Silimed's confidential and proprietary information, as well as unquantified compensatory and punitive damages. On November 15, 2016, Sientra filed its answer and counterclaims for declaratory judgment in which it denied that Silimed is entitled to any relief including, among other reasons, because of Silimed's material breach of the Silimed Agreement and Silimed's unclean hands, and further seeks declaratory relief that Sientra is the owner of certain assets it acquired from Silimed, Inc. in 2007, that Sientra owns, or is exclusively licensed, to any improvements created since April 2007, that Silimed lacks any confidential information or proprietary rights under the Silimed Agreement, and that Silimed lacks any relevant trade secret rights. On December 9, 2016, Silimed filed a motion to strike the Company's counterclaims. Briefing on that motion was completed on December 30, 2016, and the

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parties are waiting for a decision from the court. On February 1, 2017, Sientra filed a motion to stay Silimed's breach of contract claim in light of a demand for arbitration filed by Sientra against Silimed on January 20, 2017 concerning Silimed's material breaches of the Silimed Agreement, and to further dismiss, or alternatively stay, the unfair competition and misappropriation of trade secrets claims. Briefing on that motion was completed on February 22, 2017, and the parties are waiting for a decision from the court. On February 3, 2017, the court held an initial pre-trial conference and entered a pre-trial scheduling order which set a final pre-trial conference date of August 3, 2018. We believe that Silimed's claims are legally and factually unsupported and intend to defend this lawsuit vigorously.

On January 20, 2017, Sientra filed an arbitration demand in the International Center for Dispute Resolution in New York naming Silimed as the defendant and alleging material breach of the Silimed Agreement, gross negligence and tortious interference by Silimed, as well as seeking certain declaratory relief. Among other things, Sientra alleges that Silimed's supply failure constitutes a material breach of the Silimed Agreement, and that such breach was caused by Silimed's grossly negligent or other willful conduct related to its regulatory suspensions and the fire at its manufacturing facility. Silimed filed its answer to Sientra's arbitration demand on March 8, 2017. The parties nominated their party arbitrators on March 13, 2017.

Seasonality

Typically, we experience fluctuations in revenue from quarter to quarter due to seasonality. We believe that breast implant sales are subject to seasonal fluctuation due to breast augmentation patients' planning their surgery leading up to the summer season and in the period around the winter holiday season.

Corporate Information

We incorporated in Delaware on August 29, 2003 under the name Juliet Medical, Inc. and subsequently changed our name to Sientra, Inc. in April 2007. Our principal executive offices are located at 420 South Fairview Avenue, Suite 200, Santa Barbara, California, 93117, and our telephone number is (805) 562 3500. Our website is located at www.sientra.com, and our investor relations website is located at http://investors.sientra.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, reports on Form 8-K and our Proxy Statements are available through our investor relations website, free of charge, as soon as reasonably possible after we file them with the SEC.

Item 1A. Risk Factors

You should carefully consider the following risk factors, as well as the other information appearing elsewhere in this Annual Report on Form 10-K, including our financial statements and related notes, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business.

Risks Relating to Our Business and Our Industry

We may not be able to procure and qualify a new manufacturer for our silicone gel breast implants and other products previously manufactured by Silimed.

Our existing manufacturing contract with Silimed expires on its terms on April 1, 2017, and we do not intend to renew it. Moreover, our existing inventory of breast implants that were previously manufactured by Silimed is limited and we do not currently anticipate any future inventory purchases from Silimed.

Although we have entered into a definitive manufacturing agreement with Vesta, Vesta has not yet been qualified as a manufacturer to source our implants. We recently submitted a PMA supplement to the FDA for the manufacturing of our PMA-approved implants by Vesta, but the timing of when we may obtain FDA approval, if any, could be subject to delays, some of which are beyond our control. Moreover, Vesta, or any other alternate manufacturer, would need to be qualified with the FDA, which is an expensive and time-consuming process. Any delays or our inability to qualify Vesta or negotiate a manufacturing agreement and qualify another alternate manufacturer could result in a supply interruption, which would materially adversely affect our business, financial condition and results of operations.

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We are in litigation with Silimed, our former sole source supplier of our silicone gel breast implants and certain other products.

On November 6, 2016, Silimed filed a lawsuit in the United States District Court for the Southern District of New York naming Sientra as the defendant and alleging breach of contract of the Silimed Agreement, unfair competition and misappropriation of trade secrets against us. In its complaint, Silimed alleges that our theft, misuse, and improper disclosure of Silimed's confidential, proprietary, and trade secret manufacturing information was done in order for us to develop our own manufacturing capability that we intend to use to manufacture our PMA-approved products. Silimed is seeking a declaration that we are in material breach of the Silimed Agreement, a preliminary and permanent injunction to prevent our allegedly wrongful use and disclosure of Silimed's confidential and proprietary information, as well as unquantified compensatory and punitive damages. On November 15, 2016, Sientra filed its answer and counterclaims for declaratory judgment in which it denied that Silimed is entitled to any relief including, among other reasons, because of Silimed's material breach of the Silimed Agreement and Silimed's unclean hands, and further seeks declaratory relief that Sientra is the owner of certain assets it acquired from Silimed, Inc. in 2007, that Sientra owns, or is exclusively licensed, to any improvements created since April 2007, that Silimed lacks any confidential information or proprietary rights under the Silimed Agreement, and that Silimed lacks any relevant trade secret rights. On December 9, 2016, Silimed filed a motion to strike the Company's counterclaims. Briefing on that motion was completed on December 30, 2016, and the parties are waiting for a decision from the court. On February 1, 2017, Sientra filed a motion to stay Silimed's breach of contract claim in light of a demand for arbitration filed by Sientra against Silimed on January 20, 2017 concerning Silimed's material breaches of the Silimed Agreement, and to further dismiss, or alternatively stay, the unfair competition and misappropriation of trade secrets claims. Briefing on that motion was completed on February 22, 2017, and the parties are waiting for a decision from the court.

We believe Silimed's claims are legally and factually unsupported and intend to defend this lawsuit vigorously. However, we cannot provide assurance that we will be successful in our defense. If Silimed were to succeed in establishing that any protectable Silimed IP rights were in fact unlawfully compromised by our new manufacturing relationship with Vesta in a manner that warrants injunctive relief, we could be subject to an injunction which may delay or otherwise hinder our ability to procure and qualify an alternate manufacturing supplier of our silicone gel breast implants, and we could be required to pay Silimed damages, which risks could have a material adverse effect on our business, results of operations and financial condition depending on the scope of any injunctive relief and the size of any damage award. Adverse effects, if any, on our business results of operations and financial condition with respect to such claims are difficult to assess. In any event, we expect to incur increased costs associated with defending this lawsuit and the diversion of our management's attention from the existing business, which could also adversely affect our results of operations and financial condition.

We depend on a positive reaction from our Plastic Surgeons and their patients to successfully re-enter the market after our voluntary suspension of the sale of Sientra devices manufactured by Silimed.

As a result of the regulatory inquiries into Silimed-manufactured products, between October 9, 2015 and March 1, 2016, we voluntarily placed a temporary hold on the sale of all Sientra devices manufactured by Silimed and recommended that plastic surgeons discontinue implanting the devices until further notice. Each of the FDA,

ANVISA and MHRA noted that no risks to patient health have been identified in connection with implanting Silimed-manufactured products, and, accordingly, there is no need to adopt any procedure or action for those patients who have received them. Additionally, the FDA and ANVISA indicated that there have been no reports of adverse events related to the alleged presence of particles on Silimed-manufactured products. Breast implants have stringent standards for manufacturing and robust quality systems, but there is no specific or defined standard for surface particles on breast implants. Extensive independent, third-party testing and analyses of our finished goods inventory indicated no anticipated significant safety concerns with the use of Sientra's products, including our breast implants, consistent with their FDA approval status in 2012. On March 1, 2016, we lifted the temporary hold on the sale of our devices manufactured by Silimed and informed our Plastic Surgeons of our controlled market re-entry plan designed to optimize our inventory levels, which continues to be limited. Although our market re-entry decision was based on extensive testing and detailed independent third party reviews, we depend on a positive reception from our Plastic Surgeon customers and their patients to be able to reestablish the market position we had prior to the voluntary suspension. Our re-entry into the market requires us to effectively and responsibly educate accounts on the results of our testing and reconfirm our strong clinical data, while providing the same high levels of customer service to which our Plastic Surgeons are accustomed. Our plastic surgery consultants are working diligently to solidify the trust and support of all our Plastic Surgeons during this important phase of our market re-entry;

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however, if we are not successful in re-establishing these relationships, adapting our business systems, or competing effectively in this market, our sales revenues, market share and financial performance will be affected negatively.

Contracting with any third-party manufacturer and supplier involves inherent risks and various factors outside our direct control that may adversely affect the manufacturing and supply of our breast implants, tissue expanders and other products.

Our reliance on any third-party manufacturer, including Formulated Solutions, LLC, or Formulated Solutions, which supplies our bioCorneum® scar management products, SiMatrix, a Vesta subsidiary that supplies the tissue expanders we recently acquired from SSP, and Vesta or any future third-party manufacturer we procure and qualify for the manufacture of our breast implants involves a number of risks. Manufacturing and supply of our breast implants, tissue expanders and other products is technically challenging. Changes that our manufacturers may make outside the purview of our direct control can have an impact on our processes and quality, as well as the successful delivery of products to Plastic Surgeons. Mistakes and mishandling are not uncommon and can affect production and supply. Additionally, there are only a few suppliers of medical-grade silicone available, and if these suppliers become unable or unwilling to supply medical-grade silicone to Vesta, Formulated Solutions, SiMatrix or any other manufacturer that we may engage with, an alternate supply of medical-grade silicone may not be able to be found in a timely manner. Some of the additional risks with relying on third-party manufacturers and suppliers include:

- our products may not be manufactured in accordance with agreed upon specifications or in compliance with regulatory requirements or cGMP, or the manufacturing facilities may not be able to maintain compliance with regulatory requirements or cGMP, which could negatively affect the safety or efficacy of our products or cause delays in shipments of our products;

- we may not be able to timely respond to unanticipated changes in customer orders, and if orders do not match forecasts, we may have excess or inadequate inventory of materials and components;

- our products may be mishandled while in production or in preparation for transit;

- we are subject to transportation and import and export risk, particularly given the global nature of our supply chain;

- the third-party manufacturer may discontinue manufacturing and supplying products to us for risk management reasons;

- the third-party manufacturer may lose access to critical services and components, resulting in an interruption in the manufacturing or shipment of our products;

- the third-party manufacturer may encounter financial or other hardships unrelated to us and our demand for products, which could inhibit our ability to fulfill our orders;

- there may be delays in analytical results or failure of analytical techniques that we depend on for quality control and release of products;

- natural disasters, labor disputes, financial distress, lack of raw material supply, issues with facilities and equipment or other forms of disruption to business operations affecting our manufacturer or its suppliers may occur;

- latent defects may become apparent after products have been released and which may result in a recall of such products; and

- there are inherent risks if we contract with manufacturers located outside of the United States, including the risks of economic change, recession, labor strikes or disruptions, political turmoil, new or changing tariffs or trade barriers, new or different restrictions on importing or exporting, civil unrest, infrastructure failure, cultural differences in doing business, lack of contract enforceability, lack of protection for intellectual property, war and terrorism.

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The materialization of any of these risks and limitations inherent in a third-party manufacturing contractual relationship could significantly increase our costs, impair our ability to generate net sales, and adversely affect market acceptance of our products and customers may instead purchase or use our competitors' products, which could materially adversely and severely affect our business, financial condition and results of operations.

We have incurred significant net operating losses since inception and cannot assure you that we will achieve profitability.

Since our inception, we have incurred significant net operating losses. As of December 31, 2016, we had an accumulated deficit of $215.4 million. To date, we have financed our operations primarily through sales of preferred stock, borrowings under our term loans, sales of our products since 2012, our initial public offering and our follow-on public offering of our common stock. We have devoted substantially all of our resources to the acquisition and clinical development of our products, the commercial launch of our products, the development of a sales and marketing team and the assembly of a management team to manage our business.

For the year ended December 31, 2016, our net loss was $40.2 million. The extent of our future operating losses and the timing of profitability are uncertain, especially in light of our inventory supply issues. We will need to generate significant sales to achieve profitability, and we might not be able to do so. Even if we do generate significant sales, we might not be able to achieve, sustain or increase profitability on a quarterly or annual basis in the future. If our sales grow more slowly than we have forecasted, or if our operating expenses exceed our forecasts, our financial performance and results of operations will be adversely affected.

Our future profitability depends on the success of our Breast Products.

Our Breast Products have historically accounted for substantially all of our net sales and we expect our Breast Products to continue to be a substantial majority of our net sales. Our inability to manage our inventory supply issues, the inability to qualify Vesta or another third party as an alternate manufacturer, the potential loss of market acceptance of our Breast Products, or any adverse rulings by regulatory authorities, any adverse finding in the Silimed Litigation, any adverse publicity or other adverse events relating to us or our Breast Products, or the introduction of competitive products by our competitors and other third parties, would adversely affect our business, financial condition and results of operations.

Any negative publicity concerning our products could harm our business and reputation and negatively impact our financial results.

The responses of potential patients, physicians, the news media, legislative and regulatory bodies and others to information about complications or alleged complications of our products could result in negative publicity and could materially reduce market acceptance of our products. These responses or any investigations and potential resulting negative publicity may have a material adverse effect on our business and reputation and negatively impact our financial condition, results of operations or the market price of our common stock. In addition, significant negative publicity could result in an increased number of product liability claims against us.

We may not realize the benefits of our recent acquisitions which may be subject to additional risks and uncertainties.

In March 2016, we acquired bioCorneum®, an advanced silicone gel scar management product from Enaltus. In November 2016, we acquired certain assets, consisting of the Dermaspan™, Softspan™, and AlloX2® tissue expanders, from SSP. These acquisitions were made in an effort to add differentiated and complementary products that serve the

needs of Plastic Surgeons while diversifying our business mix.

Our acquisition of bioCorneum® involves risks and uncertainties including that we have limited experience in the scar management industry, our management's attention may be diverted from our existing business as we attempt to integrate bioCorneum® and the integration may not be successful. Additionally, bioCorneum® is an over-the-counter pharmaceutical registered with the FDA, and there may be risks associated with the use of bioCorneum® including skin irritation, rash, itching or accidental application into the eye or ingestion. We also rely on Formulated Solutions as our sole source, third-party manufacturer of bioCorneum® and if Formulated Solutions becomes unable or unwilling to supply bioCorneum®, we may not be able to find an alternate supplier in a timely manner.

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Our acquisition of the tissue expanders from SSP also involves risk and uncertainties including that our management's attention may be diverted from our existing business as we integrate the Dermaspan™, Softspan™, and AlloX2® tissue expanders; and the integration of these products into our existing business may not be successful or we may not achieve the anticipated benefits. Additionally, these SSP products are currently manufactured and supplied by SiMatrix, a Vesta subsidiary, and if SiMatrix becomes unable or unwilling to supply these products, we may not be able to find an alternate supplier in a timely manner. Our existing manufacturing contract with SiMatrix expires on its terms on November 1, 2017, and there can be no assurance that SiMatrix will agree to continue to manufacture and supply such products after the expiration of our contract or they may impose increased pricing terms if the contract is renegotiated or renewed.

We do not know if we will be able to successfully integrate these recently acquired products into our existing business, or whether unforeseen risks associated with their uses will materialize. Our inability to integrate these acquired products effectively or realize anticipated synergies may adversely affect our business, financial condition and results of operations.

We may not realize the benefits of partnerships with other companies, acquisitions of complementary products or technologies or other strategic alternatives.

In addition to our recent acquisitions of bioCorneum® and the tissue expanders from SSP, from time to time, we may consider opportunities to partner with or acquire other businesses, products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base or advance our business strategies. Potential partnerships or acquisitions involve numerous risks, including:

- integration of the acquired products or technologies with our existing business;
- maintenance of uniform standards, procedures, controls and policies;
- unanticipated costs associated with partnerships or acquisitions;
- diversion of management's attention from our existing business;
- uncertainties associated with entering new markets in which we have limited or no experience; and
- increased legal and accounting costs relating to the partnerships or acquisitions or compliance with regulatory matters.

We do not know if we will be able to identify partnerships or acquisitions we deem suitable, whether we will be able to successfully complete any such partnerships or acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any partnered or acquired products or technologies. Our potential inability to integrate any partnered or acquired products or technologies effectively or realize anticipated synergies may adversely affect our business, financial condition and results of operations.

We have a limited operating history and may face difficulties encountered by companies early in their commercialization in competitive and rapidly evolving markets.

We commenced operations in 2007 and began commercializing silicone gel breast implants in the second quarter of 2012. Accordingly, we have a limited operating history upon which to evaluate our business and forecast our future net sales and operating results. In assessing our business prospects, you should consider the various risks and difficulties frequently encountered by companies early in their commercialization in competitive markets, particularly

companies that develop and sell medical devices. These risks include our ability to:

- implement and execute our business strategy;
- expand and improve the productivity of our sales force and marketing programs to grow sales of our existing and proposed products;

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- increase awareness of our brand and build loyalty among Plastic Surgeons;
- manage expanding operations;
- respond effectively to competitive pressures and developments;
- enhance our existing products and develop new products;
- obtain regulatory clearance or approval to enhance our existing products and commercialize new products;
- perform clinical trials with respect to our existing products and any new products; and
- attract, retain and motivate qualified personnel in various areas of our business.

Due to our limited operating history, we may not have the institutional knowledge or experience to be able to effectively address these and other risks that we may face. In addition, we may not be able to develop insights into trends that could emerge and negatively affect our business and may fail to respond effectively to those trends. As a result of these or other risks, we may not be able to execute key components of our business strategy, and our business, financial condition and operating results may suffer.

If we fail to compete effectively against our competitors, both of which have significantly greater resources than we have, our net sales and operating results may be negatively affected.

Our industry is intensely competitive and subject to rapid change from the introduction of new products, technologies and other activities of industry participants. Our competitors, Mentor, a wholly owned subsidiary of Johnson & Johnson, and Allergan are well-capitalized global pharmaceutical companies that have been the market leaders for many years and have the majority share of the breast implant market in the United States. These competitors also enjoy several competitive advantages over us, including:

- greater financial and human resources for sales, marketing and product development;
- established relationships with health care providers and third-party payors;
- established reputations and name recognition among health care providers and other key opinion leaders in the plastic surgery industry;
- in some cases, an established base of long-time customers;
- products supported by long-term clinical data;
- larger and more established distribution networks;
- greater ability to cross-sell products; and
- more experience in conducting research and development, manufacturing, performing clinical trials and obtaining regulatory approval or clearance.

If we fail to compete effectively against our competitors, our net sales and operating results may be negatively affected.

Pricing pressure from customers and our competitors may impact our ability to sell our products at prices necessary to support our current business strategies.

Our 2012 entry into the U.S. breast implant market represented a significant expansion of the breast implant choices and technologies available in the United States. As a result of our entry into the U.S. breast implant market, our competitors intensified competitive pricing pressure for traditional round-shaped breast implants. If we are not successful

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in convincing customers or third-party payors of our breast implants as compared to our competitors' products, third-party payors may not cover or adequately reimburse our products and customers may choose our competitors' products.

The long-term safety of our products has not fully been established and our breast implants are currently under study in our PMA post-approval studies, which could reveal unanticipated complications.

We have been marketing our silicone gel breast implants in the United States with pre-market approval from the FDA since 2012. However, there could still be unanticipated complications or unforeseen health consequences of being implanted with our silicone gel breast implants over the long-term (defined as 10 years or more). Additionally, we rely on our clinical data to make favorable comparisons of our product to our competitive products, and our longer-term data may change over time. Further, future studies or clinical experience may indicate that treatment with our products is not differentiated to treatment with competitive products. Such results could slow the adoption of our products and significantly reduce our sales, which could prevent us from achieving our forecasted sales targets or achieving or sustaining profitability. Moreover, if long-term results and experience indicate that our products cause unexpected or serious complications, we could be subject to mandatory product recalls, suspension or withdrawal of clearance or approval by the FDA or other applicable regulatory bodies and significant legal liability.

Among the long-term health risks of breast implants which are being studied is the possible association between breast implants and a rare form of cancer called anaplastic large-cell lymphoma.

In January 2011, the FDA indicated that there was a possible association between saline and silicone gel breast implants and anaplastic large-cell lymphoma, or ALCL. Since our FDA approval in 2012, Sientra's breast-implant product label, which is approved by the FDA, has been required to contain a description of ALCL as a possible, though rare, outcome. Since its report in January 2011, the FDA continued to gather information about ALCL in women with breast implants through the review of medical device reports, review of medical literature, and collaboration with international regulators, scientific experts, ASPS, and other organizations. In January 2016, the FDA reiterated, after a review of information since 2011, that ALCL is a very rare condition and the FDA recommended the same measures as it had before for health care providers and patients. Further studies or clinical experience may indicate that breast implants, including our products, expose individuals to a more substantial risk of developing ALCL or other unexpected complications. As a result, we may be exposed to increased regulatory scrutiny, negative publicity and lawsuits from any individual who may develop ALCL after using our products, any of which could have a significant negative impact on our results of operations or financial condition. Moreover, if long-term results and clinical experience indicate that our products cause unexpected or serious complications, we could be subject to mandatory product recalls, suspension or withdrawal of regulatory clearances and approvals and significant legal liability.

If we are unable to train Plastic Surgeons on the safe and appropriate use of our products, we may be unable to achieve our expected growth.

An important part of our sales process includes the ability to educate Plastic Surgeons about the availability of anatomically-shaped breast implants and train Plastic Surgeons on the safe and appropriate use of our products. If we become unable to attract potential new Plastic Surgeon customers to our education and training programs, we may be unable to achieve our expected growth.

There is a learning process involved for Plastic Surgeons to become proficient in the use of our anatomically-shaped products. It is critical to the success of our commercialization efforts to train a sufficient number of Plastic Surgeons

and provide them with adequate instruction in the appropriate use of our products via preceptorships and additional demonstration surgeries. This training process may take longer than expected and may therefore affect our ability to increase sales. Following completion of training, we rely on the trained Plastic Surgeons to advocate the benefits of our products in the marketplace. Convincing Plastic Surgeons to dedicate the time and energy necessary for adequate training is challenging, and we cannot assure you that we will be successful in these efforts. If Plastic Surgeons are not properly trained, they may misuse or ineffectively use our products. This may also result in, among other things, unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us, any of which could have an adverse effect on our business and reputation.

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If we are unable to continue to enhance our existing Breast Products and develop and market new products that respond to customer needs and preferences and achieve market acceptance, we may experience a decrease in demand for our products and our business could suffer.

We may not be able to compete effectively with our competitors, and ultimately satisfy the needs and preferences of our customers, unless we can continue to enhance existing products and develop and market new innovative products. Product development requires the investment of significant financial, technological and other resources. Product improvements and new product introductions also require significant planning, design, development and testing at the technological, product and manufacturing process levels and we may not be able to timely develop product improvements or new products. Our competitors' new products may beat our products to market, be more effective with new features, obtain better market acceptance or render our products obsolete. Any new or modified products that we develop may not receive clearance or approval from the FDA, or achieve market acceptance or otherwise generate any meaningful sales or profits for us relative to our expectations based on, among other things, existing and anticipated investments in manufacturing capacity and commitments to fund advertising, marketing, promotional programs and research and development.

If changes in the economy and consumer spending reduce consumer demand for our products, our sales and profitability would suffer.

We are subject to the risks arising from adverse changes in general economic and market conditions. Certain elective procedures, such as breast augmentation and body contouring, are typically not covered by insurance. Adverse changes in the economy may cause consumers to reassess their spending choices and reduce the demand for these surgeries and could have an adverse effect on consumer spending. This shift could have an adverse effect on our net sales. Furthermore, consumer preferences and trends may shift due to a variety of factors, including changes in demographic and social trends, public health initiatives and product innovations, which may reduce consumer demand for our products.

We are required to maintain high levels of inventory, which could consume a significant amount of our resources and reduce our cash flows.

We need to maintain substantial levels of inventory to protect ourselves from supply interruptions, provide our customers with a wide range of shapes and sizes of our breast implants, and account for the high return rates we experience as Plastic Surgeons typically order our products in multiple sizes for a single surgery and then return what they do not use. As a result of our substantial inventory levels, we are subject to the risk that a substantial portion of our inventory becomes obsolete. The materialization of any of these risks may have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory. Additionally, our ability to find an alternate supplier in a timely manner, may affect our ability to maintain the level of inventory supply we require to protect ourselves from supply interruptions that could have an unfavorable impact on our net sales.

Any disruption at our facilities could adversely affect our business and operating results.

Our principal offices are located in Santa Barbara, California. Substantially all of our operations are conducted at this location, including customer service, development and management and administrative functions. Substantially all of our inventory of finished goods is held at a second location in Santa Barbara, California. Despite our efforts to safeguard our facilities, including acquiring insurance, adopting health and safety protocols and utilizing off-site storage of computer data, vandalism, terrorism or a natural or other disaster, such as an earthquake, fire or flood, could damage or destroy our inventory of finished goods, cause substantial delays in our operations, result in the loss of key information and cause us to incur additional expenses. Our insurance may not cover our losses in any particular

case. In addition, regardless of the level of insurance coverage, damage to our facilities may have a material adverse effect on our business, financial condition and operating results.

If there are significant disruptions in our information technology systems, our business, financial condition and operating results could be adversely affected.

The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage sales and marketing data, accounting and financial functions, inventory, product development tasks, clinical data, and customer service and technical support functions. Our information

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technology systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, computer viruses or hackers, power losses, and computer system or data network failures. In addition, a variety of our software systems are cloud-based data management applications hosted by third-party service providers whose security and information technology systems are subject to similar risks.

The failure of our or our service providers' information technology could disrupt our entire operation or result in decreased sales, increased overhead costs and product shortages, all of which could have a material adverse effect on our reputation, business, financial condition and operating results.

We may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters and certain other facilities are located in Santa Barbara, California, which in the past has experienced both severe earthquakes and wildfires. We do not carry earthquake insurance. Earthquakes, wildfires or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Failure to obtain hospital or group purchasing organization contracts could have a material adverse effect on our financial condition and operating results.

A portion of our net sales is derived from sales to hospitals. Many hospital customers, through the contracting process, limit the number of breast implant suppliers that may sell to their institution. Hospitals may choose to contract with our competitors who have a broader range of products that can be used in a wider variety of procedures or our competitors may actively position their broader product portfolios against us during the hospital contracting process. Any limitations on the number of hospitals to which we can sell our products may significantly restrict our ability to grow.

In addition, contracts with hospitals and group purchasing organizations, or GPOs, often have complex insurance and indemnification requirements, which may not be beneficial to us, or we may not be able to successfully negotiate contracts with a substantial number of hospitals and GPOs at all, which could adversely affect our business, financial condition and results of operations.

Our business could suffer if we lose the services of key personnel or are unable to attract and retain additional qualified personnel.

We are dependent upon the continued services of key personnel, including members of our executive management team who have extensive experience in our industry. The loss of any one of these individuals could disrupt our operations or our strategic plans. Additionally, our future success will depend on, among other things, our ability to continue to hire and retain the necessary qualified sales, marketing and managerial personnel, for whom we compete with numerous other companies, academic institutions and organizations. If we lose additional key employees, if we

are unable to attract or retain other qualified personnel, or if our management team is not able to effectively manage us through these events, our business, financial condition, and results of operations may be adversely affected.

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

As of December 31, 2016, we had approximately 89 full-time employees. Our management and personnel, and the systems and facilities we currently have in place, may not be adequate to support future growth. Effectively executing our growth strategy requires that we increase net sales through sales and marketing activities, recruit and retain additional employees and continue to improve our operational, financial and management controls, reporting systems and procedures.

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If we are not able to effectively expand our organization in these ways, we may not be able to successfully execute our growth strategy, and our business, financial condition and results of operations may suffer.

Risks Related to Our Financial Results

Our quarterly net sales and operating results are unpredictable and may fluctuate significantly from quarter to quarter due to factors outside our control, which could adversely affect our business, results of operations and the trading price of our common stock.

Our net sales and operating results may vary significantly from quarter to quarter and year to year due to a number of factors, many of which are outside of our control and any of which may cause our stock price to fluctuate. Our net sales and results of operations will be affected by numerous factors, including:

- the timing and availability of alternative manufacturing sources to supply our silicone gel breast implants and certain other products;
- our ability to integrate and achieve the anticipated benefits of our recent acquisitions of bioCorneum® and the tissue expanders from SSP;
- the impact of the buying patterns of patients and seasonal cycles in consumer spending;
- our ability to drive increased sales of anatomically-shaped breast implants products;
- our ability to establish and maintain an effective and dedicated sales organization;
- pricing pressure applicable to our products, including adverse third-party coverage and reimbursement outcomes;
- results of clinical research and trials on our existing products;
- the impact of the recent regulatory inquiries of Silimed on our brand and reputation;
- timing of our research and development activities and initiatives;
- the mix of our products sold due to different profit margins among our products;
- timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;
- the ability of our suppliers to timely provide us with an adequate supply of products;
- the evolving product offerings of our competitors;
- regulatory approvals and legislative changes affecting the products we may offer or those of our competitors;
- increased labor and related costs;
- interruption in the manufacturing or distribution of our products;
- the effect of competing technological, industry and market developments;
- changes in our ability to obtain regulatory clearance or approval for our products;
- our ability to expand the geographic reach of our sales and marketing efforts; and
- our ability to successfully defend against the claims asserted in the Silimed Litigation.

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Many of the products we may seek to develop and introduce in the future will require FDA approval or clearance before commercialization in the United States, and commercialization of such products outside of the United States would likely require additional regulatory approvals, CE Certificates of Conformity and export licenses. As a result, it will be difficult for us to forecast demand for these products with any degree of certainty. In addition, we will be increasing our operating expenses as we expand our commercial capabilities. Accordingly, we may experience significant, unanticipated quarterly losses. If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Our future capital needs are uncertain and we may need to raise additional funds in the future, and these funds may not be available on acceptable terms or at all.

As of December 31, 2016, we had $67.2 million in cash and cash equivalents. We believe that our available cash on hand will be sufficient to satisfy our liquidity requirements for at least the next 12 months. However, the planned growth of our business, including the expansion of our sales force and marketing programs, and research and development activities, and potential partnerships or strategic acquisitions could significantly increase our expenses. In addition, we expect expenses we may incur in connection with reestablishing our inventory supply, expenses we may incur defending against litigation claims, including the Silimed Litigation may have a material effect on our future cash outflows and our financial condition.

Our future capital requirements will depend on many factors, including:

- the timing and availability of alternative manufacturing sources and costs associated with procuring and qualifying such manufacturing capacity;
- net sales generated by our silicone gel breast implants and tissue expanders and any other future products that we may develop and commercialize;
- expenses we incur in connection with the Silimed Litigation, other potential litigation or governmental investigations;
- costs associated with expanding our sales force and marketing programs;
- cost associated with developing and commercializing our proposed products or technologies;
- cost of obtaining and maintaining regulatory clearance or approval for our current or future products;
- cost of ongoing compliance with regulatory requirements;
- anticipated or unanticipated capital expenditures; and
- unanticipated general and administrative expenses.

As a result of these and other factors, we do not know whether and the extent to which we may be required to raise additional capital. We may in the future seek additional capital from public or private offerings of our capital stock, borrowings under term loans or other sources. If we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaborations, licensing, joint ventures, strategic alliances, partnership arrangements or other similar arrangements, it may be necessary to relinquish valuable rights to our potential future products or proprietary technologies, or grant licenses on terms that are not favorable to us.

If we are unable to raise additional capital, we may not be able to expand our sales force and marketing programs, enhance our current products or develop new products, take advantage of future opportunities, or respond to competitive

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pressures, changes in supplier relationships, or unanticipated changes in customer demand. Any of these events could adversely affect our ability to achieve our strategic objectives, which could have a material adverse effect on our business, financial condition and operating results.

Our loan agreement contains restrictive covenants that may limit our operating flexibility.

We recently entered into a Loan and Security Agreement, or the Loan Agreement, with Silicon Valley Bank. The Loan Agreement contains certain restrictive covenants including covenants against the occurrence of a change in control, financial reporting obligations, and certain limitations on indebtedness, liens, investments, distributions (including dividends), collateral, mergers or acquisitions, taxes, corporate changes, and deposit accounts, among others. We therefore may not be able to engage in any of the foregoing transactions unless we obtain the consent of the lender or terminate the Loan Agreement. There is no guarantee that we will be able to pay the principal and interest under the Loan Agreement or that future working capital, borrowings or equity financing will be available to repay or refinance any amounts outstanding under the Loan Agreement. In addition, we may enter into debt agreements in the future that may contain similar or more burdensome terms and covenants, including financial covenants.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

As of December 31, 2016, we had federal net operating loss carryforwards, or NOLs, of approximately $170.9 million, which begin expiring in 2027, if not utilized to offset taxable income. In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. In general, an “ownership change” occurs if there is a cumulative change in our ownership by “5% shareholders” that exceeds 50 percentage points over a rolling three-year period. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we undergo one or more ownership changes in connection with future transactions in our stock, our ability to utilize NOLs could be further limited by Section 382 of the Code. As a result of these limitations, we may not be able to utilize a material portion of the NOLs reflected on our balance sheet and for this reason, we have fully reserved against the value of our NOLs on our balance sheet. We have not completed a Section 382 analysis to determine if an ownership change has occurred. Until such analysis is completed, we cannot be sure that the full amount of the existing federal NOLs will be available to us, even if we do generate taxable income before their expiration.

Future changes in financial accounting standards may cause adverse unexpected net sales or expense fluctuations and affect our reported results of operations.

A change in accounting standards could have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New pronouncements and varying interpretations of existing pronouncements have occurred and may occur in the future. Changes to existing rules or current practices may adversely affect our reported financial results of our business.

Risks Related to Our Intellectual Property and Potential Litigation

If our intellectual property rights do not adequately protect our products or technologies, others could compete against us more directly, which would hurt our profitability.

Our success depends in part on our ability to protect our intellectual property rights. We rely on a combination of trademarks, trade secrets, confidential information, copyrights, patent rights and other intellectual property rights to protect our intellectual property. In addition, to protect our trade secrets, confidential information and other

intellectual property rights, we have entered into confidentiality agreements with third parties, and confidential information and invention assignment agreements with employees, consultants and advisors. However, these agreements may not provide sufficient protection or adequate remedies for violation of our rights in the event of unauthorized use or disclosure of confidential and proprietary information. Without additional protection under the patent or other intellectual property laws, such unauthorized use or disclosure may enable competitors to duplicate or surpass our technological achievements. Moreover, the laws of certain foreign countries do not recognize intellectual property rights or protect them to the same extent as do the laws of the United States. Failure to protect our proprietary rights could seriously impair our competitive position.

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The medical device industry is characterized by patent and other intellectual property litigation and we have and could become subject to litigation that could be costly, result in the diversion of management's time and efforts, require us to pay damages or prevent us from marketing our existing or future products.

Our commercial success will depend in part on not infringing the patents or violating the other proprietary rights of others. Significant litigation regarding patent rights occurs in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. Absent specific circumstances, we do not generally conduct independent reviews of patents issued to third parties. We may not be aware of whether our products do or will infringe existing or future patents. In addition, patent applications in the United States and elsewhere can be pending for many years, and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications of others now pending of which we are unaware that may later result in issued patents that will prevent, limit or otherwise interfere with our ability to make, use or sell our products. We may not be aware of patents that have already issued that a third party might assert are infringed by our products. It is also possible that patents of which we are aware, but which we do not believe are relevant to our product candidates, could nevertheless be found to be infringed by our products. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technology involved and the uncertainty of litigation increase the risk of business assets and management's attention being diverted to patent litigation. In the future, we may receive communications from various industry participants alleging our infringement of their patents, trade secrets or other intellectual property rights and/or offering licenses to such intellectual property. Any lawsuits resulting from such allegations could subject us to significant liability for damages and invalidate our proprietary rights, even if they lack merit. Any existing or potential intellectual property litigation also could force us to do one or more of the following:

- stop making, selling or using products or technologies that allegedly infringe the asserted intellectual property;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others;
- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing;
- pay the attorney fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;
- redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and/or infeasible; or
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all.

Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, negatively impact shareholder value and harm our reputation. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages (which may be increased up to three times of awarded damages) and/or substantial royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations and financial condition.

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In addition, we generally indemnify our customers with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims against our customers. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Many of our employees were previously employed at other medical device companies, including our competitors or potential competitors, in some cases until recently. We have been the subject of and may, in the future, be subject to claims that we, our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of these former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations and financial condition.

We are and may be subject to warranty or product liability claims or other litigation in the ordinary course of business that may adversely affect our business, financial condition and operating results.

As a supplier of medical devices, we are and may be subject to warranty or product liability claims alleging that the use of our products has resulted in adverse health effects or other litigation in the ordinary course of business that may require us to make significant expenditures to defend these claims or pay damage awards. The breast implant industry has a particularly significant history of product liability litigation. The risks of litigation exist even with respect to products that have received or in the future may receive regulatory approval for commercial sale, such as our Breast Products. In addition, our silicone gel breast implants are sold with a warranty providing for no-charge replacement implants in the event of certain ruptures that occur any time during the life of the patient and this warranty also includes cash payments to offset surgical fees if the rupture occurs within 10 years of implantation.

We maintain product liability insurance, but this insurance is limited in amount and subject to significant deductibles. There is no guarantee that insurance will be available or adequate to protect against all claims. Our insurance policies are subject to annual renewal and we may not be able to obtain liability insurance in the future on acceptable terms or at all. In addition, our insurance premiums could be subject to increases in the future, which may be material. If the coverage limits are inadequate to cover our liabilities or our insurance costs continue to increase as a result of warranty or product liability claims or other litigation, then our business, financial condition and operating results may be adversely affected.

Fluctuations in insurance cost and availability could adversely affect our profitability or our risk management profile.

We hold a number of insurance policies, including product liability insurance, directors' and officers' liability insurance, general liability insurance, property insurance, employment practices, and workers' compensation insurance. If the costs of maintaining adequate insurance coverage increase significantly in the future, our operating results could be materially adversely affected. Likewise, if any of our current insurance coverage should become

unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. If we operate our business without insurance, we could be responsible for paying claims or judgments against us that would have otherwise been covered by insurance, which could adversely affect our results of operations or financial condition.

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Risks Related to Our Legal and Regulatory Environment

We are subject to extensive federal and state healthcare regulation, and if we fail to comply with applicable regulations, we could suffer severe criminal or civil sanctions or be required to restructure our operations, any of which could adversely affect our business, financial condition and operating results.

As a device manufacturer, even though we do not control referrals or bill directly to Medicare, Medicaid or other third-party payors, we are subject to healthcare fraud and abuse regulation and enforcement by the federal government and the states in which we conduct our business, as well as other healthcare laws and regulations. The healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which applies to our business activities, including our marketing practices, educational programs, pricing policies and relationships with healthcare providers, by prohibiting, among other things, knowingly and willfully soliciting, receiving, offering or providing any remuneration (including any bribe, kickback or rebate) directly or indirectly, overtly or covertly, in cash or in kind, intended to induce or in return for the purchase or recommendation of any good, facility, item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare or Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to commit a violation. Rather, if "one purpose" of the remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. In addition, following passage of the PPACA violations of the federal Anti-Kickback Statute became per se violations of the False Claims Act;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government payors that are false or fraudulent, or making a false statement to decrease or conceal an obligation to pay or transmit money or property to the federal government, and which may apply to entities that provide coding and billing advice to customers;
- HIPAA, and its implementing regulations, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- and, HIPAA, as amended by HITECH, also imposes certain regulatory and contractual requirements on certain types of people and entities subject to the law and their business associates regarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, enacted under the PPACA, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to make annual reports to the Centers for Medicare & Medicaid Services, or CMS, regarding any "transfers of value" provided to physicians and teaching hospitals. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1 million per year for "knowing failures," for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission. We are required to report detailed payment data and submit legal attestation to the accuracy of such data by March 31st of each calendar year; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be provided to healthcare providers and entities; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers and entities or marketing expenditures; and state laws governing the privacy and security of certain health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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Because of the breadth of these laws, it is possible that some of our business activities, including our relationships with physicians and other health care providers and entities, some of whom recommend, purchase and/or prescribe our products, could be subject to challenge under one or more of such laws. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and/or criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, exclusion from governmental health care programs, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

Our medical device products and operations are subject to extensive governmental regulation both in the United States and abroad, and our failure to comply with applicable requirements could cause our business to suffer.

Our medical device products and operations are subject to extensive regulation by the FDA and various other federal, state and foreign governmental authorities, such as Health Canada. Government regulation of medical devices is meant to assure their safety and effectiveness, and includes regulation of, among other things:

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical trials;
- product safety;
- marketing, sales and distribution;
- regulatory clearances and approvals including pre-market clearance and approval;
- conformity assessment procedures;
- product traceability and record keeping procedures;
- advertising and promotion;
- product complaints, complaint reporting, recalls and field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market studies; and
- product import and export.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales.

Before we can market or sell a new regulated product or a significant modification to an existing product in the United States, we must obtain either clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or FDCA, or an approval of a PMA application unless the device is specifically exempt from pre-market review. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence.

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In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on specific data, including, but not limited to, pre-clinical, clinical trial, and other product data. The PMA process is typically required for devices for which the 510(k) process cannot be used and that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. Modifications to products that are approved through a PMA application generally need FDA approval. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). The FDA's 510(k) clearance process usually takes from three to 12 months, but may last longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA until an approval is obtained.

In the United States, our silicone gel breast implants are marketed pursuant to a PMA order issued by the FDA in March 2012, and our tissue expanders are marketed pursuant to pre-market clearance under Section 510(k) of the FDCA. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline. The FDA may demand that we obtain a PMA prior to marketing certain of our future products. In addition, if the FDA disagrees with our determination that a product we market is subject to an exemption from pre-market review, the FDA may require us to submit a 510(k) or PMA in order to continue marketing the product. Further, even with respect to those future products where a PMA is not required, we cannot assure you that we will be able to obtain the 510(k) clearances with respect to those products.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- we may not be able to demonstrate to the FDA's satisfaction that our products are safe and effective for their intended uses;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions that may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products.

The FDA could also reclassify some or all of our products that are currently classified as Class II to Class III requiring additional controls, clinical studies and submission of a PMA for us to continue marketing and selling those products. We cannot guarantee that the FDA will not reclassify any of our Class II devices into Class III and require us to submit a PMA for FDA review and approval of the safety and effectiveness of our product. Any delay in, or failure to receive or maintain clearance or approval for our products under development could prevent us from generating sales from these products or achieving profitability. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could dissuade some surgeons from using our products and adversely affect our reputation and the perceived safety and efficacy of our products.

In addition, even after we have obtained the proper regulatory clearance or approval to market a product, the FDA has the power to require us to conduct post-marketing studies. For example, we are required to continue to study and report clinical results to the FDA on our silicone gel breast implants. Failure to conduct this or other required studies in a timely manner could result in the revocation of the PMA approval or 510(k) clearance for the product that is subject to such a requirement and could also result in the recall or withdrawal of the product, which would prevent us

from generating sales from that product in the United States.

Failure to comply with applicable laws and regulations could jeopardize our ability to sell our products and result in enforcement actions such as:

· warning letters;

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- fines;
- injunctions;
- civil penalties;
- termination of distribution;
- recalls or seizures of products;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- refusal of the FDA or other regulator to grant future clearances or approvals;
- withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products; and/or
- in the most serious cases, criminal penalties.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, results of operations and financial condition.

If we or if our third-party manufacturer fail to comply with the FDA's good manufacturing practice regulations, it could impair our ability to market our products in a cost-effective and timely manner.

We and our third-party manufacturers are required to comply with the FDA's QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. The FDA audits compliance with the QSR through periodic announced and unannounced inspections of manufacturing and other facilities. The FDA may conduct inspections or audits at any time. If we or our manufacturers fail to adhere to QSR requirements, have significant non-compliance issues or fail to timely and adequately respond to any adverse inspectional observations or product safety issues, or if any corrective action plan that we or our manufacturers propose in response to observed deficiencies is not sufficient, the FDA could take enforcement action against us, which could delay production of our products and may include:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or pre-market approval of new products or modified products;
- withdrawing 510(k) clearances or pre-market approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Any of the foregoing actions could have a material adverse effect on our reputation, business, financial condition and operating results. Furthermore, our manufacturer may not currently be or may not continue to be in compliance with

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all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

There is no guarantee that the FDA will grant 510(k) clearance or PMA approval of our future products, and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.

Some of our future products may require FDA clearance of a 510(k) or FDA approval of a PMA. The FDA may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or pre-market approval of new products.

Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

If we modify our FDA approved or cleared devices, we may need to seek additional clearances or approvals, which, if not granted, would prevent us from selling our modified products.

In the United States, our silicone gel breast implants are marketed pursuant to a PMA order issued by the FDA in March 2012, and our tissue expanders are marketed pursuant to pre-market clearance under Section 510(k) of the FDCA. Any modifications to a PMA-approved or 510(k)-cleared device that could significantly affect its safety or effectiveness, including significant design and manufacturing changes, or that would constitute a major change in its intended use, manufacture, design, components, or technology requires a new 510(k) clearance or, possibly, approval of a new PMA application or PMA supplement. However, certain changes to a PMA-approved device do not require submission and approval of a new PMA or PMA supplement and may only require notice to FDA in a PMA 30-Day Notice, Special PMA Supplement – Changes Being Effected or PMA Annual Report. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have modified some of our 510(k) cleared products, and have determined based on our review of the applicable FDA guidance that in certain instances the changes did not require new 510(k) clearances or PMA approvals. If the FDA disagrees with our determination and requires us to seek new 510(k) clearances or PMA approvals for modifications to our previously cleared or approved products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. Furthermore, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. Delays in receipt or failure to receive approvals, the loss of previously received approvals, or the failure to comply with any other existing or future regulatory requirements, could reduce our sales, profitability and future growth prospects.

A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products that leads to corrective actions, could have a significant adverse impact on us.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious injury or death. Manufacturers may also, under their own initiative, recall a product if any material deficiency in a device is found or withdraw a product to improve device performance or for other reasons. The FDA requires that certain classifications of recalls be reported

to the FDA within 10 working days after the recall is initiated. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Similar regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert management attention and financial resources and could cause the price of our stock to decline, expose us to product liability or other claims and harm our reputation with customers. Such events could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. A recall involving our silicone gel breast implants could be particularly harmful to our business, financial and operating results. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA or similar foreign governmental authorities. We may initiate voluntary recalls involving our products in the future that we determine do not

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require notification of the FDA or foreign governmental authorities. If the FDA or foreign governmental authorities disagree with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA or a foreign governmental authority could take enforcement action for failing to report the recalls when they were conducted.

In addition, under the FDA's medical device reporting regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall. We are also required to follow detailed record-keeping requirements for all firm-initiated medical device corrections and removals, and to report such corrective and removal actions to FDA if they are carried out in response to a risk to health and have not otherwise been reported under the medical device reporting regulations. Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our business, including our ability to market our products in the future.

Any adverse event involving our products, whether in the United States or abroad, could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

If the third parties on which we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory clearance or approval for or commercialize our products.

We often must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials and preclinical development activities. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory clearance or approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

We may be subject to regulatory or enforcement actions if we engage in improper marketing or promotion of our products.

Our educational and promotional activities and training methods must comply with FDA and other applicable laws, including the prohibition of the promotion of a medical device for a use that has not been cleared or approved by the FDA. Use of a device outside of its cleared or approved indications is known as "off-label" use. Physicians may use our products off-label in their professional medical judgment, as the FDA does not restrict or regulate a physician's

choice of treatment within the practice of medicine. However, if the FDA determines that our educational and promotional activities or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of warning letters, untitled letters, fines, penalties, injunctions, or seizures, which could have an adverse impact on our reputation and financial results. It is also possible that other federal, state or foreign enforcement authorities may take action if they consider our educational and promotional activities or training methods to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products could be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. It is also possible that other federal, state or foreign enforcement

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authorities might take action, such as federal prosecution under the federal civil False Claims Act, if they consider our business activities constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us, and harm our reputation.

Changes in existing third-party coverage and reimbursement may impact our ability to sell our products when used in breast reconstruction procedures.

Maintaining and growing sales of our products when used in breast reconstruction procedures depends, in part, on the availability of coverage and adequate reimbursement from third-party payors, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs. Breast augmentation procedures are generally performed on a cash pay basis and are not covered by third party payors. In contrast, breast reconstruction procedures may be covered by third party payors. Therefore, hospitals and other healthcare provider customers that purchase our products to use in breast reconstruction procedures typically bill various third-party payors to cover all or a portion of the costs and fees associated with the procedures in which our products are used, including the cost of the purchase of our products. Decreases in the amount third-party payors are willing to reimburse our customers for breast reconstruction procedures using our products could create pricing pressures for us. The process for determining whether a third-party payor will provide coverage for a product or procedure may be separate from the process for establishing the reimbursement rate that such a payor will pay for the product or procedure. A payor's decision to provide coverage for a product or procedure does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product or procedure does not assure that other payors will also provide such coverage. Adequate third-party reimbursement may not be available to enable us to maintain our business in a profitable way. We may be unable to sell our products on a profitable basis if third-party payors deny coverage or reduce their current levels of payment, or if our costs of production increase faster than increases in reimbursement levels.

Furthermore, the healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with service providers. Therefore, we cannot be certain that the breast reconstruction procedures using our products will be reimbursed at a cost-effective level. Nor can we be certain that third-party payors using a methodology that sets amounts based on the type of procedure performed, such as those utilized by government programs and in many privately managed care systems, will view the cost of our products to be justified so as to incorporate such costs into the overall cost of the procedure. Moreover, we are unable to predict what changes will be made to the reimbursement methodologies used by third-party payors in the future.

To the extent we sell our products internationally, market acceptance may depend, in part, upon the availability of coverage and reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government-sponsored healthcare and private insurance. We may not obtain international coverage and reimbursement approvals in a timely manner, if at all. Our failure to receive such approvals would negatively impact market acceptance of our products in the international markets in which those approvals are sought.

Legislative or regulatory health care reforms may make it more difficult and costly to produce, market and distribute our products after clearance or approval is obtained, or to do so profitably.

Recent political, economic and regulatory influences are subjecting the health care industry to fundamental changes. Both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation and regulations designed to contain or reduce the cost of health care, improve quality of care, and expand access to healthcare, among other purposes. Such legislation and regulations may result in decreased reimbursement for medical devices and/or the procedures in which they are used, which may further exacerbate industry-wide pressure to reduce the prices charged for medical devices. This could harm our ability to market and generate sales from our products.

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In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations, revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our products.

Federal and state governments in the United States have recently enacted legislation to overhaul the nation's health care system. For example, in March 2010, the PPACA was signed into law. While one goal of health care reform is to expand coverage to more individuals, it also involves increased government price controls, additional regulatory mandates and other measures designed to constrain medical costs. The PPACA substantially changes the way healthcare is financed by both governmental and private insurers, encourages improvements in the quality of healthcare items and services and significantly impacts the medical device industry. Among other ways in which the PPACA significantly impacts our industry, the PPACA:

- imposes an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions;
- expands eligibility criteria for Medicaid programs;
- establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;
- implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain health care services through bundled payment models; and
- creates an independent payment advisory board that, if impaneled, will submit recommendations to Congress to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

The medical device excise tax has been suspended by the CAA, with respect to medical device sales during calendar years 2016 and 2017. Absent further Congressional action, this excise tax will be reinstated for medical device sales beginning January 1, 2018. The CAA also temporarily delays implementation of other taxes intended to help fund PPACA programs.

There have been judicial and Congressional challenges to certain aspects of the PPACA, and we expect there will be additional challenges and amendments in the future. In January, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the PPACA. The Budget Resolution is not a law; however, it is widely viewed as the first step toward the passage of repeal legislation. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the PPACA that are repealed. We cannot predict how the PPACA, its possible repeal, or any legislation that may be proposed to replace the PPACA will impact our business.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, on August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, following passage of the Bipartisan Budget Act of 2015, and will stay in effect through 2025 unless additional Congressional action is taken. Additionally, on January 2, 2013, President Obama signed into law the ATRA, which, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

In the future there may continue to be additional proposals relating to the reform of the U.S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the amount of reimbursement

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available for our products, and could limit the acceptance and availability of our products, any of which could have a material adverse effect on our business, results of operations and financial condition.

If we fail to obtain and maintain regulatory approval in Canada, our market opportunities will be reduced.

In order to market our products in Canada, we must obtain and maintain separate regulatory approvals and comply with numerous and varying regulatory requirements. We are currently not able to obtain Health Canada's approval to market our breast implant products in Canada due to the suspension of Silimed's ISO 13485 certificate. Regardless of Silimed's ISO certification status, the time required to obtain regulatory approval in Canada may be longer than the time required to obtain FDA pre-market approval and Health Canada may want additional information prior to approval as well. The Canadian regulatory approval process includes many of the risks associated with obtaining FDA approval and we may not obtain Canadian regulatory approval on a timely basis, if at all. FDA approval does not ensure approval by regulatory authorities in other countries, including Canada, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. However, the failure to obtain clearance or approval in one jurisdiction may have a negative impact on our ability to obtain clearance or approval elsewhere. If we do not obtain or maintain necessary approvals to commercialize our products in Canada, it would negatively affect our overall market penetration.

Our customers and much of our industry are required to be compliant under the federal Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act and implementing regulations (including the final Omnibus Rule published on January 25, 2013) affecting the transmission, security and privacy of health information, and failure to comply could result in significant penalties.

Numerous federal and state laws and regulations, including HIPAA, and HITECH, govern the collection, dissemination, security, use and confidentiality of health information that identifies specific patients. HIPAA and HITECH require our surgeon and hospital customers to comply with certain standards for the use and disclosure of health information within their companies and with third parties. The Privacy Standards and Security Standards under HIPAA establish a set of standards for the protection of individually identifiable health information by health plans, health care clearinghouses and certain health care providers, referred to as Covered Entities, and the Business Associates with whom Covered Entities enter into service relationships pursuant to which individually identifiable health information may be exchanged. Notably, whereas HIPAA previously directly regulated only these Covered Entities, HITECH, which was signed into law as part of the stimulus package in February 2009, makes certain of HIPAA's privacy and security standards also directly applicable to Covered Entities' Business Associates. As a result, both Covered Entities and Business Associates are now subject to significant civil and criminal penalties for failure to comply with Privacy Standards and Security Standards.

HIPAA requires Covered Entities (like our customers) and Business Associates to develop and maintain policies and procedures with respect to protected health information that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect such information. HITECH expands the notification requirement for breaches of patient-identifiable health information, restricts certain disclosures and sales of patient-identifiable health information and provides for civil monetary penalties for HIPAA violations. HITECH also increased the civil and criminal penalties that may be imposed against Covered Entities and Business Associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney fees and costs associated with pursuing federal civil actions. Additionally, certain states have adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA.

We are not currently required to comply with HIPAA or HITECH because we are neither a Covered Entity nor a Business Associate (as that term is defined by HIPAA). However, in administering our warranties and complying

with FDA-required device tracking, we do regularly handle confidential and personal information similar to that which these laws seek to protect. We also occasionally encounter hospital customers who pressure us to sign Business Associate Agreements, or BAAs, although, to date, we have refused, given that we do not believe we are business associates to such Covered Entities under HIPAA or HITECH. If the law or regulations were to change or if we were to agree to sign a BAA, the costs of complying with the HIPAA standards are burdensome and could have a material adverse effect on our business. In addition, under such situations there would be significant risks and financial penalties for us if we were then found to have violated the laws and regulations that pertain to Covered Entities and Business Associates.

We are unable to predict what changes to the HIPAA Privacy Standards and Security Standards might be made in the future or how those changes could affect our business. Any new legislation or regulation in the area of privacy and

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security of personal information, including personal health information, could also adversely affect our business operations. If we do not comply with existing or new applicable federal or state laws and regulations related to patient health information, we could be subject to criminal or civil sanctions and any resulting liability could adversely affect our financial condition.

An adverse outcome of a sales and use tax audit could have a material adverse effect on our results of operations and financial condition.

We sell our products in all 50 states and each state (and some local governments) has its own sales tax laws and regulations. We charge each of our customers sales tax on each order and report and pay that tax to the appropriate state authority, unless we believe there is an applicable exception. In some states, there are no available exceptions; in some states, we believe our products can be sold tax-free. In other states, we believe we can sell our products tax-free only for customers who request tax-exempt treatment due to the nature of the devices we sell or due to the nature of the customer's use of our device. We may be audited by the taxing authorities of one or more states and there can be no assurance, however, that an audit will be resolved in our favor. Such an audit could be expensive and time-consuming and result in substantial management distraction. If the matter were to be resolved in a manner adverse to us, it could have a material adverse effect on our results of operations and financial condition.

Risks Related to Our Common Stock

Our stock price may be volatile, and you may not be able to resell shares of our common stock at or above the price you paid.

The market price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. For example, our common stock price declined from $20.58 to $2.78 from September 23, 2015 to November 17, 2015 primarily as a result of the then-current events concerning Silimed. These factors include those discussed in this "Risk Factors" section of this Form 10-K and others such as:

- a determination that our products are not in compliance with regulatory requirements, or our facilities, or those of our third-party manufacturers are not maintained in compliance with regulatory requirements;
- the timing and availability of alternative manufacturing sources to supply our silicone gel breast implants, tissue expanders and certain other products;
- a slowdown in the medical device industry, the aesthetics industry or the general economy;
- actual or anticipated quarterly or annual variations in our results of operations or those of our competitors;
- changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;
- actual or anticipated changes in our growth rate relative to our competitors;
- changes in earnings estimates or recommendations by securities analysts;
- fluctuations in the values of companies perceived by investors to be comparable to us;
- announcements by us or our competitors of new products or services, significant contracts, commercial relationships, capital commitments or acquisitions;
- competition from existing technologies and products or new technologies and products that may emerge;
- the entry into, modification or termination of agreements with our sales representatives or distributors;
- developments with respect to intellectual property rights;

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- sales, or the anticipation of sales, of our common stock by us, our insiders or our other stockholders, including upon the expiration of contractual lock-up agreements;
- our ability to develop and market new and enhanced products on a timely basis;
- our ability to integrate and achieve the anticipated benefits of our recent acquisitions of bioCorneum® and the tissue expanders from SSP;
- our commencement of, or involvement in, litigation;
- additions or departures of key management or technical personnel; and
- changes in laws or governmental regulations applicable to us.

In recent years, the stock markets generally have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors may significantly affect the market price of our common stock, regardless of our actual operating performance.

We do not anticipate paying any cash dividends in the foreseeable future, and accordingly, stockholders must rely on stock appreciation for any return on their investment.

We do not anticipate declaring any cash dividends to holders of our common stock in the foreseeable future. In addition, our ability to pay cash dividends is currently prohibited by our Loan Agreement. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Our executive officers, directors and principal stockholders own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of March 9, 2017, our executive officers, directors and principal stockholders beneficially owned approximately 43.52% of our outstanding voting stock. As a result, these stockholders have the ability to influence us through their ownership position and may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

We are an “emerging growth company” and intend to take advantage of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that apply to other public companies that are not “emerging growth companies.” As an emerging growth company:

- we are exempt from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act;
- we are permitted to provide less extensive disclosure about our executive compensation arrangements in our periodic reports, proxy statements and registration statements; and
- we are not required to give our stockholders non-binding advisory votes on executive compensation or golden parachute arrangements.

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In addition, the JOBS Act provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We may remain an emerging growth company until December 31, 2019 (the last day of the fiscal year following the fifth anniversary of our initial public offering). However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenue equals or exceeds $1.0 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

As a public company, we are required to assess our internal control over financial reporting on an annual basis, and any future adverse results from such assessment could result in a loss of investor confidence in our financial reports and have an adverse effect on our stock price.

As a public company, we are required to comply with certain of the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, regarding internal control over financial reporting, including a report of management on the company's internal controls over financial reporting in their annual reports on Form 10-K.

In connection with the preparation and audit of our 2016 financial statements, we identified certain deficiencies in our internal controls over financial reporting that we concluded to be a material weakness and that our internal control over financial reporting was not effective as of December 31, 2016. The material weakness resulted from the inadequate design and operation of internal controls related to the accounting for significant unusual transactions. For more information, see "Item 9.A – Controls and Procedures – Management Annual Report on Internal Control over Financial Reporting."

We are in the process of improving policies and procedures and design more effective controls to remediate this material weakness, but our remediation efforts are not complete and are ongoing. If our remedial measures are insufficient to address the material weakness, or if additional material weaknesses or significant deficiencies in our internal control are discovered or occur in the future, it may materially adversely affect our ability to report our financial condition and results of operations in a timely and accurate manner and impact investor confidence in our Company.

Due to the above referenced material weakness in our internal control over financial reporting, we may be unable to comply with the SOX 404 internal controls requirements. Additionally, for as long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to utilize the provision exempting us from the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting. The process of becoming fully compliant with Section 404 may divert internal resources and will take a significant amount of time and effort to complete, and may result in additional deficiencies and material weaknesses being identified by us or our independent registered public accounting firm. We may experience higher than anticipated operating expenses, as well as increased independent registered public accounting firm fees during the implementation of any required changes and thereafter. Completing documentation of our internal control system and financial processes, remediation of control deficiencies and management testing of internal controls will require substantial effort by us. If our internal control over financial reporting or our related disclosure controls and procedures are not effective, we may not be able to accurately report our financial results or file our periodic reports in

a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to decline.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that our officers, directors or the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. As of March 9, 2017, we had approximately 18,833,933 shares of common stock outstanding. Of these shares, all of the shares of our common stock sold in our initial public offering, which was completed on November 3, 2014, and all of the shares sold in our follow-on public offering, which was completed on September 23, 2015 are freely tradable, without restriction, in the public market.

Based on shares outstanding as of March 9, 2017, and information contained in Form 4s and Schedule 13Gs filed with the SEC, up to an additional 4,974,003 shares of common stock became eligible for sale in the public market,

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approximately 44,226 of which are held by our executive officers and directors and approximately 4,929,777 of which are held by our affiliates (including stockholders affiliated with our directors) and subject to volume limitations under Rule 144 under the Securities Act.

Holders of an aggregate of approximately 5,672,351 shares of our common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

As of March 9, 2017, options to purchase an aggregate of 3,496,266 shares of our common stock were outstanding under our 2007 Plan, our 2014 Plan and our Inducement Plan and an additional 701,062 shares of common stock are reserved for issuance under our 2014 Plan and our Inducement Plan. These shares can be freely sold in the public market upon issuance and once vested in accordance with Rule 144, including volume restrictions applicable to "control securities" held by our officers and directors.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. Future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options or warrants, or the perception that such sales may occur, however, could adversely affect the market price of our common stock and also could adversely affect our future ability to raise capital through the sale of our common stock or other equity-related securities of ours at times and prices we believe appropriate.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

As of December 31, 2016, the number of shares of common stock reserved for issuance under our 2014 plan was 2,045,495. The number of shares of our common stock reserved for issuance under the 2014 Plan automatically increases on January 1 of each year, continuing through and including January 1, 2024, by 4% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall. Pursuant to the foregoing provision, effective January 1, 2017, our board of directors increased the number of shares of common stock reserved for issuance under the 2014 Plan by 4% of the number of shares of our capital stock outstanding on December 31, 2016, or 743,947 shares.

As of December 31, 2016, the number of shares of common stock reserved for issuance under our ESPP was 584,563. The number of shares of our common stock reserved for issuance under the ESPP automatically increases on January 1 of each year, beginning on January 1, 2015 and continuing through and including January 1, 2024, by 1% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause

our stock price to fall. Pursuant to the foregoing provision, effective January 1, 2017, our board of directors increased the number of shares of common stock reserved for issuance under the ESPP by 1% of the number of shares of our capital stock outstanding on December 31, 2016, or 185,986 shares.

Pursuant to the Inducement Plan that our board of directors approved in March 2016, our compensation committee of the board of directors is authorized to grant stock options or restricted stock units which may be exercised or settled, as applicable, to new employees as inducements material to such new employees entering into employment with us in accordance with NASDAQ Marketplace Rule 5635(c)(4). Since the inception of the Inducement Plan, options to purchase

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330,000 shares had been awarded by the compensation committee and the number of shares available for future grant was 70,000 shares. The number of shares that may be granted under the Inducement Plan may be increased in the future by our board of directors.

Anti-takeover provisions in our organizational documents and under Delaware law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could reduce our stock price and prevent our stockholders from replacing or removing our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

We are subject to the provisions of Section 203 of the General Corporation Law of the State of Delaware, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including a merger, tender offer or proxy contest involving our Company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

If securities or industry analysts issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us, or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Item 1B. Unresolved Staff Comments

Not applicable.

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Item 2. Properties

Our headquarters located in Santa Barbara, California is approximately 20,000 square feet. The term of the lease for our headquarters expires in February 2020. We also lease warehouse spaces located in Santa Barbara, California, which is approximately 10,000 square feet. The lease term expires in January 2019. We believe that our existing facilities are adequate for our current needs. As additional space is needed in the future, we believe that suitable space will be available in the required locations on commercially reasonable terms.

Item 3. Legal Proceedings

From time to time, we are involved in legal proceedings and regulatory proceedings arising out of our operations. We establish reserves for specific liabilities in connection with legal actions that we deem to be probable and estimable. The ability to predict the ultimate outcome of such matters involves judgments, estimates, and inherent uncertainties. The actual outcome of such matters could differ materially from management's estimates.

Class Action Shareholder Litigation

On September 25, 2015, a lawsuit styled as a class action of the Company's stockholders was filed in the United States District Court for the Central District of California. The lawsuit names the Company and certain of our officers as defendants, or the Sientra Defendants, and alleges violations of Sections 10(b) and 20(a) of the Exchange Act, in connection with allegedly false and misleading statements concerning the Company's business, operations, and prospects. The plaintiff seeks damages and an award of reasonable costs and expenses, including attorneys' fees. On November 24, 2015, three stockholders (or groups of stockholders) filed motions to appoint lead plaintiff(s) and to approve their selection on lead counsel. On December 10, 2015, the court entered an order appointing lead plaintiffs and approving their selection of lead counsel. On February 19, 2016, lead plaintiffs filed their consolidated amended complaint, which added claims under Sections 11, 12(a)(2) and 15 of the Securities Act and named as defendants the underwriters associated with the Company's follow-on public offering that closed on September 23, 2015, or the Underwriter Defendants. On March 21, 2016, the Sientra Defendants and the Underwriter Defendants each filed a motion to dismiss, or the Motions to Dismiss, the consolidated amended complaints. On April 20, 2016, lead plaintiffs filed their opposition to the Motions to Dismiss, and the Sientra Defendants and Underwriter Defendants filed separate replies on May 5, 2016. On June 9, 2016, the court granted in part and denied in part the Motions to Dismiss. On July 14, 2016, the Sientra Defendants moved the court to reconsider its June 9, 2016 order and grant the Motions to Dismiss in full. On August 4, 2016, lead plaintiffs filed an opposition to the motion for reconsideration. On August 12, 2016, the court denied the motion for reconsideration, and the Sientra Defendants and the Underwriter Defendants each filed an answer to the consolidated amended complaint.

On October 28, November 5, and November 19, 2015, three lawsuits styled as class actions of the Company's stockholders were filed in the Superior Court of California for the County of San Mateo. The lawsuits name the Company, certain of our officers and directors, and the underwriters associated with our follow-on public offering that closed on September 23, 2015 as defendants. The lawsuits allege violations of Sections 11, 12(a)(2), and 15 of the Securities Act in connection with allegedly false and misleading statements in our offering documents associated with the follow-on offering concerning our business, operations, and prospects. The plaintiffs seek damages and an award of reasonable costs and expenses, including attorneys' fees. On December 4, 2015, defendants removed all three lawsuits to the United States District Court for the Northern District of California. On December 15 and December 16, 2015, plaintiffs filed motions to remand the lawsuits back to San Mateo Superior Court, or Motions to Remand.

On January 19, 2016, defendants filed their opposition to the Motions to Remand, and plaintiffs filed their reply in support of the Motions to Remand on January 26, 2016.

On May 20, 2016, the United States District Court for the Northern District of California granted plaintiffs' Motions to Remand, and the San Mateo Superior Court received the remanded cases on May 27, 2016. On July 19, 2016, the San Mateo Superior Court consolidated the three lawsuits. On August 2, 2016, plaintiffs filed their consolidated complaint. On August 5, 2016, defendants filed a motion to stay all proceedings in favor of the class action filed in the United States District Court for the Central District of California.

On September 13, 2016, the parties to the actions pending in the San Mateo Superior Court and the United States District Court for the Central District of California signed a memorandum of understanding that sets forth the material deal points of a settlement that covers both actions and includes class-wide relief. On September 13, 2016, and September 20, 2016, respectively, the parties filed notices of settlement in both courts. On September 22, 2016, the United States District

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Court for the Central District of California stayed that action pending the court's approval of a settlement. On September 23, 2016, the San Mateo Superior Court stayed that action as well as pending the court's approval of a settlement.

On December 20, 2016, the plaintiffs in the federal court action filed a motion for preliminary approval of the class action settlement. On January 23, 2017, the United States District Court for the Central District of California preliminarily approved the settlement. A final approval hearing in that court is scheduled for May 22, 2017. On January 5, 2017, the plaintiffs in the state court action also filed a motion for preliminary approval of the class action settlement. On February 7, 2017, the San Mateo Superior Court preliminarily approved the settlement. A final approval hearing in that court is scheduled for May 31, 2017. The settlement is contingent upon final approval by both the San Mateo Superior Court and the United States District Court for the Central District of California.

As a result of these developments, we have determined that a probable loss has been incurred and have recognized a net charge to earnings of approximately $1.6 million within general and administrative expense which is comprised of the loss contingency of approximately $10.9 million, net of expected insurance proceeds of approximately $9.4 million. We have classified the loss contingency as "legal settlement payable" and the expected insurance proceeds as "insurance recovery receivable" on the accompanying balance sheets. While it is possible that we may incur a loss greater than the amounts recognized in the accompanying financial statements, we are unable to determine a range of possible losses greater than the amount recognized.

Silimed Litigation

On November 6, 2016, Silimed filed a lawsuit in the United States District Court for the Southern District of New York naming Sientra as the defendant and alleging breach of contract of the Silimed Agreement, unfair competition and misappropriation of trade secrets against us. In its complaint, Silimed alleges that our theft, misuse, and improper disclosure of Silimed's confidential, proprietary, and trade secret manufacturing information was done in order for us to develop our own manufacturing capability that we intend to use to manufacture our PMA-approved products. Silimed is seeking a declaration that we are in material breach of the Silimed Agreement, a preliminary and permanent injunction to prevent our allegedly wrongful use and disclosure of Silimed's confidential and proprietary information, as well as unquantified compensatory and punitive damages. On November 15, 2016, Sientra filed its answer and counterclaims for declaratory judgment in which it denied that Silimed is entitled to any relief including, among other reasons, because of Silimed's material breach of the Silimed Agreement and Silimed's unclean hands, and further seeks declaratory relief that Sientra is the owner of certain assets it acquired from Silimed, Inc. in 2007, that Sientra owns, or is exclusively licensed, to any improvements created since April 2007, that Silimed lacks any confidential information or proprietary rights under the Silimed Agreement, and that Silimed lacks any relevant trade secret rights. On December 9, 2016, Silimed filed a motion to strike the Company's counterclaims. Briefing on that motion was completed on December 30, 2016, and the parties are waiting for a decision from the court. On February 1, 2017, Sientra filed a motion to stay Silimed's breach of contract claim in light of a demand for arbitration filed by Sientra against Silimed on January 20, 2017 concerning Silimed's material breaches of the Silimed Agreement, and to further dismiss, or alternatively stay, the unfair competition and misappropriation of trade secrets claims. Briefing on that motion was completed on February 22, 2017, and the parties are waiting for a decision from the court. On February 3, 2017, the court held an initial pre-trial conference and entered a pre-trial scheduling order which set a final pre-trial conference date of August 3, 2018. We believe that Silimed's claims are legally and factually unsupported and intend to defend this lawsuit vigorously.

On January 20, 2017, Sientra filed an arbitration demand in the International Center for Dispute Resolution in New York naming Silimed as the defendant and alleging material breach of the Silimed Agreement, gross negligence and

tortious interference by Silimed, as well as seeking certain declaratory relief. Among other things, Sientra alleges that Silimed's supply failure constitutes a material breach of the Silimed Agreement, and that such breach was caused by Silimed's grossly negligent or other willful conduct related to its regulatory suspensions and the fire at its manufacturing facility. Silimed filed its answer to Sientra's arbitration demand on March 8, 2017. The parties nominated their party arbitrators on March 13, 2017.

Item 4. Mine Safety Disclosures

Not applicable.

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PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock has been traded on the NASDAQ Global Select Market under the symbol "SIEN" since our initial public offering on October 29, 2014. Prior to this time, there was no public market for our common stock. The following table shows the high and low sale prices per share of our common stock as reported on the NASDAQ Global Select Market for the periods indicated:

	High	Low
Year ended December 31, 2015		
First Quarter	$ 20.93	$ 14.02
Second Quarter	26.67	15.93
Third Quarter	25.94	9.38
Fourth Quarter	10.61	2.78
Year ended December 31, 2016		
First Quarter	$ 10.45	$ 5.61
Second Quarter	8.68	5.60
Third Quarter	9.26	6.57
Fourth Quarter	10.22	6.92

On March 9, 2017, the last reported sale price for our common stock on the NASDAQ Global Select Market was $9.58 per share.

Stock Performance Graph

The graph set forth below compares the cumulative total stockholder return on our common stock between October 29, 2014 (the date of our initial public offering) and December 31, 2016, with the cumulative total return of (a) the NASDAQ Health Care Index and (b) the NASDAQ Composite Index, over the same period. This graph assumes the investment of $100 on October 29, 2014 in our common stock, the NASDAQ Health Care Index and the NASDAQ Composite Index and assumes the reinvestment of dividends, if any. The graph assumes our closing sales price on October 29, 2014 of $16.75 per share as the initial value of our common stock and not the initial offering price to the public of $15.00 per share.

The comparisons shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock. Information used in the graph was obtained from the Nasdaq Stock Market LLC, a financial data provider and a source believed to be reliable. The Nasdaq Stock Market LLC is not responsible for any errors or omissions in such information.

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CUMULATIVE TOTAL RETURN SUMMARY

December 2016

This performance graph shall not be deemed filed for purposes of Section 18 of the Exchange Act or otherwise subject to liabilities under that section and shall not be deemed to be incorporated by reference into any filing of Sientra, Inc. under the Securities Act, except as shall be expressly set forth by specific reference in such filing.

Holders of Record

As of March 9, 2017, there were approximately 109 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have not paid any cash dividends on our common stock since inception and do not anticipate paying cash dividends in the foreseeable future.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10 K.

Use of Proceeds from Public Offering of Common Stock

On November 3, 2014, we closed the sale of 5,750,000 shares of common stock to the public (inclusive of 750,000 shares of common stock sold by us pursuant to the full exercise of an overallotment option granted to the underwriters) at a price of $15.00 per share. The offer and sale of the shares in the IPO was registered under the Securities Act pursuant to registration statements on Form S 1 (File No. 333 198837), which was filed with the SEC, on September 19, 2014 and amended subsequently and declared effective on October 28, 2014. Piper Jaffray & Co. and Stifel, Nicolaus & Company, Incorporated acted as managing underwriters of the offering. We raised approximately $77.0 million in net proceeds after deducting underwriting discounts and commissions of approximately $6.0 million and other offering expenses of

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approximately $3.2 million. None of these expenses consisted of payments made by us to directors, officers or persons owning 10% or more of our common stock or to their associates, or to our affiliates.

On September 23, 2015, we closed the sale of 3,000,000 shares of common stock in a follow-on public offering at a price of $22.00 per share. The offer and sale of the shares in the follow-on offering were registered under the Securities Act pursuant to registration statements on Form S-1 (File No. 333-206755), which was filed with the SEC and declared effective on September 17, 2015. Piper Jaffray & Co. and Stifel, Nicolaus & Company, Incorporated acted as joint book-running managers and Leerink Partners, LLC and William Blair & Company, LLC acted as co-managers. We raised approximately $61.4 million in net proceeds after deducting underwriting discounts and commissions of approximately $4.0 million and other offering expenses of approximately $0.6 million. None of these expenses consisted of payments made by us to directors, officers or persons owning 10% or more of our common stock or to their associates, or to our affiliates.

Upon receipt, the net proceeds from our IPO and our follow-on public offering were held in cash and cash equivalents, primarily bank money market accounts. There has been no material change in our planned use of the net proceeds from the offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act on October 29, 2014, or from our follow-on public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act on September 23, 2015. The amount and timing of our actual expenditures depend on numerous factors, including the ongoing status of and results from clinical trials, as well as any unforeseen cash needs. Accordingly, our management has broad discretion in the application of the net proceeds. As of December 31, 2016, we have used approximately $24.5 million of the proceeds to repay outstanding debt, $6.9 million for the acquisition of bioCorneum® and related transaction costs, $5.0 million for the acquisition of Dermaspan™, Softspan™, and AlloX2® tissue expanders from SSP, and $34.4 million in working capital and other general corporate purposes.

Purchases of Equity Securities by the Issuer or Affiliated Purchasers

There were no repurchases of shares of common stock made during the year ended December 31, 2016.

Item 6. Selected Financial Data

The following selected financial data should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations”, the financial statements and related notes, and other financial information included in this Annual Report on Form 10 K.

We derived the financial data for the years ended December 31, 2016, 2015 and 2014 and as of December 31, 2016 and 2015 from our financial statements, which are included elsewhere in this Annual Report on Form 10 K. The financial data for the year ended December 31, 2012 and as of December 31, 2013 are derived from audited financial statements which are not included in this Form 10-K. Historical results are not necessarily indicative of the results to be expected in future periods.

	Year Ended December 31,				
	2016	2015	2014	2013	2012
	(in thousands, except share data)				
Statement of operations data					
Net sales	$ 20,734	$ 38,106	$ 44,733	$ 35,171	$ 10,447

Gross profit	13,854	27,452	33,233	26,579	8,095
Net loss	(40,166)	(41,230)	(5,811)	(19,125)	(23,433)
Net loss per share					
Basic and diluted	$ (2.20)	$ (2.61)	$ (2.28)	$ (82.25)	$ (85.01)
Weighted average shares					
Basic and diluted	18,233,177	15,770,972	2,545,371	232,512	275,642

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	As of December 31,			
	2016	2015	2014	2013
	(in thousands)			
Balance sheet data				
Working capital	$ 72,484	$ 118,609	$ 103,151	$ 24,509
Total assets	114,283	140,805	139,078	53,166
Long-term debt, excluding current position	—	—	21,671	15,092
Stockholders' equity (deficit)	83,617	118,871	95,639	(126,673)

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10 K. This discussion contains forward looking statements that reflect our plans, estimates and beliefs, and involve risks and uncertainties. Our actual results and the timing of certain events could differ materially from those anticipated in these forward looking statements as a result of several factors, including those discussed in the section titled "Risk Factors" included under Part I, Item 1A and elsewhere in this Annual Report. See "Special Note Regarding Forward Looking Statements" in this Annual Report.

Overview

We are a medical aesthetics company committed to making a difference in patients' lives by enhancing their body image, growing their self esteem and restoring their confidence. We were founded to provide greater choices to board certified plastic surgeons and patients in need of medical aesthetics products. We have developed a broad portfolio of products with technologically differentiated characteristics, supported by independent laboratory testing and strong clinical trial outcomes. We sell our breast implants and breast tissue expanders, or Breast Products, exclusively to board certified and board admissible plastic surgeons and tailor our customer service offerings to their specific needs, which we believe helps secure their loyalty and confidence. We have recently expanded our product portfolio through two acquisitions. We began selling bioCorneum®, an advanced silicone scar treatment directly to physicians after we acquired bioCorneum® from Enaltus in March 2016. Additionally, we began selling the AlloX2®, and Dermaspan™ lines of breast tissue expanders, as well as the Softspan™ line of general tissue expanders, after we acquired these product lines from SSP in November 2016.

Our primary products are silicone gel breast implants for use in breast augmentation and breast reconstruction procedures, which we offer in approximately 400 variations of shapes, sizes, fill volumes and textures. Our breast implants are primarily used in elective procedures that are generally performed on a cash pay basis. Many of our proprietary breast implants incorporate one or more technologies that differentiate us from our competitors, including High Strength Cohesive silicone gel and shell texturing. Our breast implants offer a desired balance between strength, shape retention and softness due to the silicone shell and High Strength Cohesive silicone gel used in our implants. The texturing on Sientra's implant shell is designed to reduce the incidence of malposition, rotation and capsular contracture.

Our breast implants were approved by the FDA, in 2012, based on data we collected from our ongoing, long term clinical trial of our breast implants in 1,788 women across 36 investigational sites in the United States, which included

3,506 implants (approximately 53% of which were smooth and 47% of which were textured). Our clinical trial is the largest prospective, long term safety and effectiveness pivotal study of breast implants in the United States and includes the largest magnetic resonance imaging, or MRI, cohort with 571 patients. The MRI cohort is a subset of study patients that underwent regular MRI screenings in addition to the other aspects of the clinical trial protocol prior to FDA approval. Post-approval, all patients in the long-term clinical trial are subject to serial MRI screenings as part of the clinical protocol. The clinical data we collected over a nine year follow up period demonstrated rupture rates, capsular contracture rates and reoperation rates that were comparable to or better than those of our competitors, at similar time points. In addition to our pivotal study, our clinical data is supported by our Continued Access Study of 2,497 women in the United States. We have also commissioned a number of bench studies run by independent laboratories that we believe further demonstrate the advantages of our breast implants over those of our competitors.

We sell our Breast Products exclusively to board certified and board admissible plastic surgeons, as determined by the American Board of Plastic Surgery, who we refer to as Plastic Surgeons. These surgeons have completed the extensive multi year plastic surgery residency training required by the American Board of Plastic Surgery. While aesthetic

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procedures are performed by a wide range of medical professionals, including dermatologists, otolaryngologists, obstetricians, gynecologists, dentists and other specialists, the majority of aesthetic surgical procedures are performed by Plastic Surgeons. Plastic Surgeons are thought leaders in the medical aesthetics industry. According to the American Board of Plastic Surgery, there are approximately 6,500 board certified plastic surgeons in the United States. We seek to provide Plastic Surgeons with differentiated services, including enhanced customer service offerings, a ten year limited warranty that we believe is the best in the industry based on: providing patients with the largest cash reimbursement for certain out of pocket costs related to revision surgeries in a covered event; a lifetime no charge implant replacement program for covered ruptures; and our industry first CapCon Care Program, or C3 Program, through which we offer no charge replacement implants to breast augmentation patients who experience capsular contracture within the first five years after implantation with our smooth or textured breast implants.

Between October 9, 2015 and March 1, 2016, we voluntarily suspended the sale of all Sientra devices manufactured by Silimed due to the suspension of Silimed's CE and ISO 13485 certifications by TÜV SÜD, Silimed's notified body under EU regulations. This was followed by Brazilian regulatory inquiries of Silimed and a suspension by the Brazilian regulatory agency ANVISA and the Department of the Secretary of State of Rio de Janeiro of the manufacturing and shipment of all medical devices made by Silimed, and their recommendation that plastic surgeons discontinue implanting the devices until further notice. See Note 1(e) to our Financial Statements for more information on the history of these developments with Silimed.

After ongoing discussions with the FDA and our own review of the matter with the assistance of independent experts in quality management systems, cGMP, and data-based risk assessment, on March 1, 2016, we lifted the temporary hold on sales. We also informed our Plastic Surgeons apprising them of our controlled market re-entry plan designed to optimize our inventory supply, which continues to be limited.

The events involving Silimed will likely continue to adversely impact our business, in particular due to the limitations on our existing inventory levels, the uncertainty of our customers' responsiveness to our controlled market re-entry plan, the fact that Silimed filed a lawsuit against us alleging, among other things, a material breach of the existing manufacturing contract, and the fact that the manufacturing contract with Silimed expires on its terms on April 1, 2017. See "Risk Factors — Risks Relating to Our Business and Our Industry" for further detail.

In response to these events and anticipated impacts on our business, we have increasingly focused our efforts on securing and qualifying an alternate manufacturing supplier.

On August 9, 2016, we announced our collaboration with Vesta, pursuant to which we are working with Vesta towards establishing a dedicated contract manufacturing facility for our breast implants. On March 14, 2017, we announced that we had executed a definitive manufacturing agreement with Vesta for the manufacture and supply of our breast implants. In addition, on March 14, 2017, we announced that we had submitted a PMA supplement to the FDA for the manufacturing of our PMA-approved breast implants by Vesta.

We sell our products in the United States through a direct sales organization, which as of December 31, 2016, consisted of 43 employees, including 36 sales representatives and 7 sales managers.

Components of Operating Results

Net Sales

We recognize revenue, net of sales discounts and estimated returns, as the customer has a standard six-month window to return purchased Breast Products. We commenced sales of our breast implants in the United States in the second quarter of 2012 and our Breast Products have historically accounted for substantially all of our net sales. However, sales of our Breast Products accounted for 79% of our net sales for the year end December 31, 2016, as compared to 98% and 97% of our net sales for the years ended December 31, 2015 and 2014, respectively. The percentage decrease in sales of Breast Products for the year ended December 31, 2016 reflects the combined effect of the temporary hold on sales and implanting of Breast Products until March 1, 2016 and the commercial introduction of our scar management products as a result of the acquisition of bioCorneum® on March 9, 2016. Sales of scar management products are included the results of operations from the date of acquisition and accounted for 18% of our net sales for the year ended December 31, 2016.

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We expect that, in the future, our net sales will fluctuate on a quarterly basis due to a variety of factors, including seasonality of breast augmentation procedures. We believe that breast implant sales are subject to seasonal fluctuation due to breast augmentation patients' planning their surgery leading up to the summer season and in the period around the winter holiday season.

Cost of Goods Sold and Gross Margin

Cost of goods sold consists primarily of costs of finished products purchased from our third party manufacturers, reserve for product warranties and warehouse and other related costs.

With respect to our breast implants, each particular style of implant has a fixed unit cost under the contract with our third-party manufacturers. Our recently acquired breast tissue expanders are manufactured in the United States under an exclusive contract with SiMatrix, a subsidiary of Vesta. Under our contract with SiMatrix, each particular product has a fixed unit cost. Our bioCorneum® scar management products are manufactured in the United States under an exclusive contract with Formulated Solutions. Under our contract with Formulated Solutions, each particular product has a fixed unit cost.

In addition to product costs, we provide a commercial warranty on our silicone gel breast implants. The warranty covers device ruptures in certain circumstances. Estimated warranty costs are recorded at the time of sale. Our warehouse and other related costs include labor, rent, product shipments from our third-party manufacturers and other related costs.

We expect our overall gross margin, which is calculated as net sales less cost of goods sold for a given period divided by net sales, to fluctuate in future periods primarily as a result of quantity of units sold, manufacturing price increases, the changing mix of products sold with different gross margins, overhead costs and targeted pricing programs.

Sales and Marketing Expenses

Our sales and marketing expenses primarily consist of salaries, bonuses, benefits, incentive compensation and travel for our sales, marketing and customer support personnel. Our sales and marketing expenses also include expenses for trade shows, our no charge customer shipping program and no-charge product evaluation units, as well as educational, promotional and marketing activities, including direct and online marketing. We expect our sales and marketing expenses to fluctuate in future periods as a result of headcount and timing of our marketing programs. However, we generally expect these costs will increase in absolute dollars.

Research and Development Expenses

Our research and development, or R&D, expenses primarily consist of clinical expenses, product development costs, regulatory expenses, consulting services, outside research activities, quality control and other costs associated with the development of our products and compliance with Good Clinical Practices, or cGCP, requirements. R&D expenses also include related personnel and consultant compensation and stock based compensation expense. We expense R&D costs as they are incurred.

We expect our R&D expenses to vary as different development projects are initiated, including improvements to our existing products, expansions of our existing product lines, new product acquisitions and our FDA required PMA post approval studies of our breast implants. However, we generally expect these costs will increase in absolute terms over time as we continue to expand our product portfolio and add related personnel.

General and Administrative Expenses

Our general and administrative, or G&A, expenses primarily consist of salaries, bonuses, benefits, incentive compensation and stock-based compensation for our executive, financial, legal, business development and administrative functions. Other G&A expenses include outside legal counsel and litigation expenses, independent auditors and other outside consultants, corporate insurance, facilities and information technologies expenses. In 2014 and 2015, G&A expenses also include the federal excise tax on the sale of our medical devices in the United States. In 2016, we did not have expense for the federal excise tax on the sale of our medical devices, as the tax was suspended for 2016 and 2017.

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We expect future G&A expenses to increase as we continue to build our finance, legal, information technology, human resources and other general administration resources to continue to advance the commercialization of our products. In addition, we expect to continue to incur G&A expenses in connection with operating as a public company, which may increase further when we are no longer able to rely on the "emerging growth company" exemption we are afforded under the Jumpstart Our Business Startups Act, or the JOBS Act.

Other (Expense) Income, net

Other (expense) income, net primarily consists of interest income, interest expense and amortization of debt discount associated with our term loans and insurance recoveries.

In 2012, the Company filed a claim with the Hartford Insurance Company, or Hartford, for reimbursement of legal costs incurred in connection with litigation with a competitor that was resolved in 2013. The Company held a D&O insurance policy with Hartford, and the Company and Hartford settled the matter in May 2014. The Company received settlement payments from Hartford and recovery of costs associated with the litigation of $0.0 million, $0.0 million, and $2.4 million for the years ended December 31, 2016, 2015 and 2014, respectively.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, net sales and expenses and the disclosure of contingent assets and liabilities in our financial statements. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about our financial condition and results of operations that are not readily apparent from other sources. Actual results may differ from these estimates.

While our significant accounting policies are more fully described in Note 2 to our financial statements, we believe that the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

We sell our products directly to customers in markets where we have regulatory approval. We offer a six month return policy; and we recognize revenue, net of sales discounts and returns, in accordance with the Financial Accounting Standards Board, or FASB, Accounting Standards Codification 605, Revenue Recognition, or ASC 605. ASC 605 requires that six basic criteria must be met before revenue can be recognized when a right of return exists:

- the seller's price to the buyer is substantially fixed or determinable at the date of sale;
- the buyer has paid the seller, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product;
- the buyer's obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product;
- the buyer acquiring the product for resale has economic substance apart from that provided by the seller;
- the seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer; and

· the amount of future returns can be reasonably estimated.

Appropriate reserves are established for anticipated sales returns based on historical experience, recent gross sales and any notification of pending returns. The Company recognizes revenue when title to the product and risk of loss transfer to customers, provided there are no remaining performance obligations required of the Company or any written matters requiring customer acceptance. The Company allows for the return of product from customers within six months after the original sale and records estimated sales returns as a reduction of sales in the same period revenue is recognized. Sales return provisions are calculated based upon historical experience with actual returns. Actual sales returns in any future period are inherently uncertain and thus may differ from the estimates. If actual sales returns differ significantly from the

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estimates, an adjustment to revenue in the current or subsequent period would be recorded. The Company has established an allowance for sales returns of $3.9 million and $0.7 million as of December 31, 2016 and 2015, respectively, recorded net against accounts receivable in the balance sheet.

A portion of the Company's revenue is generated from consigned inventory of silicone gel breast implants and tissue expanders maintained at doctor, hospital, and clinic locations. The customer is contractually obligated to maintain a specific level of inventory and to notify the Company upon use. For these products, revenue is recognized at the time the Company is notified by the customer that the product has been implanted. Notification is usually through the replenishing of the inventory and the Company periodically reviews consignment inventories to confirm accuracy of customer reporting. FDA regulations require tracking the sales of all breast implants.

Warranty Reserve

We offer a limited warranty and a lifetime product replacement program for our silicone gel breast implants. Under the limited warranty program, we will reimburse patients for certain out of pocket costs related to revision surgeries performed within ten years from the date of implantation in a covered event. Under the lifetime product replacement program, we provide no charge replacement breast implants under a covered event. The programs are available to all patients implanted with our silicone breast implants after April 1, 2012 and are subject to the terms, conditions, claim procedures, limitations and exclusions. Timely completion of a device tracking and warranty enrollment form by the patient's Plastic Surgeon is required to activate the programs and for the patient to be able to receive benefits under either program.

We recorded expense for the accrual of warranties in the amounts of $0.1 million, $0.4 million and $0.5 million, for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016 and 2015, we held total warranty liabilities of $1.4 million and $1.3 million, respectively.

Stock Based Compensation

We recognize stock based compensation using a fair value based method, for costs related to all employee share based payments, including stock options, restricted stock units, and the employee stock purchase plan. Stock-based compensation cost is measured at the date of grant based on the estimated fair value of the award, net of estimated forfeitures.

We estimate the fair value of our stock based awards to employees and directors using the Black Scholes option pricing model. The grant date fair value of a stock based award is recognized as an expense over the requisite service period of the award on a straight line basis. In addition, we use the Monte-Carlo simulation option-pricing model to determine the fair value of market-based awards. 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. Compensation costs related to these awards are recognized regardless of whether the market condition is satisfied, provided that the requisite service has been provided.

The Black Scholes and Monte-Carlo models require inputs of subjective assumptions, including the risk free interest rate, expected dividend yield, expected volatility and expected term, among other inputs. These estimates involve inherent uncertainties and the application of management's judgment. If factors change and different assumptions are used, our stock based compensation expense could be materially different in the future.

We recorded total non cash stock based compensation expense of $3.2 million, $2.4 million and $0.6 million for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, we had total unrecognized compensation costs of $4.3 million related to our stock options and employee stock purchase plan. These costs are

expected to be recognized over a weighted average period of 2.74 years. As of December 31, 2016, we had total unrecognized compensation costs of $2.2 million related to restricted stock units, or RSUs. These costs are expected to be recognized over a weighted average period of 1.86 years.

Warrant Liabilities

We have issued warrants to Oxford Finance, LLC, or Oxford, to purchase shares of common stock in connection with our previously held term loan agreement with Oxford. The warrants are recorded at fair value using either the Black Scholes option pricing model, other binomial valuation model or lattice model, depending on the characteristics of the warrants at the time of the valuation. The fair value of these warrants is re measured at each financial reporting period

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with any changes in fair value being recognized as a component of other income (expense) in the accompanying statements of operations. We will continue to re measure the warrants to fair value until exercise or expiration of the related warrant.

As of December 31, 2016 and 2015, the fair value of our warrant liability was $0.1 million and $0.0 million, respectively. We recognized an increase of other (income) expense of $39,072 for the change in fair value of warrants during the year ended December 31, 2016, a decrease of $0.4 million for the year ended December 31, 2015 and an increase of $0.2 million for the year ended December 31, 2014.

Acquisitions

We account for acquired business combinations using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recorded at fair value, with limited exceptions. Valuations are generally completed for business acquisitions using a discounted cash flow analysis. The most significant estimates and assumptions inherent in a discounted cash flow analysis include the amount and timing of projected future cash flows, the discount rate used to measure the risks inherent in the future cash flows, the assessment of the asset's life cycle, and the competitive and other trends impacting the asset, including consideration of technical, legal, regulatory, economic and other factors. Each of these factors and assumptions can significantly affect the value of the intangible asset. The excess of the fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill.

We believe the fair values assigned to the assets acquired and liabilities assumed are based on reasonable assumptions. However, these assumptions may be incomplete or inaccurate, and unanticipated events and circumstances may occur. We will finalize these amounts as we obtain the information necessary to complete the measurement processes. Any changes resulting from facts and circumstances that existed as of the acquisition dates may result in adjustments to the provisional amounts recognized at the acquisition dates. Any changes resulting from facts and circumstances that existed as of the acquisition dates may result in adjustments to the provisional amounts recognized at the acquisition dates. These changes could be significant. We will finalize these amounts no later than one year from the respective acquisition dates.

Determining the useful life of an intangible asset also requires judgment, as different types of intangible assets will have different useful lives and certain assets may even be considered to have indefinite useful lives. Useful life is the period over which the intangible asset is expected to contribute directly or indirectly to our future cash flows. We determine the useful lives of intangible assets based on a number of factors, such as legal, regulatory, or contractual provisions that may limit the useful life, and the effects of obsolescence, anticipated demand, existence or absence of competition, and other economic factors on useful life.

Acquisition-related contingent consideration associated with a business combination is initially recognized at fair value and then remeasured each reporting period, with changes in fair value recorded in general and administrative expense. We use the Monte-Carlo Simulation model to estimate the fair value of contingent consideration, which requires input assumptions about the likelihood of achieving specified milestone criteria, projections of future financial performance, and assumed discount rates. Changes in the fair value of the acquisition-related contingent consideration obligations result from several factors including changes in discount periods and rates, changes in the timing and amount of revenue estimates and changes in probability assumptions with respect to the likelihood of achieving specified milestone criteria. These estimates involve inherent uncertainties and the application of management's judgment. If factors change and different assumptions are used, our stock based compensation expense could be materially different in the future.

Recent Accounting Pronouncements

Please refer to Note 2 in the notes to our financial statements included in this Annual Report on Form 10-K for information on recent accounting pronouncements and the expected impact on our financial statements.

Results of Operations

Comparison of the Years Ended December 31, 2016 and 2015

The following table sets forth our results of operations for the years ended December 31, 2016 and 2015:

Year
Ended

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	December 31,	
	2016	2015
	(in thousands)	
Statement of operations data		
Net sales	$ 20,734	$ 38,106
Cost of goods sold	6,880	10,654
Gross profit	13,854	27,452
Operating Expenses		
Sales and marketing	20,607	25,762
Research and development	9,704	7,199
General and administrative	23,577	18,738
Goodwill impairment	—	14,278
Total operating expenses	53,888	65,977
Loss from operations	(40,034)	(38,525)
Other income (expense), net		
Interest income	63	32
Interest expense	(98)	(3,097)
Other (expense) income, net	(36)	360
Total other income (expense), net	(71)	(2,705)
Loss before income taxes	(40,105)	(41,230)
Income taxes	61	—
Net loss	$ (40,166)	$ (41,230)

Net Sales

Net sales decreased $17.4 million, or 45.6%, to $20.7 million for the year ended December 31, 2016, as compared to $38.1 million for the year ended December 31, 2015. The decrease was a result of both our voluntary hold on the sale and implanting of all Sientra devices manufactured by Silimed between October 9, 2015 and March 1, 2016 and our controlled re-entry to market designed to optimize our supply of Breast Products inventory. The decrease in Breast Product net sales was offset by $3.8 million of scar management product net sales for the year ended December 31, 2016, following the acquisition of bioCorneum® in March 2016.

As of December 31, 2016, our sales organization included 43 employees, as compared to 51 employees as of December 31, 2015.

Cost of Goods Sold and Gross Margin

Cost of goods sold decreased $3.8 million, or 35.4%, to $6.9 million for the year ended December 31, 2016, as compared to $10.7 million for the year ended December 31, 2015. This decrease was due to a decrease in sales volume driven by both our voluntary hold on sales from October 9, 2015 to March 1, 2016 and our controlled re-entry into the marketplace, offset by a decrease to our allowance for sales returns.

The gross margins for the years ended December 31, 2016 and 2015 were 66.8% and 72.0%, respectively. The decrease for the year ended December 31, 2016 was primarily due to increased inventory write-offs, partially offset by increased sales of our scar management products, which generally have higher gross margins. The increase in

inventory write-offs resulted from the timing and recognition of products anticipated to expire prior to being sold and discontinuation of certain product lines.

Sales and Marketing Expenses

Sales and marketing expenses decreased $5.2 million, or 20.0%, to $20.6 million for the year ended December 31, 2016, as compared to $25.8 million for the year ended December 31, 2015. This decrease consisted primarily of a $2.9 million decrease in employee–related costs as a result of decreased headcount and a $2.6 million decrease in marketing costs due to lower no charge customer shipping costs and less direct marketing activities.

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Research and Development Expenses

R&D expenses increased $2.5 million, or 34.8%, to $9.7 million for the year ended December 31, 2016, as compared to $7.2 million for the year ended December 31, 2015. This increase was primarily due to a $2.6 million increase in product development costs and related consulting fees, a $0.2 million increase of employee incentive compensation, offset by a $0.4 million decrease in clinical trial expenses.

General and Administrative Expenses

G&A expenses increased $4.8 million, or 25.8%, to $23.6 million for the year ended December 31, 2016, as compared to $18.7 million for the year ended December 31, 2015. This increase consisted primarily of a $2.9 million increase in outside legal counsel and litigation expenses, a $1.6 million probable loss incurred related to the proposed settlement of the class action securities litigation, and a $0.8 million increase in amortization expense related to intangible assets acquired in the current fiscal year, offset by a $0.8 million decrease in medical device excise tax costs as a result of the suspension of the tax during calendar years 2016 and 2017.

Goodwill Impairment

There were no goodwill impairment charges for the year ended December 31, 2016. Goodwill impairment charges for the year ended December 31 2015 were $14.3 million. For additional information on the goodwill impairment for the year ended December 31, 2015, see Note 5 to our Financial Statements included herein.

Other Income (Expense), net

Total other income (expense), net for the year ended December 31, 2016 was primarily associated with interest income on cash held in a money market account, interest paid on inventory payable and expense recognized for the change in fair value of warrants. Total other income (expense), net for the year ended December 31, 2015 was primarily associated with interest income on cash held in a money market account, interest expense on our Oxford term loans, which were repaid in full in the fourth quarter of 2015 and income recognized for the change in fair value of warrants.

Income Tax Expense

Income tax expense for the year ended December 31, 2016 was associated with a deferred tax liability associated with indefinite lived intangibles from acquisitions that cannot offset the deferred tax asset. There was no income tax expense for the year ended December 31, 2015.

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Comparison of the Years Ended December 31, 2015 and 2014

The following table sets forth our results of operations for the years ended December 31, 2015 and 2014:

	Year Ended December 31,	
	2015	2014
	(in thousands)	
Statement of operations data		
Net sales	$ 38,106	$ 44,733
Cost of goods sold	10,654	11,500
Gross profit	27,452	33,233
Operating Expenses		
Sales and marketing	25,762	23,599
Research and development	7,199	4,707
General and administrative	18,738	10,712
Goodwill impairment	14,278	—
Total operating expenses	65,977	39,018
Loss from operations	(38,525)	(5,785)
Other income (expense), net		
Interest income	32	—
Interest expense	(3,097)	(2,172)
Other (expense) income, net	360	2,146
Total other income (expense), net	(2,705)	(26)
Loss before income taxes	(41,230)	(5,811)
Income taxes	—	—
Net loss	$ (41,230)	$ (5,811)

Net Sales

Net sales decreased $6.6 million, or 14.8%, to $38.1 million for the year ended December 31, 2015, as compared to $44.7 million for the year ended December 31, 2014. This decrease was primarily driven by our voluntary hold on the sale and implanting of all Sientra devices manufactured by Silimed on October 9, 2015.

As of December 31, 2015, our sales organization included 51 employees, as compared to 46 employees as of December 31, 2014.

Cost of Goods Sold and Gross Margin

Cost of goods sold decreased $0.8 million, or 7.4%, to $10.7 million for the year ended December 31, 2015, as compared to $11.5 million for the year ended December 31, 2014. This decrease was primarily due to a decrease in sales volume driven by our voluntary hold on sales.

The gross margins for the years ended December 31, 2015 and 2014 were 72.0% and 74.3%, respectively. The decrease in gross margin was primarily due to an incremental $0.3 million reserve for inventory obsolescence recorded in the third quarter for product that we estimate to expire prior to being sold, greater fixed overhead as a percentage of net sales, and manufacturing cost increases.

Sales and Marketing Expenses

Sales and marketing expenses increased $2.2 million, or 9.2%, to $25.8 million for the year ended December 31, 2015, as compared to $23.6 million for the year ended December 31, 2014. This was primarily due to a $3.2 million increase in employee related expenses for the sales department offset by a $0.9 million decrease in marketing costs.

Research and Development Expenses

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R&D expenses increased $2.5 million, or 52.9%, to $7.2 million for the year ended December 31, 2015, as compared to $4.7 million for the year ended December 31, 2014. This was primarily due to an increase in product development costs.

General and Administrative Expenses

G&A expenses increased $8.0 million, or 74.9%, to $18.7 million for the year ended December 31, 2015, as compared to $10.7 million for the year ended December 31, 2014. This increase was primarily due to an increase in expenses that relate to operating as a public company, termination benefits for certain former executives, and outside legal counsel costs.

Goodwill Impairment

Goodwill impairment charges for the year ended December 31, 2015 were $14.3 million. There were no goodwill impairment charges for the year ended December 31, 2014. For additional information on these goodwill impairments, see Note 5 to our Financial Statements included herein.

Other (Expense) Income, net

Total other (expense) income, net for the year ended December 31, 2015 was primarily associated with interest expense on our term loans of $3.1 million, offset by income recognized for the change in fair value of warrants of $0.4 million. Total other (expense) income, net for the year ended December 31, 2014 was primarily associated with interest expense on our term loans of $2.2 million, offset by income from settlement payments from Hartford and recovery of costs associated with the litigation of $2.4 million.

Liquidity and Capital Resources

Since our inception, we have incurred significant net operating losses and anticipate that our losses will continue in the near term. We expect our operating expenses will continue to grow as we expand our operations. We will need to generate significant net sales to achieve profitability. To date, we have funded our operations primarily with proceeds from the sales of preferred stock, borrowings under our term loans, sales of our products since 2012, and the proceeds from the sale of our common stock in public offerings. As of December 31, 2016, we had no long-term debt.

In November 2014, we completed our IPO of common stock in which we sold 5,750,000 shares at a price of $15.00 per share, raising approximately $77.0 million in net proceeds after deducting underwriting discounts and commissions of approximately $6.0 million and offering expenses of approximately $3.2 million.

On September 23, 2015, we completed a follow-on public offering of common stock in which we sold 3,000,000 shares at a price of $22.00 per share, raising approximately $61.4 million in net proceeds after deducting underwriting discounts and commissions of approximately $4.0 million and offering expenses of approximately $0.6 million.

As of December 31, 2016, we had $67.2 million in cash and cash equivalents. Our historical cash outflows have primarily been associated with research and development activities, especially related to obtaining FDA approval for

our breast implant portfolio and complying with the FDA's post-approval requirements, activities relating to commercialization and increases in working capital, including the purchase of inventory as well as the expansion of our sales force and marketing programs. In addition, we have used cash to fund recent acquisitions, including $6.9 million for the acquisition of bioCorneum from Enaltus, which closed on March 9, 2016 and $5.0 million for the acquisition of assets from SSP, which closed on November 2, 2016. We believe that our available cash on hand will be sufficient to satisfy our liquidity requirements for at least the next 12 months from the date our financial statements are issued.

However, we expect that uncertainty regarding expenses we may continue to incur in connection with establishing new manufacturing capacity with Vesta or any other third-party manufacturer for our breast implants, and our uncertainty regarding the amount of additional expenses we may incur in connection with regulatory inquiries, as well as expenses we may incur defending against litigation claims, including the Silimed Litigation, may have a material effect on our future cash outflows and our liquidity. As a result, we may be required to seek additional funds in the future from public or private offerings of our capital stock, borrowings under term loans or from other sources.

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On March 13, 2017 we entered into a Loan and Security Agreement, or the Loan Agreement, with Silicon Valley Bank, or SVB. Under the terms of the Loan Agreement, SVB made available to us a revolving line of credit of up to $15.0 million and a $5.0 million term loan. We have not borrowed any amounts under the Loan Agreement. For further details on the Loan Agreement, see Item 9B — "Other Information."

Cash Flows

The following table shows a summary of our cash flows provided by (used in) operating, investing and financing activities for the periods indicated:

	Year Ended December 31,		
	2016	2015	2014
	(in thousands)		
Net cash (used in) provided by:			
Operating activities	$ (34,430)	$ (18,184)	$ 450
Investing activities	(12,835)	(1,128)	(439)
Financing activities	1,676	35,384	86,996
Net change in cash and cash equivalents	$ (45,589)	$ 16,072	$ 87,007

Cash (used in) provided by operating activities

Net cash used in operating activities was $34.4 million and $18.2 million during the years ended December 31, 2016 and 2015, as compared to net cash provided by operating activities of $0.5 million during the year ended December 31, 2014. The $16.2 million increase in cash used in operating activities between the years ended December 31, 2016 and 2015 was primarily associated with a $17.4 million decrease in net sales, a $2.1 million increase in operating expenses, excluding goodwill impairment for 2015, and an increase in cash outflows from operating assets and liabilities resulting from customer deposits and timing of accounts payable and accrued liability payments. The $18.6 million increase in cash used in operating activities between the years ended December 31, 2015 and 2014 was primarily associated with the increase in net loss of $35.4 million, which was affected by our voluntary hold on the sale and implanting of all Sientra devices manufactured by Silimed since October 9, 2015, offset by a decrease in cash outflows from operating assets and liabilities resulting from a decrease in inventory purchases and timing of accounts payable payments.

Cash used in investing activities

Net cash used in investing activities was $12.8 million, $1.1 million and $0.4 million during the years ended December 31, 2016, 2015 and 2014, respectively. The increase in cash used in investing activities of $11.7 million between the years ended December 31, 2016 and 2015 was primarily due to $6.9 million for the acquisition of bioCorneum® in March 2016 and $5.0 million for the acquisition of the AlloX2® and Dermaspan™ lines of breast tissue expanders, in addition the Softspan™ line of general tissue expanders in November 2016. The $0.7 million increase in cash used in investing activities between the years ended December 31, 2015 and 2014 was due to an increase in property and equipment purchases.

Cash provided by financing activities

Net cash provided by financing activities was $1.7 million during the year ended December 31, 2016 as compared to $35.4 million during the year ended December 31, 2015. The decrease in cash provided by financing activities of $33.7 million between the years ended December 31, 2016 and 2015 was primarily the result of decrease in cash proceeds from the issuance of our common stock. For the year ended December 31, 2015, we received cash proceeds from the issuance of common stock, net of underwriters discount in a follow-on offering of $62.0 million, offset by the repayment of long-term debt of $26.6 million. The decrease in cash provided by financing activities of $51.6 million between the years ended December 31, 2015 and 2014 was primarily the result of the decrease in cash proceeds from the issuance of

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our common stock. For the year ended December 31, 2014, we received cash proceeds from the issuance of common stock, net of the underwriters discount in an IPO of $80.2 million.

Our liquidity position and capital requirements are subject to a number of factors. For example, our cash inflow and outflow may be impacted by the following:

- the timing and availability of alternative manufacturing sources, and costs associated with procuring and qualifying such manufacturing capacity;
- net sales generated by our Breast Products, scar management products, and any other future products that we may develop and commercialize;
- costs associated with expanding our sales force and marketing programs;
- cost associated with developing and commercializing our proposed products or technologies;
- expenses we incur in connection with potential litigation or governmental investigations;
- cost of obtaining and maintaining regulatory clearance or approval for our current or future products;
- cost of ongoing compliance with regulatory requirements;
- anticipated or unanticipated capital expenditures; and
- unanticipated G&A expenses.

Our primary short-term capital needs, which are subject to change, include expenditures related to:

- support of our sales and marketing efforts related to our current and future products;

- new product acquisition and development efforts;
- facilities expansion needs;
- investment in inventory required to meet customer demands; and
- expenses we incur in connection with defending against litigation, including the Silimed Litigation.

Although we believe the foregoing items reflect our most likely uses of cash in the short-term, we cannot predict with certainty all of our particular short-term cash uses or the timing or amount of cash used. If cash generated from operations is insufficient to satisfy our working capital and capital expenditure requirements, we may be required to sell additional equity or debt securities or obtain credit facilities. Additional capital, if needed, may not be available on satisfactory terms, if at all. Furthermore, any additional equity financing may be dilutive to stockholders, and debt financing, if available, may include restrictive covenants. For a discussion of other factors that may impact our future liquidity and capital funding requirements, see “Risk Factors — Risks Related to Our Financial Results.”

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Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2016 (in thousands):

	Payments Due by Period				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
	(in thousands)				
Operating lease obligations	$ 1,560	$ 532	$ 1,028	$ —	$ —
Purchase obligations (1)	2,571	2,571	—	—	—
Total contractual obligations (2)	$ 4,131	$ 3,103	$ 1,028	$ —	$ —

(1) Purchase obligations include the following: (i) accounts payable and (ii) open purchase commitments with our contract manufacturers. We currently expect to fund these commitments with cash flows from operations and existing cash balances.
(2) This table reflects our contractual obligations as of December 31, 2016 and does not reflect the Loan Agreement with SVB discussed above, which was entered into on March 13, 2017.

Off Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off balance sheet arrangements as defined under SEC rules.

Item 7A. Quantitative and Qualitative Disclosures about Market Risks

As of December 31, 2016, we had $67.2 million in cash and cash equivalents. We generally hold our cash in checking accounts and interest-bearing money market accounts. Our exposure to market risk related to interest rate sensitivity is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents.

Item 8. Financial Statements and Supplementary Data

The financial statements required to be filed pursuant to this Item 8 are appended to this report beginning on page F 1. An index of those financial statements is included in Part IV, Item 15 below.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated 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. The term “disclosure controls and procedures,” as defined in

Rules 13a 15(e) and 15d 15(e) under the Exchange Act. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is (i) recorded, processed, summarized and reported, within the time periods specified in the SEC rules and form; and accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

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Based on this evaluation, the Company's principal executive officer and principal financial officer have concluded that, as of December 31, 2016, the Company's disclosure controls and procedures were not effective as a result of a material weakness described below in Management's Annual Report on Internal Control over Financial Reporting.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America and includes policies and procedures that:

•pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;

•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

•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 inherent limitations, internal control over financial reporting may not prevent or detect misstatements. In addition, 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.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

As of December 31, 2016, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control – Integrated Framework (2013), or the COSO 2013 Framework. Based on this assessment, management concluded that as of December 31, 2016, our internal control over financial reporting was not effective because of the material weakness described below.

The Company did not maintain sufficiently trained resources with knowledge of internal control over financial reporting as it relates to accounting for significant unusual transactions, including coordination with external service providers. As a result, the Company did not design and implement effective management review controls over business combinations, specifically key assumptions, financial data and calculations used to measure the fair value of acquired assets and liabilities, including contingent consideration prepared by its external service provider.

This material weakness resulted in material misstatements in the current period to intangible assets, goodwill and contingent consideration, which were corrected by management prior to the issuance of the Company's financial statements included herein. These deficiencies represented a material weakness in our internal control over financial reporting as of December 31, 2016 because there is a reasonable possibility that material misstatements to our consolidated financial statements will not be prevented or detected on a timely basis.

This annual report does not include an attestation report of the company's registered public accounting firm due to the established rules of the Securities and Exchange Commission.

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Changes in Internal Control over Financial Reporting

Except for the material weakness described herein, there was no change in our internal control over financial reporting that occurred during the three months ended December 31, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Remedial Measures

The Company is in the process of improving its policies and procedures relating to the recognition and measurement of significant unusual transactions, including those involving external service providers and designing more effective controls to remediate the material weakness described above. Management plans to enhance its controls related to non-routine transactions by supplementing with additional resources as necessary, enhancing the design and documentation of management review controls, and improving the documentation of internal control procedures.

Item 9B. Other Information

Manufacturing Agreement with Vesta

On March 10, 2017, we entered into a manufacturing agreement with Vesta pursuant to which Vesta shall manufacture and supply our breast implant products. The term of the manufacturing agreement is five years, subject to customary termination rights by either party including termination for a material breach of the agreement. The manufacturing agreement also contains certain provisions regarding the rights and responsibilities of the parties with respect to manufacturing specifications, forecasting and ordering, delivery arrangements, payment terms, packaging requirements, limited warranties, confidentiality and indemnification, including indemnification by us for a breach of certain representations and warranties related to confidentiality and intellectual property, the breach of which or the failure to provide such indemnity would qualify as a material breach.

The foregoing description of the manufacturing agreement is not complete and is qualified entirely by reference to the full text of the agreement, a copy of which will be filed with our Quarterly Report on Form 10-Q for the fiscal quarter ending March 31, 2017.

PMA Supplement Submission

On March 13, 2017, we submitted a PMA supplement to the FDA for the manufacturing of our PMA-approved breast implants by Vesta, pursuant to a manufacturing agreement entered into between the parties on March 10, 2017.

Loan and Security Agreement with Silicon Valley Bank

On March 13, 2017, we entered into a Loan Agreement with SVB. Under the terms of the Loan Agreement, SVB made available to us a revolving line of credit of up to $15.0 million, or the Revolving Line, and a $5.0 million term loan, or the Term Loan. We have not borrowed any amounts under the Revolving Line or the Term Loan. We intend to use the proceeds from the Loan Agreement for working capital and other general corporate purposes.

Any indebtedness under the Term Loan and the Revolving Line bear interest at a floating per annum rate equal to the prime rate as reported in The Wall Street Journal plus 1.00%, which as of the closing date is 3.75%. The Term Loan has a scheduled maturity date of March 1, 2020. We must make monthly payments of accrued interest under the Term Loan from the funding date of the Term Loan, or the Funding Date, until April 1, 2018, followed by monthly installments of principal and interest through the term loan maturity date. The interest-only period may be extended until April 1, 2019 if we have obtained FDA certification of the manufacturing facility operated by Vesta by March 31, 2018. We may prepay all, but not less than all, of the Term Loan prior to its maturity date provided we pay SVB a prepayment charge based on a percentage of the then-outstanding principal balance which shall be equal to 2% if the prepayment occurs prior to the second anniversary of the Funding Date, and 1% if the prepayment occurs thereafter. Upon making the final payment of the Term Loan, whether upon prepayment, acceleration or at maturity, we are required to pay a 12.5% fee on the original principal amount of the Term Loan.

The amount of loans available to be drawn under the Revolving Line is based on a borrowing base equal to 80% of our eligible accounts; provided that if we maintain an adjusted quick ratio (as defined in the Loan Agreement) of 1.5:1.0 for three continuous consecutive months, we may access the full Revolving Line. We may make (subject to the applicable

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borrowing base at the time) and repay borrowings from time to time under the Revolving Line until the maturity of the facility on March 13, 2022.

The Loan Agreement includes customary affirmative and restrictive covenants and representations and warranties, including a financial covenant to maintain the adjusted quick ratio (as defined in the Loan Agreement) of 1.15:1.0 while borrowings are outstanding and until we have obtained FDA certification of the manufacturing facility operated by Vesta, a covenant against the occurrence of a "change in control," financial reporting obligations, and certain limitations on indebtedness, liens, investments, distributions (including dividends), collateral, mergers or acquisitions, taxes, corporate changes, and deposit accounts. The Loan Agreement also includes customary events of default, including payment defaults, breaches of covenants following any applicable cure period, the occurrence of any "material adverse change" as set forth in the Loan Agreement, penalties or judgements in an amount of at least $1,000,000 rendered against us by any governmental agency and certain events relating to bankruptcy or insolvency. Upon the occurrence of an event of default, a default interest rate of an additional 5.0% may be applied to any outstanding principal balances, and SVB may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement. Our obligations under the Loan Agreement are secured by a security interest in substantially all of our assets, other than intellectual property.

In connection with the entry into the Term Loan, we will issue a warrant to SVB, or the Warrant, exercisable for such number of shares of our common stock as equal to $87,500 divided by a price per share equal to the average closing price of the Company's common stock on the NASDAQ Capital Market for the five trading days prior to the Funding Date. The Warrant may be exercised on a cashless basis, and is immediately exercisable from the Funding Date through the earlier of (i) the five year anniversary of the Funding Date, and (ii) the consummation of certain acquisition transactions involving the Company as set forth in the Warrant.

At the closing of the Loan Agreement, SVB earned a commitment fee of $937,500 of which we paid $187,500 on the closing date and the remainder of which is due and payable by us in increments of $187,500 on each anniversary thereof.

The foregoing descriptions of the Loan Agreement and the Warrant are not complete and are qualified entirely by reference to the full text of the Loan Agreement and Warrant which will be filed with our Quarterly Report on Form 10-Q for the fiscal quarter ending March 31, 2017.

Executive Officer Employment Agreement Amendment

On March 10, 2017 we amended our employment agreement with Charles Huiner, our Chief Operating Officer and Senior Vice President of Corporate Development & Strategy, to provide for the acceleration of his unvested equity awards in certain limited situations.

The foregoing description of the amendment to Mr. Huiner's employment agreement is not complete and is qualified entirely by reference to the full text of the amendment, a copy of which is filed herewith as Exhibit 10.17 and incorporated herein by reference.

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PART III

Item 10. Directors, Executive Officers, and Corporate Governance

Incorporated by reference from the information in our Proxy Statement for our 2017 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10 K relates.

Item 11. Executive Compensation

Incorporated by reference from the information in our Proxy Statement for our 2017 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10 K relates.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Incorporated by reference from the information in our Proxy Statement for our 2017 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10 K relates.

Item 13. Certain Relationships and Related Transactions and Director Independence

Incorporated by reference from the information in our Proxy Statement for our 2017 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10 K relates.

Item 14. Principal Accountant Fees and Services

Incorporated by reference from the information in our Proxy Statement for our 2017 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10 K relates.

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PART IV

Item 15. Exhibits, Financial Statements and Schedule

(a)(1)Financial Statements.

The response to this portion of Item 15 is set forth under Item 8 above.

(a)(2)Financial Statement Schedule.

All schedules have been omitted because they are not required or because the required information is given in the Financial Statements or Notes thereto.

(a)(3)Exhibits.

See the Exhibit Index immediately following the signature page of this Annual Report on Form 10 K. The exhibits listed in the Exhibit Index below are filed or incorporated by reference as part of this Annual Report on Form 10 K.

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Sientra, Inc.

INDEX TO FINANCIAL STATEMENTS AND FINANCIAL STATEMENT SCHEDULE

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Sientra, Inc.:

We have audited the accompanying balance sheets of Sientra, Inc. (the Company) as of December 31, 2016 and 2015, and the related statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the three year period ended December 31, 2016. In connection with our audits of the financial statements, we also have audited the related financial statement schedule II – valuation and qualifying accounts. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements and financial statement schedule referred to above present fairly, in all material respects, the financial position of Sientra, Inc. as of December 31, 2016 and 2015, and the results of its operations and its cash flows for each of the years in the three year period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

(signed) KPMG LLP

Los Angeles, California
March 14, 2017

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Sientra, Inc.

Balance Sheets

(in thousands, except per share data)

	December 31,	
	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	$ 67,212	$ 112,801
Accounts receivable, net of allowances of $4,329 and $1,116 at December 31, 2016 and December 31, 2015, respectively	3,082	4,249
Inventories, net	18,484	20,602
Insurance recovery receivable	9,375	—
Prepaid expenses and other current assets	1,852	1,473
Total current assets	100,005	139,125
Property and equipment, net	2,986	1,404
Goodwill	4,878	—
Other intangible assets, net	6,186	53
Other assets	228	223
Total assets	$ 114,283	$ 140,805
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,555	$ 4,069
Accrued and other current liabilities	6,507	6,959
Legal settlement payable	10,900	—
Customer deposits	6,559	9,488
Total current liabilities	27,521	20,516
Warranty reserve and other long-term liabilities	3,145	1,418
Total liabilities	30,666	21,934
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.01 par value – Authorized 10,000,000 shares; none issued or outstanding	—	—
Common stock, $0.01 par value — Authorized 200,000,000 shares; issued 18,671,409 and 18,066,143 and outstanding 18,598,682 and 17,993,416 shares at December 31, 2016 and December 31, 2015 respectively	186	180
Additional paid-in capital	299,133	294,227
Treasury stock, at cost (72,727 shares at December 31, 2016 and December 31, 2015)	(260)	(260)
Accumulated deficit	(215,442)	(175,276)
Total stockholders' equity	83,617	118,871
Total liabilities and stockholders' equity	$ 114,283	$ 140,805

See accompanying notes to financial statements.

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Sientra, Inc.

Statements of Operations

(in thousands, except per share data)

	Year Ended December 31,		
	2016	2015	2014
Net sales	$ 20,734	$ 38,106	$ 44,733
Cost of goods sold	6,880	10,654	11,500
Gross profit	13,854	27,452	33,233
Operating expenses:			
Sales and marketing	20,607	25,762	23,599
Research and development	9,704	7,199	4,707
General and administrative	23,577	18,738	10,712
Goodwill impairment	—	14,278	—
Total operating expenses	53,888	65,977	39,018
Loss from operations	(40,034)	(38,525)	(5,785)
Other income (expense), net:			
Interest income	63	32	—
Interest expense	(98)	(3,097)	(2,172)
Other (expense) income, net	(36)	360	2,146
Total other income (expense), net	(71)	(2,705)	(26)
Loss before income taxes	(40,105)	(41,230)	(5,811)
Income taxes	61	—	—
Net loss	$ (40,166)	$ (41,230)	$ (5,811)
Basic and diluted net loss per share attributable to common stockholders	$ (2.20)	$ (2.61)	$ (2.28)
Weighted average outstanding common shares used for net loss per share attributable to common stockholders:			
Basic and diluted	18,233,177	15,770,972	2,545,371

See accompanying notes to financial statements.

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Sientra, Inc.

Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

(in thousands, except per share data)

	Convertible preferred stock		Common stock		Treasury stock		Additional paid-in	Accumulated	Total stockholders' equity
	Shares	Amount	Shares	Amount	Shares	Amount	capital	deficit	(deficit)
Balances at December 31, 2013	24,593,087	$ 150,456	279,879	$ 3	72,727	$ (260)	1,819	$ (128,235)	$ (126,673)
Conversion of convertible preferred stock to common stock	(24,593,087)	(150,456)	8,942,925	89	—	—	150,367	—	150,456
Proceeds from IPO, net of costs	—	—	5,750,000	58	—	—	76,977	—	77,035
Stock option exercises	—	—	12,900	—	—	—	38	—	38
Employee stock-based compensation expense	—	—	—	—	—	—	594	—	594
Net loss	—	—	—	—	—	—	—	(5,811)	(5,811)
Balances at December 31, 2014	—	$ —	14,985,704	$ 150	72,727	$ (260)	229,795	$ (134,046)	$ 95,639
Proceeds from follow-on offering, net of costs	—	—	3,000,000	30	—	—	61,367	—	61,397
Employee stock-based compensation expense	—	—	—	—	—	—	2,382	—	2,382
Stock option exercises	—	—	36,189	—	—	—	119	—	119
Employee stock purchase program (ESPP)	—	—	44,250	—	—	—	564	—	564
Net loss	—	—	—	—	—	—	—	(41,230)	(41,230)
	—	$ —	18,066,143	$ 180	72,727	$ (260)	$ 294,227	$ (175,276)	$ 118,871

Balances at December 31, 2015	—	—	—	—	—	—	3,236	—	3,236
Employee stock-based compensation expense	—	—	—	—	—	—	918	—	923
Stock option exercises	—	—	478,099	5	—	—	752	—	753
Employee stock purchase program (ESPP)	—	—	122,667	1	—	—	—	—	—
Vested restricted stock			4,500	—	—	—	—	(40,166)	(40,166)
Net loss	—	—	—	—	—	—	—		
Balances as of December 31, 2016	—	$ —	18,671,409	$ 186	72,727	$ (260)	$ 299,133	$ (215,442)	$ 83,617

See accompanying notes to financial statements.

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Sientra, Inc.

Statements of Cash Flows

(in thousands)

	Year Ended December 31,		
	2016	2015	2014
Cash flows from operating activities:			
Net loss	$ (40,166)	$ (41,230)	$ (5,811)
Adjustments to reconcile net loss to net cash used in operating activities:			
Goodwill impairment	—	14,278	—
Depreciation and amortization	1,177	318	275
Provision for doubtful accounts	437	233	39
Provision for warranties	71	385	447
Provision for inventory	1,384	469	—
Change in fair value of warrants	39	(360)	220
Change in fair value of contingent consideration	37	—	—
Non-cash interest expense	3	1,386	490
Stock-based compensation expense	3,236	2,382	594