

Sientra, Inc.  
Form 10-K  
March 18, 2015

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 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, 2014

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File Number: **001-36709**

**Sientra, Inc.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**20-5551000**  
(IRS Employer Identification No.)

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

**93117**  
(Zip Code)

**(805) 562-3500**  
(Registrant's Telephone Number, Including Area Code)

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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       Smaller reporting company   
(Do not check if a 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 registrant did not have a public float on the last business day of its most recently completed second fiscal quarter because there was no public market for the registrant's common equity as of such date. As of March 13, 2015, there were 14,924,949 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 2015 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 contains forward-looking statements within the meaning of Section 27A of the Securities Act, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements involve risks and uncertainties as well as assumptions that, if they never materialize or prove incorrect, could cause our results could differ materially from those expressed or implied by such forward-looking statements.

Forward-looking statements are often identified by the use of words such as, "anticipate," "believe," "may," "might," "could," "will," "aim," "estimate," "continue," "intend," "expect," "plan," or the 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. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled "*Risk Factors*" included under Part I, Item 1A below. Forward-looking statements in this Annual Report on Form 10-K include, but are not limited to, statements about:

our history of net operating losses and uncertainty regarding our ability to achieve profitability;

our dependence on sales of silicone gel breast implants to generate a significant amount of our net sales;

our reliance on a foreign, sole source, third-party to manufacture and supply our silicone gel breast implants, tissue expanders and other products;

our limited operating history and any difficulties encountered by us as a result of being a company early in its commercialization;

our ability to successfully commercialize our products;

our inability to operate in a competitive industry and compete successfully against competitors that have greater resources than we do;

pricing pressure from customers and our competitors;

concern about the safety and efficacy of our products, which is based on limited long-term clinical data;

the failure of our products to achieve and maintain market acceptance;

our inability to expand our sales force and marketing programs;

the productivity of our sales representatives and ability to achieve expected growth;

our inability to retain a high percentage of our customer base;

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any inaccuracies in our assumptions about the breast implant market;

our inability to protect our intellectual property;

our failure to comply with the applicable governmental regulations to which our products and operations are subject;

the accuracy of our estimates regarding expenses, net sales, capital requirements and needs for additional financing;

our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act; and

our use of the proceeds from this offering.

We caution you that the risks, uncertainties and other factors referenced above may not contain all of the risks, uncertainties and other factors that are important to you. In addition, we cannot guarantee future results, level of activity, performance or achievements. Any forward-looking statement made by us in this Annual Report on Form 10-K speaks only as of the date of this 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**

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 choice 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. These advantages have allowed us to increase our market share each year since we entered the market in 2012.

Our primary products are silicone gel breast implants for use in breast augmentation and breast reconstruction procedures, which we offer in over 150 variations of shapes, sizes and textures. Our breast implants are primarily used in elective procedures which are generally performed on a cash-pay basis. Many of our breast implants incorporate one or more differentiated technologies, including a proprietary high-strength, cohesive silicone gel and proprietary texturing branded TRUE Texture. Our breast implants offer a desired balance between strength, shape retention and softness due to the high-strength, cohesive silicone gel used in our manufacturing process. TRUE Texture provides texturing on the implant shell that is designed to reduce the incidence of malposition, rotation and capsular contracture. We also offer breast tissue expanders and a range of other aesthetic and specialty products. We do not have any patents or patent applications, but rely on trade secrets, proprietary know-how and regulatory barriers to protect our products and technologies.

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. Our clinical trial is the largest prospective, long-term safety and effectiveness pivotal study of breast implant patients in the United States. The clinical data we collected over a five-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 six-year data. 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 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 Society of Plastic Surgeons, or ASPS, there are approximately 6,400 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 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 \$44.7 million, \$35.2 million and \$10.4 million for the years ended December 31, 2014, 2013 and 2012, respectively. Our net loss was \$5.8 million, \$19.1 million and \$23.4 million for the years ended December 31, 2014, 2013 and 2012, respectively.

**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 ASAPS, in 2013, consumers in the United States spent approximately \$12.4 billion on aesthetic procedures overall, including both surgical and non-invasive cosmetic treatments. Of this amount, more than \$7.2 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 313,000 primary breast augmentation procedures and 55,000 revision augmentation procedures were performed in the United States in 2013. These procedures provide cosmetic solutions generally to enhance breast size and shape, correct breast asymmetries or help restore fullness after breastfeeding. For breast reconstruction, ASPS estimates that approximately 96,000 procedures were performed in the United States in 2013. 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 implants per procedure, we estimate that the U.S. market for breast implants and breast tissue expanders exceeded \$600 million in 2013. Based on data from ASAPS and ASPS, between 1997 and 2013, the number of breast augmentation and breast reconstruction procedures has grown at a compound annual growth rate of approximately 7.3% and 4.4%, respectively. We believe several factors are contributing to the ongoing growth of these procedures, including:

the introduction of new technologies and products to the market, such as anatomically-shaped implants;

medical professionals increasingly promoting aesthetic procedures;

a growing number of patients proactively seeking to have aesthetic procedures performed to enhance their body image, grow their self-esteem and restore their confidence;

a greater awareness among patients who have undergone mastectomies in recent years about the breast reconstruction options available to them;

changes in laws now requiring insurance coverage for some post-mastectomy breast reconstruction; and

an increasing number of patients who are at high risk of developing breast cancer seeking prophylactic mastectomies and breast reconstruction.

**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 pre-market approval, or PMA, from the FDA before they may be marketed in the United States. The PMA application process is lengthy and uncertain, and the PMA application must be supported by valid scientific evidence, which typically requires long-term



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follow-up of a large number of enrolled patients, as well as extensive technical, pre-clinical, clinical and manufacturing data to demonstrate safety and effectiveness. At present, we are not aware of any ongoing clinical studies in the United States for silicone breast implants other than those post-approval studies being performed by us and our two U.S. competitors. We believe that in the near term, it is likely that the companies currently providing silicone 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 recently, 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 choice and providing services tailored specifically to the needs of Plastic Surgeons, we believe we can continue to enhance our position in the breast implant market. Our competitive strengths include:

***Differentiated silicone gel and texturing technologies.*** We incorporate differentiated technologies into our breast implants, including a proprietary high-strength, cohesive silicone gel and proprietary texturing branded TRUE Texture. Our breast implants offer a desired balance between strength, shape retention and softness due to the gel used in our manufacturing process. We believe the beneficial properties of our breast implants using high-strength, cohesive silicone gel arise both from the characteristics of the gel itself, as well as the unique integration of the gel with our implant shell. Inside each of our breast implants, the unique way that the gel adheres to the shell creates additional strength and shape retention. This allows us to deliver implants that have strength and shaping capability without sacrificing the desired softness. In addition, TRUE Texture technology provides texturing on the implant shell that is designed to reduce the incidence of malposition, rotation and capsular contracture. We do not have any patents or patent applications, but rely on trade secrets, proprietary know-how and regulatory barriers to protect our products and technologies.

***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. Our clinical trial is the largest prospective, long-term pivotal study of breast implant patients in the United States and we have published the safety and effectiveness data that we collected over a five-year follow-up period. Our clinical data 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 six-year data.

***Innovative services that deliver an improved customer experience.*** Our customer service offerings are intended to accommodate and anticipate the needs of Plastic Surgeons so that they can focus on providing better services to their patients. For example, we provide Plastic Surgeons with three warranty programs. Our ten-year limited warranty 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. Our lifetime no-charge implant replacement program provides patients replacement devices in the event of a covered rupture. Our C3 program is an industry-first, no-charge implant replacement program for breast augmentation patients who experience capsular contracture within the first five years after implantation with our smooth or textured breast implants. We also provide specialized educational initiatives for both Plastic Surgeons and patients to educate them about our technology, products and services and provide

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greater security and confidence in choosing our breast implants. In addition, we provide a streamlined ordering, shipping and billing process that is tailored for Plastic Surgeons to help enhance their practices.

**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. This helps ensure that our products are implanted by the most highly-skilled surgeons in the field. 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.

**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, which consists of ten executives, including our founder and chief executive officer, Hani Zeini, collectively have more than 125 years of medical aesthetics industry experience. Plastic Surgeons value working with a team comprised of highly skilled professionals who have in-depth knowledge of the industry and an understanding of their needs.

**Our Strategy**

Our objective is to become a leading provider of differentiated medical aesthetic products and services tailored to meet the needs of Plastic Surgeons, allowing us to deliver on our commitment to enhance and make a difference in patients' lives. We are currently focused on growing the breast implant and breast tissue expander markets and our share of them in the United States, and intend 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.** To date, we have focused most of our marketing efforts on Plastic Surgeons to promote and create awareness of the benefits of our products. We believe that investing in expanded marketing initiatives will have a positive impact on our business. We offer educational initiatives exclusively to Plastic Surgeons through our Sientra Education Forum. We provide this education through iBook applications, webinars and online forums, at national, regional and local plastic-surgery meetings, as well as through preceptorships. We plan to expand our recent initiative to educate consumers considering breast augmentation or breast reconstruction about our technologies, products and services to drive adoption of our products. We have also partnered with entities such as RealSelf to help Plastic Surgeons reach a broader audience of potential patients and allow them to offer increased education, confidence and comfort to patients seeking an aesthetic procedure.

**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.

**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

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expanded product choices will allow Plastic Surgeons to potentially achieve better outcomes for their patients.

**Expand to new markets.** We are pursuing regulatory approval for our breast implants in Canada and intend to expand into the Canadian market upon receipt of such approval. We regularly evaluate additional expansion opportunities and in the future may also expand our business to cover new markets and geographic territories.

**Selectively pursue acquisitions.** We may 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.

**Our Products**

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

**Breast Augmentation and Breast Reconstruction Products**

**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 TRUE Texture technology. 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 configurations: round-base, classic-base and oval-base. Our round-base implants are available in eight volumes, our classic-base implants are available in eight volumes and our oval-base implants are available in three projection profiles and 25 volumes.

*Round textured.* A full line of textured, round HSC breast implants, all of which incorporate our high-strength, cohesive silicone gel and TRUE Texture 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 and high. Our low projection implants are available in 15 volumes, our moderate projection implants are available in 16 volumes and our high projection implants are available in 14 volumes.

*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 17 volumes with moderate projection and 18 volumes with high projection. Additionally, in the fourth quarter of 2014, we introduced implants available in two new projections and 30 new volumes.

**Breast Tissue Expanders.** We offer a full line of breast tissue expanders, most of which are marketed as ACX, in 25 different shapes and sizes that include single and double chamber tissue expanders. Our double chamber tissue expanders are unique to the marketplace and feature technology that was designed to allow controlled and differentiated expansion of breast tissue. Our breast tissue expanders are used in breast reconstruction and implanted during or after the completion of a mastectomy and before the patient has enough tissue to adequately cover a breast implant. Our breast tissue expanders are temporary devices

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intended to aid in the process of recreating tissue coverage to allow for the placement of the final implant to reconstruct the breast.

**Other Products**

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

body contouring and other implants, including gluteal, pectoral, calf, facial and nasal implants, and nasal stents, all made from single pieces of silicone elastomer;

silicone elastomer oval carving blocks that can be shaped and sized by surgeons to address deformity caused by trauma, congenital and other deformities or cancer therapy;

scar management specialty products under the brand Medgel that use a compound of biocompatible, medical-grade silicone gel or sheeting specifically formulated to treat or prevent various types of scars;

temporary, single-use, saline-filled breast sizers that can be used to help identify the correct style and size implant for an individual patient; and

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 manufacturing process. The use of high-strength, cohesive silicone gel in our HSC and HSC+ breast implants allows the breast implants to hold a controlled shape while maintaining a soft feel.

The raw silicone stock 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 this special raw material in our products.

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 unique 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,

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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.

**TRUE Texture.** We sell breast implants that are available with a smooth outer surface or with an outer surface that is textured using TRUE Texture technology. We believe our textured breast implants using TRUE Texture technology 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 TRUE Texture technology 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 five-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 TRUE Texture technology has the right combination of surface disruption without overly aggressive texturing.

We use the competitive advantages demonstrated by the independent laboratory results above for our breast implants incorporating high-strength, cohesive silicone gel and TRUE Texture technology to market and differentiate 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. 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 implant patients conducted in the United States. As shown in the tables below, the clinical data we collected over a five-year follow-up period demonstrates that our HSC round implants and HSC+ shaped implants have low rupture rates, as measured by the percent of implants suspected to have ruptured in the body following implantation, low capsular contracture rates, as measured by the percent of implants that result in moderate-to-severe capsular contracture, low rotation rates, as measured by the percent of implants that rotate in the pocket/body following implantation, and low reoperation rates, as measured by the percent of implant procedures that result in the need for at least one additional operation due to patient choice or undesirable clinical outcome.

We, and our two competitors were required to run independent ten-year clinical studies to obtain PMA approval from the FDA. Even though these PMA studies were not designed to facilitate head-to-head comparisons, we believe that these studies, all of which were reviewed by the FDA, measured similar end points under similar protocols and are regularly provided to Plastic Surgeons for their interpretation. However, since Allergan and Mentor published six-year data in some cases, and our data is currently reported over a five-year period, our data and that of our competitors' may change as data from all three PMA studies continue to be analyzed.

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**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 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.

**Enhanced Customer Service.** As we focus exclusively 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 and 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.

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 eBooks 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 eBooks, 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

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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.



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*Patients.* We have recently begun to engage directly with consumers who are considering breast augmentation or reconstruction. We have 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 warranty and C3 programs; and

a one-year exclusive relationship 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.

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, 2014, we had a sales organization of 46 employees, including sales representatives and sales management. 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, tradeshow 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 \$4.7 million, \$4.5 million and \$3.7 million for the years ended December 31, 2014, 2013 and 2012, respectively. Our research and development expenses primarily consist of costs associated with our clinical and post-approval studies, regulatory activity and product development, including our efforts to seek approval for a range of breast implant line extensions that would allow us to sell Breast Products in additional styles, sizes and projections that we do not currently offer.

**Manufacturing and Quality Assurance**

All of our products are listed under our FDA Medical Device Establishment Registration where it indicates we are the specification developer of our products and we are the owner of our products' FDA approvals and clearances. This means that we are primarily responsible for the manufacturing and quality assurance of our products. However, we do not manufacture our products ourselves. Instead, we rely on Silimed, as our contract manufacturer, to manufacture and package our silicone gel breast implants, tissue expanders and other products to our specifications. Silimed has over 34 years of experience manufacturing silicone-based implants and distributes its products to over 60 countries worldwide. When we receive products from Silimed, we inspect the products prior to shipping them to our customers. We maintain strategic levels of inventory at our storage facilities located in Santa Barbara, California.

We and Silimed are subject to the FDA's Quality System Regulation, or QSR, reporting requirements and 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

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the manufacturing process. Both we and Silimed have been inspected by the FDA regularly, and no FDA Form 483 observations, which are issued when an FDA inspector believes that observed conditions or practices indicate the possibility that an FDA-regulated product may be in violation of FDA's requirements, have been made in connection with these inspections. Silimed has had three FDA inspections in seven years and is also audited periodically by our quality department to ensure conformity with the specifications, policies and procedures for our products.

At present, all of our products, including our silicone gel breast implants and breast tissue expanders, are manufactured by Silimed pursuant to an amended and restated exclusivity agreement with Silimed which we refer to as the Silimed Agreement. Pursuant to the Silimed Agreement, Silimed manufactures and supplies products ordered by us for distribution in the United States and Canada, which we refer to as the Territory. We agreed to use commercially reasonable efforts to promote, sell and distribute the products in the Territory. In addition to Silimed's existing products, we have the exclusive right to sell and distribute any new products manufactured by Silimed during the term of the Silimed Agreement. Silimed sells the products to us at a fixed cost, which may be increased by no more than a low single-digit percentage per annum.

The Silimed Agreement provides that Silimed will not provide its products to any third party in the Territory, with the exception of the distribution of one of its gastric products pursuant to a pre-existing supply agreement that it has with a third-party distributor, and we have agreed not sell Silimed's products to any third party if we have reason to believe that such products have been or will be distributed outside of the Territory. We have also agreed not to distribute any product that directly competes with a product manufactured by Silimed in the Territory.

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. Pursuant to the Silimed Agreement, Silimed granted to us an exclusive, royalty-free, non-transferable license to use certain of its trademarks in 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 allocates intellectual property rights between the parties, 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.

The Silimed Agreement can be terminated by either party under certain limited circumstances, including in connection with the other party's breach of any of its material obligations which such breaching party fails to cure within 60 days of receiving notice from the non-breaching party. If the breach relates only to single product, then the non-breaching party is entitled to terminate the agreement with respect to that specific product. The parties may also terminate the agreement at any time on a product-by-product basis upon mutual written agreement of the parties.

The term of the Silimed Agreement will continue until April 2017.

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**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, and 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 medical devices 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. We currently market our tissue expanders and facial implants in Canada, and are awaiting Health Canada's approval to market our breast implant products in Canada. Although we do not anticipate any additional nonclinical or clinical study requirements, we may be delayed in obtaining approval to sell our breast implants in Canada if we need to respond to requests for information from Health Canada during the review process, which remains ongoing.

**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;

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establishment registration and product listing with the FDA;

product manufacturing;

product labeling and storage;

pre-market clearance or approval;

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post-market studies;

advertising and promotion;

product sales and distribution;

recordkeeping 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 pre-market approval, or PMA, application. Both the 510(k) clearance and PMA 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. Devices deemed to pose low to moderate risk are placed in Class I or II, which, absent an exemption, requires the manufacturer to obtain a 510(k) clearance. Class I devices are subject to general controls such as labeling, pre-market notification and adherence to the FDA's Quality System Regulation, or QSR, which cover manufacturers' methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of products. 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 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 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

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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 PMA application(s). In addition, the FDA is currently evaluating the 510(k) process and may make substantial changes to industry requirements.

Silicone gel-filled 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 technical information regarding device design and development, pre-clinical and clinical trial data, and manufacturing and labeling information 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 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 application supplements are required for significant modifications to the manufacturing process, labeling and design of a device that is approved through the PMA modifications that 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 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

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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 selection, 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 recordkeeping 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.

Also, the FDA requires us to conduct post-market surveillance studies and to maintain a system for tracking our products through the chain of distribution to the patient level. The FDA and the Food and Drug Branch of the California Department of Health Services enforce 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;

finest 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;





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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;

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 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, fraud and abuse, false claims, physician sunshine and 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 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, 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 Laws.** 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, or 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 less 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.

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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 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 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 significant administrative, civil and/or criminal penalties and fines, including our debarment or exclusion from Medicare, Medicaid or other governmental programs and restrictions on our ability to operate in certain jurisdictions.

**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 \$5,500 and \$11,000 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" 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 Law.** 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 this statute 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 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, created two new 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,

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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 omnibus rule published on January 25, 2013, mandates, among other things, the adoption of 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.

***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 device manufacturers 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." Device manufacturers were required to begin collecting data on August 1, 2013 and submit reports on aggregate payment data to the government for the first reporting period (August 1, 2013 December 31, 2013) by March 31, 2014, and were required to report detailed payment data for the first reporting period and submit legal attestation to the completeness and accuracy of such data by June 30, 2014. Thereafter, device manufacturers must submit reports by the 90<sup>th</sup> day of each subsequent calendar year. CMS released the data for the first reporting period on a public website on September 30, 2014.

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, 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

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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.

**Coverage and Reimbursement; Healthcare Reform.** 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. 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.

By way of example, in the United States, the recent implementation of PPACA is an example that has 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.

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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, and will stay in effect through 2024 unless Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals.

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**

Our intellectual property portfolio consists primarily of trademarks and trade secrets and does not presently consist of any patents or patent applications. We do not currently intend to file any patent applications in the United States or elsewhere.

Our trademark portfolio consists of five registered U.S. trademarks and six pending Canadian trademark applications. We maintain a program to protect our marks and will institute legal action where necessary to prevent others from using and registering confusingly similar marks.

In addition, to protect our trade secrets 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, there can be no assurance that these measures will be successful in any given case and third parties may still obtain this information or we may be unable to protect our rights.

**Employees**

As of December 31, 2014, we had 95 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 2016.

**Legal Proceedings**

From time to time, we may be involved in various disputes and litigation matters that arise in the ordinary course of business. We are currently not a party to any material legal proceedings.

**Seasonality**

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.

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**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](http://www.sientra.com), and our investor relations website is located at <http://investors.sientra.com>.

**Item 1A. Risk Factors**

*You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this Annual Report on Form 10-K, including our financial statements and related notes thereto, before deciding to invest in our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects.*

**Risks Relating to Our Business and Our Industry**

*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, 2014, we had an accumulated deficit of \$134.0 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, and our recent initial 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.

We commenced sales of our breast implants in the second quarter of 2012. For the year ended December 31, 2014, our gross profit was \$33.2 million. However, although we have achieved a positive gross profit, we had an operating loss of \$5.8 million in 2014. The extent of our future operating losses and the timing of profitability are uncertain, especially in light of the recent commercialization of our silicone gel breast implants, which makes forecasting our sales more difficult. 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.*

Sales of our Breast Products accounted for 97%, 97% and 96% of our net sales for the years ended December 31, 2014, 2013 and 2012, respectively. We expect our net sales to continue to be based primarily on sales of our Breast Products. Any product liability lawsuits, introduction of competitive products by our competitors and other third parties, the loss of market acceptance of our Breast Products, adverse rulings by regulatory authorities, adverse publicity or other adverse events relating to us or our Breast Products may significantly impact our sales and profitability, which would adversely affect our business, financial condition and results of operations.

*We rely on a foreign, sole source, third-party to manufacture and supply our silicone gel breast implants, tissue expanders and other products.*

We rely on Silimed Industria de Implantes Ltda. (formerly, Silimed-Silicone e Instrumental Medico-Cirurgio e Hospitalar Ltda.), or Silimed, our sole source, third-party manufacturer located in Brazil, to

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manufacture and supply our silicone gel breast implants, tissue expanders and other products, and Silimed relies on Applied Silicone Corporation, or ASC, its sole source, third-party supplier of medical-grade silicone based in Santa Paula, California. If ASC becomes unable or willing to supply medical-grade silicone to Silimed or if Silimed becomes unable or unwilling to manufacture and supply our silicone gel breast implants, tissue expanders and other products, we will not be able to replace ASC or Silimed quickly, and we have not qualified another silicone supplier nor another manufacturer to source our implants in that event. Even if we were able to identify a replacement manufacturer or silicone supplier, either would have to be qualified with the FDA, which is an expensive and time-consuming process during which we may experience a supply interruption. As a result, our financial position and results of operations may be adversely affected. There can also be no guarantee that ASC or Silimed will be able to meet our demand to produce sufficient quantities of medical-grade silicone or our products in a timely manner. Furthermore, our current contract with Silimed expires in 2017, and there can be no assurance that Silimed will agree to continue to manufacture and supply our products after the expiration of our contract, which would have a material adverse effect on our business, financial condition and results of operations.

In addition, our reliance on Silimed involves a number of other risks, including, among other things, that:

our products may not be manufactured in accordance with agreed upon specifications or in compliance with regulatory requirements, or its manufacturing facilities may not be able to maintain compliance with regulatory requirements, 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;

we may be subject to price fluctuations when a supply contract is renegotiated or if our existing contract is not renewed;

our agreement with Silimed does not permit us to sell the products we obtain from Silimed in any country other than the United States and Canada;

we, Silimed or ASC may lose access to critical services and components, resulting in an interruption in the manufacture or shipment of our products;

Silimed may not be able to find an alternate supplier in a timely manner if the medical-grade silicone becomes unavailable from ASC or we may not be able to find an alternate supplier in a timely manner if the products become unavailable from Silimed;

we may be required to obtain regulatory approvals related to any change in our supply chain;

ASC may discontinue manufacturing and supplying products to Silimed for risk management reasons;

Silimed may discontinue manufacturing and supplying products to us for risk management reasons; and

Silimed or ASC may encounter financial or other hardships unrelated to our demand for products, which could inhibit its ability to fulfill our orders and meet our requirements.

If any of these risks materialize, it could significantly increase our costs, our ability to generate net sales would be impaired, market acceptance of our products could be adversely affected and customers may instead purchase or use our competitors' products, which could materially adversely affect our business, financial condition and results of operations.





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***There are inherent risks in contracting with manufacturers located outside of the United States such as in Brazil.***

Silimed is our sole source, third-party manufacturer and its manufacturing plant is located in Brazil. There are inherent risks in contracting with manufacturers located outside of the United States such as in Brazil, 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. If any of these risks were to materialize, we and Silimed would both be materially adversely affected and our business, financial condition and results of operations would suffer.

***Various factors outside our direct control may adversely affect manufacturing and supply of our breast implants, tissue expanders and other products.***

Manufacturing and supply of our breast implants, tissue expanders and other products is technically challenging. Changes that our manufacturer may make outside the purview of our direct control can have an impact on our processes, on quality and the successful delivery of products to Plastic Surgeons. Mistakes and mishandling are not uncommon and can affect production and supply. Some of these risks include:

failure of our manufacturer to follow Good Manufacturing Practices, or cGMP, requirements or mishandling of our products while in production or in preparation for transit;

transportation and import and export risk, particularly given the global nature of our supply chain;

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; and

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

If any of these risks were to materialize, our ability to provide our products to customers on a timely basis would be adversely impacted.

***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;

increase awareness of our brand and build loyalty among Plastic Surgeons;

manage expanding operations;

respond effectively to competitive pressures and developments;

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enhance our existing products and develop new products;

obtain regulatory clearance or approval to enhance our existing products and commercialize new products;

obtain and maintain adequate levels of coverage and reimbursement for our 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 Worldwide, LLC, or Mentor, a division of Johnson & Johnson, and Allergan, Inc., or Allergan, are well-capitalized 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 in convincing customers or third-party payors of the differentiation of the gel technology used in our implants and selection of shapes and products as compared to our competitors' products, third-party payors may not cover or adequately reimburse our products and customers may choose our competitors' products. Additionally, as more competitors

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introduce anatomically-shaped products that compete with ours, we may face additional pricing pressure that will impact our future results.

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

We currently market our silicone gel breast implants in the United States. These products have received pre-market approval from the FDA. 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 FDA clearance or approval and significant legal liability.

***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.

***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, preferences and trends 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, which could 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.

***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 and technical support, development and management and administrative functions. In addition, 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.

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***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 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 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.

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***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. The loss of key personnel or our inability to attract or retain other qualified personnel could have a material adverse effect on our business, results of operations and financial condition.

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

As of December 31, 2014, we had approximately 95 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. 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.

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

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 currently have no commitments with respect to any partnership or acquisition. 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.



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**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 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;
- 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; and
- our ability to expand the geographic reach of our sales and marketing efforts.

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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 import 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.

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***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, 2014, we had \$96.7 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 18 months. However, the continued growth of our business, including the expansion of our sales force and marketing programs, and research and development activities, will significantly increase our expenses. In addition, the amount of our future product sales is difficult to predict, especially in light of the recent commercialization of our silicone gel breast implants, and actual sales may not be in line with our forecasts. As a result, we may be required to seek additional funds in the future. Our future capital requirements will depend on many factors, including:

net sales generated by our silicone gel breast implants and tissue expanders 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;

cost of obtaining and maintaining regulatory clearance or approval for our current or future products;

cost of ongoing compliance with regulatory requirements;

expenses we incur in connection with potential litigation or governmental investigations;

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, subject to the restrictions under our Loan and Security Agreement with Oxford, which was amended and restated on June 30, 2014, or the Amended Term Loan Agreement. 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 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 term loan agreement contains restrictive covenants that may limit our operating flexibility.***

Our Amended Term Loan Agreement with Oxford contains certain restrictive covenants that limit our ability to transfer or dispose of certain assets, engage in new lines of business, change the composition of our management, merge with or acquire other companies, incur additional debt, create new liens and encumbrances, pay dividends or subordinated debt and enter into material transactions with affiliates, 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 Amended Term Loan Agreement. The Amended Term Loan Agreement also contains financial reporting requirements. There is no guarantee that we will be able



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to pay the principal and interest under the Amended Term Loan Agreement or that future working capital, borrowings or equity financing will be available to repay or refinance the amounts outstanding under the Amended Term 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, 2014, we had federal net operating loss carryforwards, or NOLs, of approximately \$101.2 million, which expire in various years beginning 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 this offering or 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. Our intellectual property portfolio consists of no patents or patent applications, and we do not currently plan to file for patent protection in the future, in the United States or elsewhere. We instead rely on trade secrets, proprietary know-how and regulatory barriers to protect our products and technologies and seek protection of our rights, in part, through confidentiality and proprietary information agreements. 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 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.

***If our exclusive license to use certain trademarks in the United States is terminated, we may be required to cease using those trademarks, which could interfere with our ability to market existing or future products under those trademarks.***

We rely on a license from our manufacturer for use of the Silimed trademark. In the event Silimed believes that our products do not meet its commercially reasonable quality expectations and we do not cure

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any deficiency within a commercially reasonable period of time to Silimed's reasonable satisfaction, Silimed may revoke our exclusive license to use the Silimed trademark. If such license is terminated, the inability to use that trademark could result in a loss of sales to us as a result of the goodwill associated with the Silimed trademark, and a competitor may use that trademark to capitalize on the goodwill associated with the Silimed trademark. Either of these outcomes could seriously impair our competitive position.

***The medical device industry is characterized by patent litigation and we 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. Generally, we do not 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 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

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our core business 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.

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 may be subject to substantial 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 may be subject to substantial 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. 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

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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 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.

**Risks Related to Our Legal and Regulatory Environment**

***We are subject to extensive federal and state 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. The laws 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 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 Anti-Kickback Statute or specific intent to violate it. In addition, the government may assert that 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 false claims laws;

federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, or FCA, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent, or making a false statement material to 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;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and its implementing regulations, which created 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, as amended by the Health Information Technology for Economic and Clinical Health Act, also imposes certain regulatory and contractual requirements regarding the privacy, security and transmission of individually identifiable health information;



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federal "sunshine" requirements imposed by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or PPACA, on certain device manufacturers 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. The period between August 1, 2013 and December 31, 2013 was the first reporting period, and manufacturers were required to report aggregate payment data by March 31, 2014, and were required to report detailed payment data and submit legal attestation to the accuracy of such data by June 30, 2014. Thereafter, manufacturers must submit reports by the 90th day of each subsequent 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.

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, 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;



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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 pre-market approval, or 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. 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 extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling 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.



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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. For example, in 2011, the FDA announced a Plan of Action to modernize and improve the FDA's pre-market review of medical devices, and has implemented, and continues to implement, reforms intended to streamline the pre-market review process. In addition, as part of the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, Congress enacted several reforms entitled the Medical Device Regulatory Improvements and additional miscellaneous provisions which will further affect medical device regulation both pre- and post-approval. 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. Under new changes instituted by FDASIA, the FDA may now change the classification of a medical device by administrative order instead of by regulation. Although the revised process is simpler, the FDA must still publish a proposed order in the Federal Register, hold a device classification panel meeting and consider comments from affected stakeholders before issuing the reclassification order. 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;

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;



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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 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 manufacturer are required to comply with the FDA's Quality System Regulation, or 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 manufacturer 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 manufacturer 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 premarket 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 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.

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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.



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***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 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 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.

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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 recordkeeping 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. In addition, in December of 2012, the FDA issued a draft guidance intended to assist the FDA and industry in distinguishing medical device recalls from product enhancements. Per the guidance, if any change or group of changes to a device addresses a violation of the FDCA, that change would generally constitute a medical device recall and require submission of a recall report to the FDA. 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 prepare our regulatory submissions. 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

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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 might 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 authorities might take action 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, 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. 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. Changes 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. 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.

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***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.***

Recent political, economic and regulatory influences are subjecting the health care industry to fundamental changes. The sales of our products depend, in part, on the availability of coverage and adequate reimbursement from third-party payors such as government health programs, private health insurers, health maintenance organizations and other health care-related organizations. 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. 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.

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 or 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. In March 2010, the PPACA was signed into law. While the 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 things, 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;

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 will submit recommendations to Congress to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. 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 and will stay in effect through 2024 unless additional 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, 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 available for our products, and could limit the acceptance and availability

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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 limited.***

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 currently market our tissue expanders and facial implants in Canada, but are awaiting Health Canada's approval to market our breast implant products in Canada. Although we do not anticipate any additional nonclinical or clinical study requirements, we may be delayed in obtaining approval to sell our breast implants in Canada if we need to respond to requests for information from Health Canada during the review process, which remains ongoing. The time required to obtain regulatory approval in Canada may be longer than the time required to obtain FDA pre-market approval. The Canadian regulatory approval process includes many of the risks associated with obtaining FDA clearance 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 the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, govern the collection, dissemination, security, use and confidentiality of health information that identifies specific patients. HIPAA and the HITECH Act 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, the HITECH Act, 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. The HITECH Act 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. The HITECH Act 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.

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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 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. These factors include those discussed in this "Risk Factors" section of this Form 10-K and others such as:

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;

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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;

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 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 could be subject to securities class action litigation.***

In the past, securities class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Securities litigation brought against us following volatility in our stock price, regardless of the merit or ultimate results of such litigation, could result in substantial costs, which would hurt our financial condition and operating results and divert management's attention and resources from our business.

#### ***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 the terms of our Amended Term Loan Agreement and may be prohibited by future loan agreements. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

#### ***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 13, 2015, our executive officers, directors and principal stockholders beneficially owned approximately 75.04% 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.





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***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.

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.

***We will incur increased costs as a result of operating as a public company and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.***

As a public company, and increasingly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and NASDAQ impose numerous requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Also, the Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel will need to devote a substantial amount of time to compliance with these laws and regulations. These requirements have increased and will continue to increase our legal, accounting and financial compliance costs and have made and will continue to make some activities more time consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or our board committees or as executive officers.

Overall, we estimate that our incremental costs resulting from operating as a public company, including compliance with these rules and regulations, may be between \$1.5 million and \$3.0 million per year. However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

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***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. However, 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.

Prior to becoming a public company, we were not required to comply with the requirements of Section 404 but previously we had identified two material weaknesses in our internal control over financial reporting for certain financial statement periods included in this report. A "material weakness" is a deficiency, or a 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 financial statements will not be prevented or detected on a timely basis. The identified material weaknesses related to our not having properly designed controls in place to account for complex debt and equity transactions, including preferred stock and warrants associated with debt issuances, and to record bonus accrual and related expense in the appropriate period. While we believe we have remediated these previously reported material weaknesses, we cannot assure you that we will not be required to take further remedial action with respect to those material weaknesses or that there will not be material weaknesses or significant deficiencies in our internal controls in the future.

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.

***Future sales of shares of our common stock by existing stockholders 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 13, 2015, we had approximately 14,924,949 shares of common stock outstanding. Of these shares, only the 5,750,000 shares of common stock sold in our IPO and 48,388 shares of common stock held by existing stockholders are freely tradable, without restriction, in the public market, unless purchased by our affiliates or our existing stockholders subject to lock-up agreements. Each of our directors and officers, and certain of our stockholders, have entered into lock-up agreements with the underwriters that restrict their ability to sell or transfer their shares (including any shares purchased through the directed share program). The lock-up agreements pertaining to our IPO will expire on April 27, 2015. Piper Jaffray & Co. and Stifel, Nicolaus & Company, Incorporated, however, may, in their sole discretion, permit our officers, directors and other existing stockholders who are subject to the contractual lock-up to sell shares prior to the expiration of the lock-up agreements. After the lock-up agreements expire, based on shares outstanding as of March 13, 2015, up to an additional 9,126,561 shares of common stock will be eligible for sale in the public market, approximately 90,909 of which are held by our directors and executive officers, and will be subject to volume limitations under Rule 144 under the

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Securities Act. In addition, 1,635,106 shares of our common stock that are subject to outstanding options as of March 13, 2015 will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements, the lock-up agreements and Rules 144 and 701 under the Securities Act.

Holders of an aggregate of approximately 8,942,925 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.

In addition, we have registered on Form S-8 1,631,922 shares of common stock subject to outstanding options granted under our 2007 Equity Incentive Plan, or the 2007 Plan, 1,027,500 shares of common stock that we may issue under our 2014 Equity Incentive Plan, or the 2014 Plan, as well as 255,500 share of common stock that we may issue under our 2014 Employee Stock Purchase Plan, or ESPP, that we adopted concurrently with the completion of our IPO. These shares can be freely sold in the public market upon issuance and once vested, subject to the 180-day lock-up period under the lock-up agreements described above.

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 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 2014 Plan and ESPP, 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.

Pursuant to the 2014 Plan, our management is authorized to grant stock options to our employees, directors and consultants.

Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2014 Plan is 1,027,500 shares. Additionally, the number of shares of our common stock reserved for issuance under the 2014 Plan will automatically increase on January 1 of each year, beginning on January 1, 2015 and 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.

Our board of directors adopted our ESPP in July 2014 and our stockholders approved the ESPP in October 2014. Our ESPP is intended to qualify as an employee stock purchase plan under Section 423 of the Code. The ESPP became effective upon the completion of the IPO. A total of 255,500 shares were initially reserved for issuance under the ESPP, subject to certain annual increases.

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***Our management team may invest or spend the proceeds from our IPO in ways with which you may not agree or in ways which may not yield a return.***

Our management has considerable discretion in the application of the net proceeds from our IPO, and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from our IPO, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment. We expect to use the net proceeds from our IPO primarily for the continued expansion of our sales force and marketing programs, our ongoing research and development activities, and the acquisition of new product lines. We intend to use the remaining proceeds for working capital and general corporate purposes. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from our IPO in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from our IPO in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

***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



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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.

**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 space located in Santa Barbara, California, which is approximately 10,000 square feet. The term of the lease for our warehouse expires in January 2016. 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**

In the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements and other matters. While the outcome of these proceedings and claims cannot be predicted with certainty, as of December 31, 2014, we were not party to any legal or arbitration proceedings that may have, or have had in the recent past, significant effects on our financial position or profitability. No governmental proceedings are pending or, to our knowledge, contemplated against us. We are not a party to any material proceedings in which any director, member of senior management or affiliate of ours is either a party adverse to us or our subsidiaries or has a material interest adverse to us or our subsidiaries.

**Item 4. Mine Safety Disclosures**

Not applicable.

Table of Contents**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:

	<b>High</b>	<b>Low</b>
Fourth Quarter 2014 (beginning October 29, 2014)	\$ 19.99	\$ 12.53

On March 13, 2015, the last reported sale price for our common stock on the NASDAQ Global Select Market was \$18.74 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, 2014, 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.

**CUMULATIVE TOTAL RETURN SUMMARY**  
**December 2014**

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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 13, 2015, there were approximately 28 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 over-allotment 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 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. There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on October 29, 2014 pursuant to Rule 424. We invested the funds received in cash equivalents and other short-term investments in accordance with our investment policy.

**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, 2014.

**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, 2014, 2013 and 2012 and as of December 31, 2014 and 2013 from our financial statements, which are included elsewhere in this Annual



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Report on Form 10-K. Historical results are not necessarily indicative of the results to be expected in future periods.

Statement of Operations Data:	Years Ended December 31,		
	2014	2013	2012
	(in thousands, except per share data)		
Net sales	\$ 44,733	\$ 35,171	\$ 10,447
Gross profit	33,233	26,579	8,095
Net loss	(5,811)	(19,125)	(23,433)
Net loss per share:			
Basic and diluted	(2.28)	(82.25)	(85.01)
Weighted average shares:			
Basic and diluted	2,545,371	232,512	275,642

Balance Sheet Data:	As of December 31,	
	2014	2013
	(in thousands)	
Working capital	\$ 103,151	\$ 24,509
Total assets	139,078	53,166
Long-term debt, excluding current portion	21,671	15,092
Stockholders' equity (deficit)	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 choice 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.

Our primary products are silicone gel breast implants for use in breast augmentation and breast reconstruction procedures, which we offer in over 150 variations of shapes, sizes and textures. Our breast implants are primarily used in elective procedures which are generally performed on a cash-pay basis. Many of our breast implants incorporate one or more differentiated technologies, including a proprietary high-strength, cohesive silicone gel and proprietary texturing branded TRUE Texture. We also offer breast tissue expanders and a range of other aesthetic and specialty products. We do not have any patents or patent applications, but rely on trade secrets, proprietary know-how and regulatory barriers to protect our products and technologies.

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. Our clinical trial is the largest prospective, long-term safety and effectiveness pivotal study of breast implant patients in the United States.

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We commenced sales of our breast implants in the United States in the second quarter of 2012. We sell our breast implants and breast tissue expanders, or Breast Products, exclusively to board-certified and board-admissible plastic surgeons, who we refer to as Plastic Surgeons, and tailor our customer service offerings to their specific needs, which we believe helps secure their loyalty and confidence. We currently sell our products in the United States where we sell our products through a direct sales organization consisting of 46 employees, including sales representatives and sales management, as of December 31, 2014.

**2007 Acquisition of Grader Street**

On April 4, 2007, we acquired substantially all of the assets of Grader Street Medical Products, Inc., or Grader Street (formerly, Silimed, Inc.), a privately held Texas-based company engaged in the development and sale of medical devices, including breast implants, under the terms of an Asset Purchase Agreement, or APA. The consideration paid by us to Grader Street was \$29.9 million in cash, 90,909 shares of our common stock and a series of future contingent payments with a potential total value of \$70.0 million.

In March 2012, we initiated an arbitration proceeding against Grader Street, which we refer to as the Grader Street arbitration, to seek a decision that, under the terms of the APA, we were entitled to a substantial reduction in the purchase price reducing contingent payments owed to Grader Street. On May 16, 2013, we, Grader Street and Grader Street's founder reached an agreement in which we agreed to pay Grader Street a gross amount of \$18.0 million and release all claims that we had against Grader Street and its founder. Grader Street and its founder also released all claims against us, including all future contingent payments, under the APA. In addition, under the terms of the agreement, we paid \$0.3 million to repurchase 72,727 shares (of the original 90,909 shares issued) held by Grader Street's founder.

**Components of Operating Results**

*Net Sales*

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. Sales of our Breast Products accounted for 97%, 97% and 96% of our net sales for the years ended December 31, 2014, 2013 and 2012 respectively.

We recognize revenue, net of sales discounts and returns, as the customer has a standard six-month window to return purchased products. We anticipate our net sales will increase as we expand our sales force and marketing programs, increase awareness of our products and increase the comfort of Plastic Surgeons using anatomically-shaped breast implants. We also 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 manufacturer, reserve for product warranties and warehouse and other related costs.

Our silicone gel breast implants, tissue expanders and other products are manufactured under an exclusive contract with Silimed. Under our contract with Silimed, each particular style of implant has a fixed unit cost. In addition to product costs, we provide a commercial warranty on our silicone gel filled 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 manufacturer and other related costs.

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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 manufacturing price increases, the changing mix of products sold with different gross margins 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 tradeshows, our no-charge customer shipping program and product evaluation, as well as educational, promotional and marketing activities, including direct and online marketing. We expect our sales and marketing expenses to increase in absolute dollars as we increase our headcount and expand our marketing programs.

***Research and Development Expenses***

Our research and development, or R&D, expenses, primarily consist of clinical expenses, regulatory expenses, product development, 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 and completed, including improvements to our existing products, expansions of our existing product lines, new product acquisitions and our FDA-required PMA and 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 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, insurance, benefits, facilities and information technologies expenses. Beginning in 2013, G&A expenses also include the federal excise tax on the sale of medical devices in the United States.

In 2012, Mentor filed one lawsuit against us and one of our employees, in addition to thirteen lawsuits against fifteen of our employees who were all former Mentor employees, which we refer to as the Mentor litigation. In general, these lawsuits alleged that the former employees of Mentor breached their confidentiality and non-compete agreements when they resigned in favor of employment with us, misappropriated confidential Mentor information and trade secrets, and breached their respective duties of loyalty. Although not a party to thirteen of the lawsuits, we provided for the defense of our employees. In those lawsuits, all of Mentor's claims for preliminary injunctive relief were denied and, following that, each of those lawsuits was dismissed. In the sole lawsuit against us and our employee, we prevailed at trial with verdicts of "no liability" rendered by the jury and judge on all claims. Final judgment in this case was entered on October 3, 2013 with Mentor ordered to reimburse us for certain court costs, and in 2014, Mentor waived its right to appeal. For the years ended December 31, 2014, 2013 and 2012, we incurred \$0.1 million, \$10.2 million and \$3.0 million, respectively, of G&A expenses related to the Mentor litigation, net of Mentor's reimbursement for certain court costs and preliminary insurance recoveries.

In addition, for the years ended December 31, 2014, 2013 and 2012, we incurred \$0.0 million, \$1.2 million and \$0.3 million, respectively, of G&A expenses related to the Grader Street arbitration.

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Excluding the historic litigation and arbitration expenses described above, we expect future G&A expenses to increase as we 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 incur increased G&A expenses in connection with becoming 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 expense and amortization of debt discount associated with our term loans and insurance recoveries.

**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* (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



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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 estimates, an adjustment to revenue in the current or subsequent period would be recorded. The Company has established an allowance for sales returns of \$10.0 million and \$8.3 million as of December 31, 2014 and 2013, respectively, recorded net against accounts receivable in the balance sheet.

A portion of the Company's revenue is generated from consigned inventory of breast implants 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 implanted products.

***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 accrued for warranties issued in 2014, 2013 and 2012 in the amounts of \$0.5 million, \$0.4 million and \$0.1 million, respectively. As of December 31, 2014 and 2013, we held total warranty liabilities of \$1.0 million, \$0.5 million, respectively.

***Stock-Based Compensation***

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.

We recorded total non-cash stock-based compensation expense of \$0.6 million, \$0.3 million and \$0.4 million for the years ended December 31, 2014, 2013 and 2012, respectively. As of December 31, 2014 and 2013, we had total unrecognized compensation costs of \$1.9 million and \$0.7 million, respectively, related to these stock options. As of December 31, 2014, these costs are expected to be recognized over a weighted average period of 2.84 years.

The Black-Scholes model requires the input 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. These assumptions are estimated as follows:

*Risk-free interest rate* The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected term of the options for each option group.

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*Dividend yield* We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

*Expected volatility* As we do not have a significant trading history for our common stock, the expected stock price volatility for our common stock was estimated by taking the average of (i) the median historic price volatility and (ii) the median of the implied volatility averages, with a three-month lookback from the valuation date, for any trading options of industry peers based on daily price observations over a period equivalent to the expected term of the time to a liquidity event. We intend to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of our own common stock share price becomes available.

*Expected term* The expected term represents the period that our stock-based awards are expected to be outstanding.

The following table presents the weighted-average assumptions used to estimate the fair value of options granted during the periods presented:

	Year ended December 31,	
	2014	2013
Expected term (in years)	5.77 to 6.08	6.08
Expected volatility	52% to 57%	56%
Risk-free interest rate	1.71% to 2.00%	1.00% to 1.76%
Dividend yield		

In addition to the assumptions used in the Black-Scholes option pricing model, the amount of stock-based compensation expense we recognize in our financial statements includes an estimate of stock option forfeitures. We estimate our forfeiture rate based on an analysis of our actual forfeitures and will continue to evaluate the appropriateness of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover and other factors. Changes in the estimated forfeiture rate can have a significant impact on our stock-based compensation expense as the cumulative effect of adjusting the rate is recognized in the period the forfeiture estimate is changed. If a revised forfeiture rate is higher than the previously estimated forfeiture rate, an adjustment is made that will result in a decrease to the stock-based compensation expense recognized in the financial statements. If a revised forfeiture rate is lower than the previously estimated forfeiture rate, an adjustment is made that will result in an increase to the stock-based compensation expense recognized in our financial statements.

**Warrant Liabilities**

We have issued warrants to Oxford to purchase shares of common stock in connection with our term loan agreement. 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 with any changes in fair value being recognized as a component of other (expense) income 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.

**Recent Accounting Pronouncements**

In May 2014, the FASB issued accounting standard update 2014-09, *Revenue from Contracts with Customers*. The standard was issued to provide a single framework that replaces existing industry and transaction specific US GAAP with a five step analysis of transactions to determine when and how revenue is recognized. This accounting standard update is expected to be effective for the Company beginning in

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fiscal year 2018. The Company is currently assessing the impact that the standard will have on the financial statements upon adoption of the guidance.

In August 2014, the FASB issued accounting standard update 2014-15, *Presentation of Financial Statement Going Concern*. The standard was issued to provide guidance about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. This accounting standard updated will be effective for the Company beginning in fiscal year 2016. The Company anticipates there will be no impact on its financial statement upon adoption of this guidance.

**Results of Operations*****Comparison of the Years Ended December 31, 2014 and 2013***

The following table sets forth our results of operations for the years ended December 31, 2014 and 2013.

	<b>Year Ended December 31</b>	
	<b>2014</b>	<b>2013</b>
	<b>(in thousands)</b>	
<b>Statement of operations data</b>		
Net sales	44,733	35,171
Cost of goods sold	11,500	8,592
Gross profit	33,233	26,579
<b>Operating Expenses</b>		
Sales and marketing	23,599	22,229
Research and development	4,707	4,479
General and administrative	10,712	18,078
Total operating expenses	39,018	44,786
Loss from operations	(5,785)	(18,207)
<b>Other (expense) income, net:</b>		
Interest expense	(2,172)	(872)
Other (expense) income, net	2,146	(46)
Total other (expense) income, net	(26)	(918)
Net loss	(5,811)	(19,125)

***Net Sales***

Net sales increased \$9.6 million, or 27.2%, to \$44.7 million for the year ended December 31, 2014, as compared to \$35.2 million for the year ended December 31, 2013. This increase was primarily driven by sales of our Breast Products in the United States resulting from increased sales and marketing activities and boarder adoption of Sientra's product offerings by board-certified Plastic Surgeons. As of December 31, 2014, our sales organization included 46 employees, as compared to 39 employees as of December 31, 2013.

***Cost of Goods Sold and Gross Margin***

Cost of goods sold increased \$2.9 million, or 33.8%, to \$11.5 million for the year ended December 31, 2014, as compared to \$8.6 million for the year ended December 31, 2013. This increase was primarily due to an increase in sales volume.





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The gross margins for the years ended December 31, 2014 and 2013 were 74.3% and 75.6%, respectively. The decrease in gross margin was primarily due to a manufacturing price increase, and the launch of new line extension in the fourth quarter, offset by holding fixed overhead relatively constant.

***Sales and Marketing Expenses***

Sales and marketing expenses increased \$1.4 million, or 6.2%, to \$23.6 million for the year ended December 31, 2014, as compared to \$22.2 million for the year ended December 31, 2013. This was primarily due to a \$1.8 million increase in employee related expense for the sales department offset by a \$0.4 million decrease in marketing costs.

***Research and Development Expenses***

R&D expenses increased \$0.2 million, or 5.1%, to \$4.7 million for the year ended December 31, 2014, as compared to \$4.5 million for the year ended December 31, 2013. This was primarily due to an increase in employee related expenses and costs associated with our post-approval study.

***General and Administrative Expenses***

G&A expenses decreased \$7.4 million, or 40.7%, to \$10.7 million for the year ended December 31, 2014, as compared to \$18.1 million for the year ended December 31, 2013. This decrease was primarily due to the \$10.1 million decrease in litigation expenses related to the Mentor litigation partially offset by an increase in expenses related to accounting related costs and federal excise tax.

***Other (Expense) Income, net***

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 and income from recovery of costs associated with the Mentor litigation of \$2.4 million. Total other (expense) income, net for the year ended December 31, 2013 was primarily associated with interest expense on our term loans of \$0.9 million.

Table of Contents**Comparison of the Years Ended December 31, 2013 and 2012**

The following table sets forth our results of operations for the years ended December 31, 2013 and 2012.

	<b>Year Ended December 31</b>	
	<b>2013</b>	<b>2012</b>
	<b>(in thousands)</b>	
<b>Statement of operations data</b>		
Net sales	35,171	10,447
<b>Cost of goods sold</b>	<b>8,592</b>	<b>2,352</b>
Gross profit	26,579	8,095
<b>Operating Expenses</b>		
Sales and marketing	22,229	17,919
Research and development	4,479	3,670
General and administrative	18,078	9,938
<b>Total operating expenses</b>	<b>44,786</b>	<b>31,527</b>
Loss from operations	(18,207)	(23,432)
<b>Other (expense) income, net:</b>		
Interest expense	(872)	
Other (expense) income, net	(46)	(1)
Total other (expense) income, net	(918)	(1)
<b>Net loss</b>	<b>(19,125)</b>	<b>(23,433)</b>

**Net Sales**

We commenced sales of our breast implants in the United States in May 2012. Our net sales increased \$24.7 million, or 236.7%, to \$35.2 million for the year ended December 31, 2013, as compared to \$10.4 million for the year ended December 31, 2012. As there was no material change in pricing, this increase was primarily due to having a full year of sales in 2013, as compared to less than eight months of sales in 2012. We also began commercialization activities in May 2012 and continued to increase these activities, resulting in greater familiarity with our products and customer service offerings by Plastic Surgeons, in 2013 as compared to 2012. When our commercialization activities began in May 2012, our sales organization included 29 employees. Our sales organization included 39 employees as of December 31, 2013.

**Cost of Goods Sold and Gross Margin**

Cost of goods sold increased \$6.2 million, or 265.3%, to \$8.6 million for the year ended December 31, 2013, as compared to \$2.4 million for the year ended December 31, 2012. This increase was primarily due to an increase in sales volume resulting from having a full year of sales in 2013, as compared to less than eight months of sales in 2012.

The gross margins for the years ended December 31, 2013 and 2012 were 75.6% and 77.5%, respectively. This decrease was primarily due to manufacturing price increases and incremental warehouse costs.

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***Sales and Marketing Expenses***

Sales and marketing expenses increased \$4.3 million, or 24.1%, to \$22.2 million for the year ended December 31, 2013, as compared to \$17.9 million for the year ended December 31, 2012. This increase was primarily a result of a \$2.2 million increase related to expanding our headcount following commercialization in May 2012 and a \$1.4 million increase in marketing costs.

***Research and Development Expenses***

R&D expenses increased \$0.8 million, or 22.0%, to \$4.5 million for the year ended December 31, 2013, as compared to \$3.7 million for the year ended December 31, 2012. This increase was primarily due to an increase in employee related costs and post-approval study costs.

***General and Administrative Expenses***

G&A expenses increased \$8.1 million, or 81.9%, to \$18.1 million for the year ended December 31, 2013, as compared to \$9.9 million for the year ended December 31, 2012. This increase was primarily due to the \$7.2 million increase in expenses related to the Mentor litigation and \$0.9 million increase in expenses related to the Grader Street arbitration. This increase was partially offset by a reduction in certain administrative expenses.

***Other (Expense) Income, net***

Other (expense) income, net for the year ended December 31, 2013 was primarily associated with interest expense on our term loans of \$0.9 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 our recent initial public offering. To date, we have received gross proceeds from the sales of preferred stock totaling \$151.0 million. We issued and sold preferred stock for aggregate gross proceeds of \$65.0 million in March 2012, which was our most recent issuance and sale of preferred stock. As of December 31, 2014, we had \$25.4 million outstanding on our term loans.

On November 3, 2014, we completed our IPO of common stock in which we sold 5,000,000 shares at a price of \$15.00 per share. Additionally, the underwriters exercised their option to purchase an additional 750,000 shares at \$15.00 per share. As a result of our IPO, we raised a total of 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. Costs directly associated with our IPO were capitalized and recorded as deferred IPO costs in other current assets prior to the completion of our IPO. Upon completion of the IPO, the issuance costs were reclassified to additional-paid-in capital to offset the IPO proceeds. Upon completion of our IPO, all outstanding shares of our convertible preferred stock were converted into 8,942,925 shares of common stock.

As of December 31, 2014, we had \$96.7 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 18 months. However, the continued growth of our business, including the expansion of our sales force and marketing programs, and research and development activities, will significantly increase our expenses. In addition, the amount of our future product sales is difficult to predict, especially in light of the recent commercialization of our silicone gel breast implants, and actual sales may be not be in line with our

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forecasts. 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 other sources, subject to the restrictions under our Amended Term Loan Agreement.

Our historical cash outflows have primarily been associated with R&D related to obtaining FDA approval for our breast implant portfolio and complying with the FDA's post-approval requirements, the Mentor litigation, activities relating to commercialization and increases in working capital, including the purchase of inventory.

***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:

	<b>Year Ended December 31</b>	
	<b>2014</b>	<b>2013</b>
	<b>(in thousands)</b>	
Net cash provided by (used in):		
Operating activities	450	(25,877)
Investing activities	(439)	(18,071)
Financing activities	86,996	14,462
Net change in cash and cash equivalents	87,007	(29,486)

***Cash provided by (used in) operating activities***

Net cash provided by operating activities was \$0.5 million during the year ended December 31, 2014 as compared to net cash used in operating activities of \$25.9 million during the year ended December 31, 2013. The decrease in cash used in operating activities between the years ended December 31, 2014 and 2013 was primarily associated with the decrease in net loss of \$13.3 million and a decrease in cash outflows from operating assets and liabilities resulting from a decrease in inventory purchases, an increase in customer deposits and collections of accounts receivable, offset by a reduction in accounts payable.

***Cash used in investing activities***

Net cash used in investing activities was \$0.4 during the year ended December 31, 2014 as compared to \$18.1 million during the year ended December 31, 2013. The decrease in cash used in investing activities of \$17.6 million between the years ended December 31, 2014 and 2013 was primarily due to a nonrecurring \$18.0 million payment made to Grader Street in May 2013 in connection with the obligations relating to our 2007 acquisition of Grader Street.

***Cash provided by financing activities***

Net cash provided by financing activities was \$87.0 million during the year ended December 31, 2014 as compared to \$14.5 million during the year ended December 31, 2013. The increase in cash provided by financing activities of \$72.5 million between the years ended December 31, 2014 and 2013 was primarily the result of the cash proceeds from the issuance of our common stock, net of the underwriters discount in the IPO of \$80.2 million, offset by the payment of equity transaction costs of \$3.1 million during the year ended December 31, 2014. 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:

net sales generated by our Breast Products and any other future products that we may develop and commercialize;

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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;

expenses we incur in connection with potential litigation or governmental investigations;

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;

payment of monthly interest due under our term loans; and

facilities expansion needs

investment in inventory required to meet customer demands

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 additional credit facilities. Additional capital, if needed, may not be available on satisfactory terms, if at all. Our term loans restrict our ability to incur additional *pari passu* debt. 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 and Need for Financing."

**Indebtedness**

***Term Loan Agreement***

On January 17, 2013, we entered into a Loan and Security Agreement with Oxford, which was amended and restated on June 30, 2014, or the Amended Term Loan Agreement. Under the Amended Term Loan Agreement, we have (i) a \$7.5 million tranche A term loan, (ii) a \$2.5 million tranche B term loan, (iii) a \$5.0 million tranche C term loan and (iv) a \$10.0 million tranche D term loan. The tranche A, B and C term loans mature on February 1, 2017 and the tranche D term loan matures on January 1, 2019. The term loans are collateralized by a first-priority security interest in substantially all of our assets. The term loans bear interest at a rate equal to 8.4% per annum. The interest-only period for the tranche A, B and C term loans ends on August 1, 2015 and the interest-only period for the tranche D term loan was extended from

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August 1, 2015 to August 1, 2016 as a result of having raised at least \$50.0 million in gross proceeds in the IPO and the completion of the IPO before June 30, 2015.

We may voluntarily repay amounts outstanding under the term loan at any time, subject to paying the final payment. Upon making the final payment of each term loan, whether on prepayment or at maturity, we are required to pay a 6.5% fee on the aggregate principal amount of the term loan being paid. In connection with the Amended Term Loan Agreement, we issued to Oxford (i) seven-year warrants in January 2013 to purchase shares of our common stock with a value equal to 3.0% of the tranche A, B and C term loans amounts and (ii) seven-year warrants in June 2014 to purchase shares of our common stock with a value equal to 2.5% of the tranche D term loan amount. The warrants have an exercise price per

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share equal to the lesser of (i) the Series C preferred stock conversion price of \$14.671 per share or (ii) the price per share in a subsequent qualified round of financing where gross proceeds are greater than \$10.0 million.

The Amended Term Loan Agreement contains various negative and affirmative covenants, including certain restrictive covenants that limit our ability to transfer or dispose of certain assets, engage in new lines of business, change the composition of our management, merge with or acquire other companies, incur additional debt, create new liens and encumbrances, pay dividends or subordinated debt and enter into material transactions with affiliates, among others. The Amended Term Loan Agreement also contains financial reporting requirements.

**Contractual Obligations and Commitments**

The following table summarizes our contractual obligations and commitments as of December 31, 2014:

	Payments Due by Period				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
	(In thousands)				
Long-term debt obligations	\$ 25,000	\$ 3,757	\$ 16,652	\$ 4,591	\$ 0
Interest and other payments related to long-term debt	5,884	2,048	2,958	878	0
Operating lease obligations	2,217	500	803	843	71
Total contractual obligations	\$ 33,101	\$ 6,305	\$ 20,413	\$ 6,312	\$ 71

**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**

We are exposed to market risks in the ordinary course of our business. Our cash and cash equivalents include cash in readily available checking accounts. Additionally, the interest rate on our term loans is fixed and not subject to changes in market interest rates.

**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**

PricewaterhouseCoopers LLP, or PwC, was previously our independent auditors since 2007. On December 13, 2013, we dismissed PwC and KPMG LLP was engaged as our independent auditors. The decision to change our independent auditors was approved by our board of directors.

During the years ended December 31, 2011 and 2012 and the subsequent interim period through December 13, 2013, there were no (i) disagreements with PwC on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedures which disagreements if not resolved to PwC's satisfaction would have caused them to make reference thereto in their reports on the financial statements for such years, or (ii) reportable events as defined in Item 304(a)(1)(v) of



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Regulation S-K, except as described below. PwC did not issue any audit reports for the years ended December 31, 2012 and 2013.

During October 2013, PwC notified us that it was in disagreement with our revenue recognition policies relating to the timing of revenue recognition given our terms and conditions and practices regarding returns. The subject matter of this disagreement was not discussed between our board of directors and PwC prior to PwC's dismissal. We authorized PwC to respond fully to the inquiries of KPMG LLP concerning the subject matter of this disagreement. We requested PwC to provide us with a letter addressed to the SEC stating whether or not PwC agrees with the above disclosures. A copy of PwC's letter, dated October 9, 2014, is attached as Exhibit 16.1 to the registration statement on Form S-1 filed with the SEC on October 9, 2014.

KPMG LLP audited our financial statements for the years ended December 31, 2012 and 2013 and the audit reports of KPMG LLP for such years did not contain an adverse opinion or a disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles. During the two fiscal years ended December 31, 2012 and through the subsequent interim period prior to KPMG LLP becoming the Company's independent auditors, the Company did not consult with KPMG LLP on either (i) the application of accounting principles to a specified transaction, either completed or proposed, (ii) the type of audit opinion that may be rendered on the Company's financial statements; or (iii) any matter that was either the subject of a disagreement, as defined in Item 304(a)(1)(iv) of Regulation S-K, or a reportable event. We are unable to quantify the impact of the matters subject to the disagreement and cannot state what the effect on our financial statements would have been as an evaluation of such matters was not completed prior to the dismissal of our former independent auditors.

**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 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 means control and other procedures of a company that are 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 recorded, processed, summarized and reported, within the time periods specified in the SEC rules and forms. 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 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. Based on the evaluation of our disclosure controls and procedures as of December 31, 2014, our principal executive officer and principal financial officer have concluded that as of such date, our disclosure controls and procedures were effective.

***Management's Annual Report on Internal Control Over Financial Reporting***

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

***Inherent Limitations of Internal Controls***

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls will prevent or detect all errors and all

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fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

***Changes in Internal Control over Financial Reporting***

There were no changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

None.

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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 2015 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 2015 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 2015 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 2015 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 2015 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 Schedules**

- (a)  
    (1) Financial Statements.

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

- (a)  
    (2) Financial Statement Schedules.

All schedules have been omitted because they are not required or because the required information is given in the Financial Statements or Notes thereto set forth under Item 8 above.

- (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**

	<b>Pages</b>
<u>Report of Independent Registered Public Accounting Firm</u>	<u>71</u>
<u>Balance Sheets</u>	<u>72</u>
<u>Statements of Operations</u>	<u>73</u>
<u>Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)</u>	<u>74</u>
<u>Statements of Cash Flows</u>	<u>75</u>
<u>Notes to Financial Statements</u>	<u>76</u>
<u>Schedule II Valuation and Qualifying Accounts</u>	<u>98</u>

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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, 2014 and 2013, 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, 2014. In connection with our audits of the financial statements, we 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 referred to above present fairly, in all material respects, the financial position of Sientra, Inc. at December 31, 2014 and 2013, and the results of its operations and its cash flows for each of the years in the three year period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles. Also in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, present fairly, in all material respects, the information set forth therein.

/s/ KPMG LLP

Woodland Hills, California  
March 18, 2015

Table of Contents**Sientra, Inc.****Balance Sheets****(in thousands, except per share data)**

	<b>December 31,</b>	
	<b>2014</b>	<b>2013</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 96,729	\$ 9,722
Accounts receivable, net of allowances of \$10,330 and \$8,543 at December 31, 2014 and 2013, respectively	5,198	6,111
Inventories, net	20,174	21,533
Prepaid expenses and other current assets	1,782	884
<b>Total current assets</b>	<b>123,883</b>	<b>38,250</b>
Property and equipment, net	555	254
Goodwill	14,278	14,278
Other intangible assets, net	114	207
Other assets	248	177
<b>Total assets</b>	<b>\$ 139,078</b>	<b>\$ 53,166</b>
<b>Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)</b>		
Current liabilities:		
Current portion of long-term debt	\$ 3,757	\$
Accounts payable	2,589	4,768
Accrued and other current liabilities	5,772	4,065
Customer deposits	8,614	4,908
<b>Total current liabilities</b>	<b>20,732</b>	<b>13,741</b>
Long-term debt	21,671	15,092
Warranty reserve and other long-term liabilities	1,036	550
<b>Total liabilities</b>	<b>43,439</b>	<b>29,383</b>
Commitments and contingencies (Note 9)		
Convertible preferred stock, \$0.01 par value Authorized, issued and outstanding 24,593,087 shares at December 31, 2013 (Liquidation preference of \$151,000 as of December 31, 2013)		150,456
Stockholders' equity (deficit):		
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 and 30,200,000 shares; issued 14,985,704 and 279,879 and outstanding 14,912,977 and 207,152 shares at December 31, 2014 and 2013, respectively	150	3
Additional paid-in capital	229,795	1,819
Treasury stock, at cost (72,727 shares at December 31, 2014 and 2013)	(260)	(260)
Accumulated deficit	(134,046)	(128,235)
<b>Total stockholders' equity (deficit)</b>	<b>95,639</b>	<b>(126,673)</b>
<b>Total liabilities, convertible preferred stock and stockholders' equity (deficit)</b>	<b>\$ 139,078</b>	<b>\$ 53,166</b>

See accompanying notes to financial statements.



Table of Contents**Sientra, Inc.****Statements of Operations****(in thousands, except per share data)**

	<b>Year Ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
Net sales	\$ 44,733	\$ 35,171	\$ 10,447
Cost of goods sold	11,500	8,592	2,352
<b>Gross profit</b>	<b>33,233</b>	<b>26,579</b>	<b>8,095</b>
Operating expenses:			
Sales and marketing	23,599	22,229	17,919
Research and development	4,707	4,479	3,670
General and administrative	10,712	18,078	9,938
Total operating expenses	39,018	44,786	31,527
Loss from operations	(5,785)	(18,207)	(23,432)
Other (expense) income, net:			
Interest expense	(2,172)	(872)	
Other (expense) income, net:	2,146	(46)	(1)
Total other (expense) income, net	(26)	(918)	(1)
Loss before income taxes	(5,811)	(19,125)	(23,433)
Income taxes			
Net loss	\$ (5,811)	\$ (19,125)	\$ (23,433)