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

Use these links to rapidly review the document

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

(Mark One)

ý **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

o **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	**20-5551000**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
420 South Fairview Avenue, Suite 200 Santa Barbara, California	**93117**
(Address of Principal Executive Offices)	(Zip Code)

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

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

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** o **No** ý

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** ý **No** o

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** ý **No** o

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. ý

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

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

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.

Table of Contents

Table of Contents

Table of Contents

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;

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.

Table of Contents

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.

Table of Contents

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

Table of Contents

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

Table of Contents

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

Table of Contents

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

Table of Contents

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,

Table of Contents

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.

Table of Contents

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 iBooks and more.

we host symposia with one or more key-note speakers who speak on topics ranging from our corporate identity and customer service offerings to surgical tips and suggestions from thought-leading Plastic Surgeons.

we produce comprehensive guides for Plastic Surgeons via the Internet, referred to as iBooks, to provide them training and expertise on the implantation of anatomically-shaped breast implants.

we send a limited number of Plastic Surgeons to Europe to observe surgeries and train with world-renowned surgeons who have been implanting anatomically-shaped breast implants for decades and, upon return to the United States, we engage

them as consultant-educators to conduct training sessions for other U.S.-based Plastic Surgeons.

we periodically sponsor educational surgical preceptorships where a small group of Plastic Surgeons are able to observe a live surgery conducted by one of our trained preceptors and train with that preceptor.

Table of Contents

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

Table of Contents

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.

Table of Contents

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;

establishment registration and product listing with the FDA;

product manufacturing;

product labeling and storage;

pre-market clearance or approval;

Table of Contents

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

Table of Contents

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 alway