Sientra, Inc.
Form 10-K
March 14, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Commission file number: 001-36709

SIENTRA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware (State or Other Jurisdiction of Incorporation or Organization)	20-5551000 (I.R.S. 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)

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value $0.01 per share	NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit 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, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer”, “accelerated filer”, “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

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

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

The aggregate market value of registrant's common stock held by non-affiliates of the registrant, based upon the closing price of a share of the registrant's common stock on June 30, 2018 as reported by NASDAQ Global Select Market on such date was approximately $442,698,000. The determination of affiliate status is not necessarily a

conclusive determination for other purposes.

As of March 4, 2019, there were 29,211,896 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 2019 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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"Sientra", "Sientra Platinum20", "Sientra Full Circle", "OPUS", "Allox", "Allox2", "BIOCORNEUM", "Dermaspan", "Softsp "Silishield", "miraDry", "Miramar Labs", "miraDry and Design", "miraDry Fresh", "bioTip", "The Sweat Stops Here", "No Sw Stress", "Sweat Less Live More", "Drop Design", "miraWave", "miraSmooth", "miraFresh", "freshRewards", "freshNet", "freshEquity", and "ML Stylized mark" are trademarks of our company. Our logo and our other trade names, trademarks and service marks appearing in this document are our property. Other trade names, trademarks and service marks appearing in this document are the property of their respective owners. Solely for convenience, our trademarks and

trade names referred to in the document, appear without the TM or the (R) symbol, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the rights of the applicable licensor to these trademarks and trade names.

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10 K, or Annual Report contains forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward looking statements are often identified by the use of words such as, “anticipate,” “believe,” “may,” “might,” “could,” “will,” “aim,” “estimate,” “continue,” “intend,” “expect,” “pla negative of those terms, and similar expressions that convey uncertainty of future events or outcomes to identify these forward looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Forward looking statements in this Annual Report on Form 10 K include, but are not limited to, statements about:

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

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

PART I

Item 1. Business

Overview

Sientra, Inc. (“Sientra”, the “Company,” “we,” “our” or “us”) is a medical aesthetics company committed to making a differenc in patients’ lives by enhancing their body image, growing their self esteem and restoring their confidence. We were founded to provide greater choices to board certified plastic surgeons and patients in need of medical aesthetics products. We have developed a broad portfolio of products with technologically differentiated characteristics, supported by independent laboratory testing and strong clinical trial outcomes. We sell our breast implants and breast tissue expanders, or Breast Products, exclusively to board certified and board admissible plastic surgeons and tailor our customer service offerings to their specific needs, which we believe helps secure their loyalty and confidence.

On June 11, 2017, we entered into a Merger Agreement with miraDry (formerly Miramar Labs) pursuant to which we commenced a tender offer to purchase all of the outstanding shares of miraDry’s common stock. Pursuant to the transaction, which closed on July 25, 2017 we added the miraDry System, the only FDA cleared device to reduce underarm sweat, odor and hair of all colors to our aesthetics portfolio. Following our acquisition of miraDry in July 2017, we began selling the miraDry System and bioTips. As a result of the miraDry acquisition, we determined that we will conduct our business in two operating segments. The Breast Products segment is comprised of our breast implants, tissue expanders and scar management products. The miraDry segment is comprised of our miraDry System and bioTips.

We sell both our Breast Products and miraDry products in the U.S. through a direct sales organization, which as of December 31, 2018, consisted of 103 employees, including 86 sales representatives and 17 sales managers. Additionally, we also sell our miraDry System in several international markets where we leverage a combination of distributor relationships and direct sales efforts. As of December 31, 2018, our international operations were supported by 6 sales representatives, as well as a number of consultants supporting both direct sales efforts and distributer relationships.

We commenced sales of our breast implants in the United States in the second quarter of 2012. Our Breast Products segment net sales were $37.0 million, $31.5 million and $20.7 million for the years ended December 31, 2018, 2017 and 2016, respectively. For our miraDry segment, we generate revenues from sales of our miraDry System and from the sales of bioTips which are required for use for each miraDry procedure performed. We generated net sales of $31.1 million for the year ended December 31, 2018 and $5.1 million for the year ended December 31, 2017 from the acquisition date on July 25, 2017.

Our Market

The global market for aesthetic procedures is significant. The American Society of Plastic Surgeons, or ASPS, estimates that U.S. consumers spent approximately $17 billion on approximately eighteen million cosmetic procedures in 2017, including both surgical and non-invasive cosmetic treatments.

Breast Products

Breast augmentation surgery remains the leading aesthetic surgical procedure by dollars and number of procedures in the United States. According to the American Society for Aesthetic Plastic Surgery, or ASAPS, over 333,000 primary

breast augmentation procedures were performed in the United States in 2017. Based on the number of procedures reported by ASAPS and ASPS and our estimates of average selling price, implant mix and implants per procedure, we estimate the global breast market to be approximately $1.5 billion, with the currently addressable U.S. market for our currently available breast products at approximately $700 million.

We sell our breast implants and tissue expanders exclusively to board-certified and board-admissible plastic surgeons, as determined by the American Board of Plastic Surgery, who we refer to as Plastic Surgeons. These surgeons have completed the extensive multi-year plastic surgery residency training required by the American Board of Plastic Surgery. While aesthetic procedures are performed by a wide range of medical professionals, including dermatologists, otolaryngologists, obstetricians, gynecologists, dentists and other specialists, the majority of aesthetic surgical procedures are performed by Plastic Surgeons. Plastic Surgeons are thought leaders in the medical aesthetics industry. According to the American Board of Plastic Surgery, there are approximately 7,000 board certified plastic surgeons actively practicing in the United States.

miraDry

Laser and light-based hair removal continues to be the largest volume among non-surgical and non-injectable procedures. As an emerging market, energy-based procedures for sweat and odor reduction are not currently tracked by ASAPS data. No one treatment procedure is offered by all physicians, and treatments vary in terms of the treatment goal and desired effect. As a result, the total aesthetic market as reported by ASAPS does not represent the market potential for miraDry or any other single product or treatment, but illustrates that each year patients elect to have millions of aesthetic procedures. We believe several factors are contributing to the ongoing growth in aesthetic procedures, including:

- Broader availability of safe non-surgical aesthetic procedures. Technological developments have resulted in the introduction of a broader range of safe, non-surgical aesthetic procedures. According to ASAPS, non-surgical aesthetic treatments are growing faster than invasive surgical procedures.

- Increased physician focus on aesthetic procedures. We believe increased restrictions imposed by managed care and government agencies on reimbursement for medical treatments are motivating our customers to establish or expand their elective aesthetic practices, which generally consist of procedures paid for directly by patients. We expect this trend to continue as our customers look for ways to expand their practices and improve profitability.

Hyperhidrosis is a medical condition of varying degree in which a person sweats excessively. The prevalence of hyperhidrosis in the United States is significant. A study published by Strutton et al. in the June 2004 issue of the Journal of the American Academy of Dermatology, or AAD, titled “U.S. prevalence of hyperhidrosis and impact on individuals with axillary hyperhidrosis: Results from a national survey,” estimated that 2.8% of the general population has hyperhidrosis (in this study defined as excessive or abnormal sweating) with 50.8% thereof having axillary hyperhidrosis. Additionally, the general consensus of medical practitioners is that the definition of hyperhidrosis includes anyone who is bothered by their sweat. As such, the definition of axillary hyperhidrosis is broad in scope and the condition depends upon whether patients have determined that their sweating is excessive or abnormal. Because this assessment is subjectively determined by the patients themselves, there is no quantifiable standard that medical practitioners use to determine whether a patient is suffering from axillary hyperhidrosis. If patients subjectively determine that their sweating is excessive and as such are bothered by their sweating, such patients are considered to be suffering from axillary hyperhidrosis.

In 2017, we commissioned a survey of over 2,000 consumers, evaluating several criteria including sweat-bothered, dissatisfaction with current treatment, interest in a non-surgical long-term solution, and interest in the miraDry product description. Based on this survey, we believe there are approximately 37 million people in the U.S. alone that are bothered by sweat, dissatisfied with their current treatment and/or have an interest in seeking a long-term solution, and that approximately 15 million people would be interested in our miraDry solution. Based on this survey and our average selling price per bioTip, we estimate the size of our addressable consumables market to be approximately $6 billion in the U.S. Further, based on this survey, our estimates of the number of aesthetic practices in the U.S., the indicated number of people interested in a miraDry solution and our average selling price per miraDry console, we estimate the size of our addressable equipment market to be approximately $1.4 billion on a global basis, with the size of our addressable U.S. market estimated at approximately $700 million.

Our Opportunity

Breast Products

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

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

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

miraDry

The miraDry procedure addresses a large underpenetrated market in the non-surgical, lifestyle aesthetics category. The miraDry treatment is the first and only FDA cleared solution to reduce underarm sweat, odor and hair of all colors with as little as one 60-minute treatment, allowing most patients to achieve immediately noticeable and durable results without the pain, expense, downtime, or repeat visits associated with surgical procedures. The sweat glands in the treated area are destroyed through targeted heating of the tissue, and because the body does not regenerate sweat glands, we believe the results will be lasting, although some patients may need to repeat the miraDry procedure to achieve the lasting results. Due to these advantages, we believe that the miraDry treatment is appealing to a wide range of individuals seeking a lasting solution to underarm sweat.

The miraDry System has been cleared by the FDA as indicated for use in the treatment of primary axillary hyperhidrosis, or a condition characterized by abnormal sweating in excess of that required for regulation of body temperature, plus unwanted underarm hair removal, and reduction of underarm hair. When used for the treatment of primary axillary hyperhidrosis, the miraDry System may reduce underarm odor. In addition, the miraDry System received CE mark approval for the treatment of primary axillary hyperhidrosis and approval in several other countries. We are approved to sell the miraDry System in over 40 international markets outside of North America, including countries in Asia, Europe, the Middle East and South America.

Our Competitive Strengths

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

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

Breast Products

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

Strong clinical trial outcomes. Our clinical trial results demonstrate the safety and effectiveness of our breast implants. Our breast implants were approved by the FDA based on data we collected from our long-term clinical trial of our breast implants in 1,788 women across 36 investigational sites in the United States. The clinical data we collected over a ten-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 ten-year data.

Innovative services that deliver an improved customer experience. Our customer service offerings are intended to accommodate and anticipate the needs of our Plastic Surgeons so they can focus on providing better services to their patients. On April 25, 2018, we announced our new Sientra Platinum20 Warranty, which we believe provides an industry leading policy of no-charge replacement implants, as well as financial assistance, for certain qualifying events occurring within twenty years of the initial procedure. We also offer specialized educational initiatives and a streamlined ordering, shipping and billing process. For sales prior to May 1, 2018, we provided an industry-leading ten-year limited warranty that provides patients with a cash reimbursement for certain out-of-pocket costs related to revision surgeries in a covered event, a lifetime no-charge implant replacement program for covered ruptures, and our industry-first C3 Program through which we offer no-charge replacement implants to breast augmentation patients who experience capsular contracture within the first five years after implantation with our smooth or textured breast implants.

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

miraDry

Strong clinical trial outcomes. The miraDry System is the only FDA cleared device to reduce underarm sweat, odor and hair of all colors. Clinical studies involving more than 150 patients have shown that one or two miraDry procedures can noticeably and measurably reduce the amount of sweat from the axilla, or underarm. In our study involving 120 subjects, 89% of patients that received treatment experienced reduction in their sweat with no reported deaths, injuries requiring immediate medical attention to prevent death, or permanent impairment. In a second study involving 31 patients, patients reported an average of 82% sweat reduction at 12 months and 100% of patients reported an improvement in their Hyperhidrosis Disease Severity Scale, or HDSS, score at 24 months, with all patients reporting their sweating as either never noticeable or tolerable. Because sweat glands do not regenerate after the procedure, we believe the results are lasting.

Patient satisfaction. miraDry allows most patients to achieve noticeable and measurable aesthetic results without the pain, expense, downtime, and risks associated with more invasive procedures for sweat, odor and hair reduction. In addition, unlike many other non-surgical procedures, patients are not required to undergo multiple or recurring treatment procedures to obtain aesthetic results. According to RealSelf.com, a leading online community helping

people make confident choices in elective cosmetic procedures, as of February 6, 2019, the miraDry procedure received a 90% “worth it” rating from patients.

Reproducible results. The miraDry procedure requires limited training and skill to obtain successful aesthetic results. The miraDry System was designed to be easy to operate and largely automated, resulting in a more consistent application and reproducible results.

Differentiated, high-value product for physician practices. Our selective distribution strategy was designed to enable our customers to market miraDry as a highly differentiated, non-surgical sweat, odor, and hair reduction procedure. Based on our commercial data and customer experiences, we have seen attractive economic benefits for our customers.

Our Strategy

Our objective is to become a leading global provider of differentiated medical aesthetic products and services tailored to meet the needs of physicians, allowing us to deliver on our commitment to enhance and make a difference in patients' lives. To achieve our objective, we are pursuing the following business strategies:

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

Selectively pursue acquisitions and expand into new markets. We may continue to selectively pursue domestic and international acquisitions of businesses or technologies that may allow us to leverage our relationships with Plastic Surgeons and our existing commercial infrastructure to provide us with new or complementary products or technologies, and allow us to compete in new geographic markets or market segments or to increase our market share. For example, we began selling BIOCORNEUM directly to physicians in the United States after we acquired the rights to do so, in addition to rights relating to certain other specified sales channels from Enaltus in March 2016. We began selling the AlloX2 and Dermaspan lines of breast tissue expanders, and the Softspan line of general tissue expanders, after we acquired these product lines from SSP in November 2016. We began selling the miraDry System and bioTips after the acquisition of miraDry in July 2017.

Broaden our product portfolio and launch new products and services. We plan to continue to develop products that address the unmet needs of physicians and patients by leveraging our innovative technologies in combination with our regulatory and product development expertise. We have a number of new breast implants and tissue expanders under development with different characteristics and configurations. We believe these expanded product choices will allow Plastic Surgeons to potentially achieve better outcomes for their patients. In addition, we plan to take advantage of cross selling and product bundling opportunities.

Highly optimized, experienced and fully trained sales force. We maintain separate North American sales forces within our Breast Products and miraDry segments. Our Breast Products sales force primarily consists of Plastic Surgery Consultants, or PSCs, focused on selling all Breast Products exclusively to board-certified and board-admissible plastic surgeons. Additionally, our Breast Products segment is also supported by MSCs that sell scar management products directly to physicians. Our miraDry sales force is a bifurcated organization of employees and consultants that is split between Area Sales Managers, or ASMs, who focus on system sales, and Practice Development Managers, or PDMs, who focus on high margin consumable bioTip sales, assisting practices to market miraDry to patients, undergo product training and drive system utilization. We have continued to hire high quality, experienced sales representatives and sales management personnel in all categories and train the sales organization to optimize performance in their respective roles. We believe our sales force will continue to generate increased customer adoption and patient awareness momentum in the marketplace.

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.

Increase our international presence. There is strong global demand for aesthetic procedures outside of North America. We intend to increase our market penetration outside of North America and build global brand recognition. We have received regulatory approval or are otherwise free to market miraDry in numerous

international markets. We intend to seek regulatory approval to market miraDry in additional international markets, as well as grow our international sales and marketing organization to focus on increasing sales and market share, as well as strengthening our customer relationships. As part of this strategy, we are and intend to continue to opportunistically deploy a direct sales force in select international markets.

Our Products

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

Breast Products

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

In addition, since 2016, we have offered BIOCORNEUM, an advanced silicone scar treatment, directly to physicians, surgeons, and dermatologists.

We sell our silicone gel breast implants and tissue expanders exclusively to Plastic Surgeons. We seek to provide Plastic Surgeons with differentiated services, including enhanced customer service offerings and a twenty-year limited warranty that provides patients with 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 the industry's-first policy of no-charge replacement implants to patients who experience covered capsular contracture, double capsule and late-forming seroma events within twenty years of the initial implant procedure.

miraDry

In July 2017, we completed our acquisition of miraDry, following which we began selling the miraDry System, the only FDA cleared device indicated to reduce underarm sweat, odor and hair of all colors through the precise and non-surgical delivery of microwave energy to the region where sweat glands reside. The energy generates heat at the dermal-fat interface which results in destruction of the sweat glands. At the same time, a continuous hydro-ceramic cooling system protects the superficial dermis and keeps the heat focused at the dermal-fat interface where the sweat glands reside. Because sweat glands do not regenerate after the procedure, we believe the results are lasting. Microwaves are the ideal technology as the energy can be focused directly at the dermal-fat interface where the glands reside.

The miraDry System has been cleared by the FDA as indicated for use in the treatment of primary axillary hyperhidrosis, or a condition characterized by abnormal sweating in excess of that required for regulation of body temperature, plus unwanted underarm hair removal, and permanent reduction of underarm hair of all colors for Fitzpatrick skin types I – IV. Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime. When used for the treatment of primary axillary hyperhidrosis, the miraDry System may reduce underarm odor. In addition, the miraDry

System received CE mark approval for the treatment of primary axillary hyperhidrosis and approval in several other countries.

The miraDry System provides patients with a non-surgical and durable procedure to selectively destroy underarm sweat glands for both severely hyperhidrotic patients and those that are bothered by their underarm sweat. The miraDry System has been evaluated in clinical studies, which showed that the system reduced sweat in one or more procedures of approximately 60-minutes, allowing most patients to achieve immediately noticeable and durable results without the pain, expense, downtime, or repeat visits associated with surgical procedures. The sweat glands in the treated area are destroyed through targeted heating of the tissue, and because the body does not regenerate sweat glands, we believe the results will be lasting in most patients, although some patients may need to repeat the miraDry procedure to achieve the lasting results.

The miraDry System consists of a console and a handheld device which uses consumable single-use bioTips. The miraDry procedure is not technique-dependent, does not require significant training or skill for the healthcare provider, and the user-interface guides the provider through each step of the procedure for each treatment. We sell our miraDry System and consumable single-use bioTips only to physicians, consisting of dermatologists, plastic surgeons, aesthetic specialists and physicians specializing in the treatment of hyperhidrosis. Aesthetic specialists are physicians who elect to offer aesthetic procedures as a significant part of their practices but are generally not board-certified dermatologists or plastic surgeons. Physicians can market the miraDry procedure as a premium, highly-differentiated, non-surgical sweat reduction procedure. We are approved to sell the miraDry System in over 40 international markets outside of North America, including countries in Asia, Europe, the Middle East and South America.

Our Technology

Breast Products

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

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

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

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

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

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

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

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

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

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

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

miraDry

miraDry Technology. Our technology platform utilizes microwave energy to create heat within the skin or subcutaneous locations to create a therapeutic effect. Microwave energy has been used in various medical specialties for heating tissue for decades. In the dermatologic field, it is important that heating is confined to a very precise location, which the miraDry technology platform is designed to do. Due to its proprietary handpiece designs, when used with appropriate energy parameters, the miraDry System can heat dermatologic tissue in a precise and controlled manner.

Our miraDry System utilizes microwave energy to deliver heat to the location of the skin where most underarm sweat glands reside – at or just below the skin-fat interface. We designed a proprietary handpiece that automatically focuses the energy at the skin-fat interface, regardless of skin thickness. When the physician or medical professional places the handpiece to a specific area of the underarm as instructed by the graphic user interface, the energy is delivered

automatically to the target tissue. The heat generated in the tissue exceeds the threshold for cellular

necrosis, thereby ablating the sweat glands where the energy is focused. Surface cooling prevents the heat from damaging the superficial tissue above the skin-fat interface. In the underarm, many of the hair follicles are in the same relative location as the sweat glands. Therefore, the heating will also cause destruction and elimination of the hair follicles in those areas.

Our miraDry treatment has been clinically demonstrated to reduce sweat and hair from the underarm without causing injury to critical surrounding structures. The surface cooling protects the epidermis and the majority of the dermis from damaging heat. The deeper underlying structures are protected by two mechanisms. First, our anesthesia protocol calls for creating a distance barrier between the underlying structures and the surface of the skin where the handpiece is positioned. A significant volume of anesthesia fluid is administered between the skin (and target tissue) and the underlying structures, which causes a separation of the target tissue from the underlying structure. As the handpiece is positioned just outside the skin, the underlying structures are further away from the handpiece, keeping them safe from damaging heat. Second, we employ a vacuum suction system in the handpiece where the skin is pulled up into a vacuum chamber within the handpiece. Typically, the underlying structures either remain stationary or move slightly with the vacuum action, thereby creating further distance between the handpiece and the underlying structures.

Our Clinical Data

Breast Products

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

Our breast implant clinical trial is the largest prospective, long term safety and effectiveness pivotal study of breast implants in the United States and included the largest magnetic resonance imaging, or MRI, cohort with 571 patients. The MRI cohort is a subset of study patients that underwent regular MRI screenings in addition to the other aspects of the clinical trial protocol prior to FDA approval. Post-approval, all patients in the long-term clinical trial were subject to serial MRI screening as part of the clinical protocol. The clinical data we collected over a ten year follow up period demonstrated rupture rates, capsular contracture rates and reoperation rates that were comparable to or better than those of our competitors, at similar time points. In addition to our pivotal study, our clinical data is supported by our Continued Access Study of 2,497 women in the United States. We have also commissioned a number of bench trials run by independent laboratories that we believe further demonstrate the advantages of our breast implants over those of our competitors. An additional large prospective Post Approval Study, or PAS, is being conducted on our breast implants. The PAS is a newly enrolled U.S. cohort designed to evaluate long-term clinical performance under general conditions in the postmarket environment (i.e., “real-world” study). The study involves 5,197 Sientra patients and 301 control patients followed annually for 10 years.

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

miraDry

Our DRI-UP clinical trial, conducted as an FDA-approved Investigational Device Exemption study, involved 120 subjects. The results of the study indicated that subjects with axillary hyperhidrosis receiving treatment for the reduction of axillary sweat using the miraDry System had a success rate of 89% as compared to the control group success rate of 54%, with no serious adverse events or unanticipated adverse device effects reported.

A second study on the long-term effect of the miraDry System showed all patients who participated in this study reported being no longer bothered by their hyperhidrosis at 24 months, with no serious adverse events or unanticipated adverse side effects.

A third, single center study designed to quantify the amount of odor reduction in the axillae after treatment(s) with the miraDry System treated 36 subjects with a miraDry treatment with follow-up visits at 1 month, 3 month and 6 month intervals after treatment. The study data did not show a statistically significant majority of treated subjects having at least a two point lower malodor score (scale of 0 to 10) but did show a statistically significant average malodor score difference between the treated and untreated axilla using both quantitative odor judges' scores as well as patients' subjective self-reported odor severity score (scale of 1 to 10).

Our Services

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

Industry Leading Product Programs and Warranties

On April 25, 2018, we announced our new Sientra Platinum20 Warranty, which we believe provides an industry-leading policy of no-charge replacement implants, as well as financial assistance, for certain qualifying events occurring within twenty years of the initial procedure.

Through our C3 Program, we provide no charge replacement gel breast implants to patients who experience capsular contracture in the first five years following primary breast augmentation for every patient implanted with our smooth or textured breast implants. For surgeries prior to May 1, 2018, we also provide a 10 year limited warranty that provides 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

Breast Products

Our Breast Products customer service policies have been specifically tailored to meet the needs of Plastic Surgeons, including:

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

miraDry

Our miraDry customer service policies have been designed to meet the needs of both physicians and distributors, including:

- In the event of a technical issue with a miraDry System in North America, one of our customer service personnel will call the physician and determine whether the technical issue may be resolved over the telephone or whether the issue requires an intervention. If the issue cannot be resolved by telephone, our customer service personnel will request our third-party logistics provider to visit the physician and provide on-site technical support. If the service provider determines that a replacement system is required, our logistics provider will deliver the replacement miraDry System or module into the physician's office, set it up and ensure that the miraDry System is working properly.
- In most markets outside of North America, our miraDry System is serviced and supported through our independent distributors and certified third-party service providers. We require our distributors to maintain adequate inventory of miraDry Systems and components to facilitate quick response time to service events and to maximize customer "up time."
- We provide a standard one year warranty on our miraDry Systems in the U.S. In addition to these product warranties, we offer extended service agreements to our customers to provide protection of their system and handpiece against breakage. However, we do not obtain a material portion of our revenue from our service contracts.

Educational and Marketing Initiatives

Breast Products

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

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

- we have developed a tablet based mobile marketing tool for our sales representatives to use while calling on accounts that includes access to our patient and surgeon labeling, published clinical studies, marketing literature, details on our warranty and C3 programs, our educational iBooks and more.
- we host symposia with one or more key note speakers who speak on topics ranging from our corporate identity and customer service offerings to surgical tips and suggestions from thought leading Plastic Surgeons.
- we produce comprehensive guides for Plastic Surgeons via the Internet, referred to as iBooks, to provide them training and expertise on the implantation of anatomically shaped breast implants.
- we 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.
- We provide an educational series on Practice Management for Plastic Surgeons in the form of ENHANCE Webinars and Consulting, to provide them with insights and expertise on how to market and run their practices.

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

- our own consumer website, branded with our "Feel So Good" campaign, that provides resources for consumers considering breast augmentation or reconstruction, including referrals and commentaries, product descriptions, patient planning guides and educational brochures and information regarding our rupture warranty and C3 programs; and
- Our social media profiles, educating those interested in breast augmentation, breast reconstruction and scar treatment through Facebook, Instagram, LinkedIn and Twitter. We deliver four distinct content series to educate patients – Breast Implant Basics, Board-Certified Plastic Surgeons Basics, Scarring, and From Her Lips – as well as sharing applicable third party content about breast procedures and scarring.

miraDry

We have implemented targeted marketing and practice support programs.

Health Care Provider Marketing

- Globally, we offer a physician loyalty program called Fresh Rewards, which provides quarterly benefits and incentives to customers based on their bioTip purchases in the previous quarter. The program includes co-op advertising with usage guidelines to help increase patient demand for miraDry. The program also provides access to miraDry branded assets, physician locator priority ranking, and a service contract discount at all levels.
- Our Practice Development Managers, or PDMs, are focused on implementing our marketing programs in North America and International direct markets. Our PDMs provide all initial trainings for our miraDry System to our physician customers and their staff following the delivery of the system to the practice. Following this initial training, our PDMs, also educate our physician customers on current best practices and provide physicians and their staff with sales and marketing training and support to help them increase patient demand for the miraDry treatment.
- We engage with prospective customers through nurturing campaigns to inform them of the miraDry procedure and benefits of partnering with our Company to attract patients to their practice. The primary initiatives include local prospect events, email campaigns, and webinars.
- We also participate in industry tradeshows, clinical workshops, and conferences with expert panelists.

Consumer/Patient Marketing

- Our consumer website, miraDry.com, provides a resource for consumers including a product and procedure overview, physician locator, media clips, and FAQs.
- In North American and certain International markets, we provide digital direct-to-consumer, or DTC, advertising to help increase patient awareness and demand for our brand and customers.
- We continually update our social media profiles and post content to educate and engage consumers interested in a miraDry treatment through Facebook, Instagram, YouTube, LinkedIn and Twitter.

Sales and Marketing

We sell both our Breast Products and miraDry products in the U.S. through a direct sales organization, which as of December 31, 2018, consisted of 103 employees, including 86 sales representatives and 17 sales managers. Additionally, we also sell our miraDry System in several international markets where we leverage a combination of distributor relationships and direct sales efforts. As of December 31, 2018, our international operations were supported by 6 sales representatives, as well as a number of consultants supporting both direct sales efforts and distributer relationships.

We continue to increase our penetration into the international markets in which we currently distribute the miraDry System, as well as expand into new markets through the identification and training of qualified distributors specializing in medical device distribution. We require our international distributors to provide ongoing training and support of their physician customers and invest in the marketing support of practices to expand the market and demand for the miraDry System for physicians and patients. Our distribution agreements generally provide the exclusive right to distribute our products within a designated territory.

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

Research and Development

We have incurred, and expect to continue to incur, significant research and development expenses. Our research and development expenses were approximately $10.9 million, $9.8 million and $9.7 million for the years ended December 31, 2018, 2017 and 2016, respectively. The addition of miraDry added $2.0 million and $0.9 for the years ended December 31, 2018 and 2017, respectively from the acquisition date of July 25, 2017. Our Breast Products segment research and development is focused on enhancing and improving our breast products and tissue expanders, increasing our breast implant portfolio, product development related activities and expanding into synergistic markets. Our miraDry research and development is focused on products and procedure enhancements and development of products for new indications. Product and procedure enhancements include changes to improve efficacy of the therapy, the patient experience, and the physician/operator experience. As related to the miraDry System, for products for new indications, we will seek to leverage our miraWave microwave energy platform to develop products to serve additional needs in dermatology and plastic surgery. The goal is to be able to treat multiple indications with the existing miraDry console using different handpieces and custom software. Our miraDry research and development group is comprised of engineers, microwave scientists and technicians. We believe research and development is important to the success of the Company as we continue to develop and expand our product portfolio.

Manufacturing and Quality Assurance

Breast Products

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

We, along with our third-party manufacturers are subject to the FDA's Quality System Regulation, or QSR, reporting requirements and current Good Manufacturing Practices, or cGMP, audits by the FDA. Under the QSR and cGMP requirements, manufacturers, including third-party manufacturers, must follow stringent design, testing, production, control, supplier and contractor selection, complaint handling, documentation and other quality assurance procedures

during all aspects of the manufacturing process. The FDA has regularly inspected both the Company and our suppliers. The Company has never been the subject of any 483 Observations or Warning Letters, or any other FDA assertions that we are in violation of the FDCA.

We have obtained the following international certifications for breast implants and tissue expanders: ISO 13485:2016 Quality Management Systems Requirements, and the Medical Device Single Audit Program (MDSAP), representing conformance to 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A through D) and Canadian Medical Devices Regulations – Part 1 - SOR-98/282, positioning us to register our breast implants and tissue expanders in Canada and other international markets.

On August 9, 2016, we announced our collaboration with Vesta Intermediate Funding, Inc., or Vesta, a Lubrizol Lifesciences company, pursuant to which we worked with Vesta towards establishing a dedicated contract manufacturing facility for our breast implants. On March 14, 2017, we announced that we had executed a definitive manufacturing agreement with Vesta for the manufacture and supply of our breast implants. In addition, on March 14, 2017, we announced that we had submitted a PMA supplement to the FDA for the manufacturing of our PMA-approved breast implants by Vesta. On January 30, 2018, we announced the FDA has granted approval of the site-change PMA, supplement for our contract manufacturer, Vesta, to manufacture our silicone gel breast implants. In support of the move to the Vesta manufacturing facility, we also implemented new manufacturing process improvements which, in consultation with the FDA, required three (3) additional filings. In addition to approving the manufacturing site-change supplement, the FDA approved all three (3) process enhancement filings, as of April 17, 2018.

miraDry

We occupy an approximately 29,000 square foot facility located in Santa Clara, California dedicated to the manufacture, distribution, and servicing of miraDry Systems and accessories.

All final assembly, calibration and testing of our miraDry Systems are performed at our Santa Clara facility. The consumable bioTip is manufactured by a contract manufacturer, Healthcare Technology International Limited (HTI), at their facility in Dongguan, China. Consumables are tested and packaged at our Santa Clara facility, then some consumables intended for sale in countries requiring sterile product are sent to Parter Sterilization Services in Carson, CA for ethylene oxide sterilization.

A critical component of our miraDry System is the custom microwave power amplifier contained in the miraDry console. The amplifier is manufactured by a single source manufacturer, Broadband Wireless, LLC, in Reno, Nevada (a subsidiary of United States Technologies, Inc.), or Broadband. We fully own the design and manufacturing process for this amplifier.

Manufacturing facilities that produce finished medical devices intended for distribution in the United States and internationally are subject to regulation and periodic unannounced inspection by the FDA and other domestic and international regulatory agencies. In the United States, we are required to manufacture our products in compliance with the FDA's Quality System Regulation, or QSR, which cover the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage, and shipping of our products. The FDA most recently inspected our facility in August 2016 and at the conclusion of such routine audit, a Form 483 was issued with two observations. The FDA acknowledged receipt of periodic status reports documenting the completion of corrections and corrective actions taken by us to address each of the two observations. The FDA will verify acceptability of the actions taken during its next routine inspection. No further actions are required at this time. In international markets, we are required to obtain and maintain various quality management system certifications. We have obtained the following international certifications for the miraDry System: ISO 13485:2003 Quality Management Systems Requirements, in support of both our CE marking and Canadian Medical Devices Conformity Assessment System (CMDCAS) requirements. Our notified body, NSAI, most recently audited our facility in November 2017 and subsequently renewed our ISO 13485-2003 certification.

HTI, our disposables manufacturer, and Parton Sterilization Services, our sterilization service provider comply with the FDA's QSR and are registered in good standing with the FDA. Additionally, we have procedures in place designed to ensure that all other purchased products and materials conform to specified requirements, including evaluation of suppliers, and where required, qualification of the components supplied.

Competition

Breast Products

The medical device industry is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products or other market activities of industry participants. We primarily compete with two companies that

manufacture and sell breast implants in the United States: Johnson & Johnson through its wholly owned subsidiary, Mentor Worldwide, LLC, or Mentor, and Allergan plc, or Allergan.

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

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

We believe the primary competitive factors in our markets include:

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

miraDry

The medical technology and aesthetic product markets are highly competitive and dynamic, and are characterized by rapid and substantial technological development and product innovations. Demand for the miraDry treatment could be limited by the products and technologies offered now or in the future by our competitors as well as the limited capital expenditure budgets of our physician customers. We designed the miraDry treatment to address the concerns of individuals who seek a durable solution to their axillary sweat. Therefore, we compete both directly and indirectly with those companies marketing botulinum toxin and other medical device companies. To a lesser extent, we indirectly compete with antiperspirants. We expect aesthetic medical device companies to pursue technological advances in the treatment of sweat, hair and odor removal that will continue to alter the competitive environment.

In the United States, our major competitor in the treatment of sweat is Allergan, which manufactures Botox; Botox is approved for the treatment of severe primary axillary hyperhidrosis. Cynosure, a division of Hologic, also has received FDA clearance to market PrecisionTX for the treatment of primary axillary hyperhidrosis. Dermira, Inc. recently received FDA approval for Qbrexza, a topical prescription treatment indicated for primary axillary hyperhidrosis. These competitors may have more resources than us and may prevent our miraDry System from gaining widespread market acceptance.

Due to less stringent regulatory requirements, there are many more aesthetic products and procedures available for use in international markets than are approved or cleared for use in the United States. There are also fewer limitations on the claims our competitors in international markets can make about the effectiveness of their products and the manner in which they can market them. As a result, we face more competition in these markets than in the United States.

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Government Regulation

Our products are subject to extensive regulation by the FDA and other federal and state regulatory authorities, and other regulatory bodies in other countries.

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

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

Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States will require 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, a de novo application seeking authorization to market the device, or approval from the FDA of a PMA application. These processes can be expensive, lengthy and require payment of significant user fees, unless an exemption is available.

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

requiring a PMA application has not been issued by the FDA. In addition there are some "unclassified" devices in FDA's regulatory framework, which are preamendment devices for which a classification regulation has not been promulgated by the agency. Until the unclassified device type has been formally classified and a regulation established, marketing of new devices within this type requires submission of a 510(k) premarket notification. If a device of a type that FDA has not previously classified does not qualify for the 510(k) pre-market notification process because no legally marketed predicate device to which it is substantially equivalent can be identified, the device is automatically classified into Class III. Under the de novo process an applicant may seek the "down-classification" to Class I or II for a new product type that would otherwise automatically be placed into Class III, but is lower risk. If the FDA agrees with the down-classification, the de novo applicant will then receive authorization to market the device, and a classification regulation will be established for the device type. The device can then be used as a predicate device for future 510(k) submissions by the manufacturer or a competitor.

Our tissue expanders and our body contouring, facial and nasal implants received FDA clearance at various dates prior to approval of our breast implants in March 2012. Additionally, the miraDry System is currently regulated as a Class II device that requires 510(k) clearance. Our BIOCORNEUM product contains silicone for scar management, which is a Class I exempt device, and contains sunscreen which FDA regulates as an over-the-counter drug.

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, 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, and provides some guidance on decision making, but the FDA can review any such decision at any time 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, de novo marketing authorization, or approval of a PMA application is obtained. If the FDA requires us to seek 510(k) clearance or approval of a PMA application for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. In addition, in these circumstances, we may be subject to significant regulatory fines or penalties for failure to submit the requisite marketing applications. In addition, the FDA is currently evaluating the 510(k) process and may make substantial changes to industry requirements.

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

manufacturers to implement and follow elaborate design, testing, control, documentation and other quality assurance procedures in the device design and manufacturing process.

The FDA may approve a PMA application with post approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution and collection of long term follow up data from patients in the clinical study that supported approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval. New PMA applications or PMA supplements are required for significant modifications

to the manufacturing process, labeling and design of a device that could affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. PMA supplements often require submission of the same type of information as a PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

Clinical Trials. A clinical trial is almost always required to support a PMA application and may be required for a 510(k) pre market notification. In the United States, absent certain limited exceptions, human clinical trials intended to support product clearance or approval require an Investigational Device Exemption, or IDE, application. Some types of studies deemed to present "non significant risk" are deemed to have an approved IDE once certain requirements are addressed and institutional review board, or IRB, approval is obtained. If the device presents a "significant risk" to human health, as defined by the FDA, the Sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to evaluate the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of subjects, unless the product is deemed a non significant risk device and eligible for more abbreviated IDE requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the responsible institutional review boards at the clinical trial sites. There can be no assurance that submission of an IDE will result in the ability to commence clinical trials. Additionally, after a trial begins, the FDA may place it on hold or terminate it if, among other reasons, it concludes that the clinical subjects are exposed to unacceptable health risks that outweigh the benefits of participation in the study. During a study, we are required to comply with the FDA's IDE requirements for investigator selection, clinical trial monitoring, reporting, record keeping and prohibitions on the promotion of investigational devices or making safety or efficacy claims for them. We are also responsible for the appropriate labeling and distribution of investigational devices. Our clinical trials must be conducted in accordance with FDA regulations and federal and state regulations concerning human subject protection, including informed consent and healthcare information privacy. The investigators must also obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices and comply with all reporting and record-keeping requirements. The FDA's grant of permission to proceed with clinical testing does not constitute a binding commitment that the FDA will consider the study design adequate to support clearance or approval. In addition, there can be no assurance that the data generated during a clinical study will meet chosen safety and effectiveness endpoints or otherwise produce results that will lead the FDA to grant marketing clearance or approval.

Other Regulatory Requirements. Even though our devices 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;
- various state-level requirements for licensure of medical device manufacturing and/or distribution;
- 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 (in addition, the Federal Trade Commission has oversight of the advertising of medical devices other than "restricted" devices);
- 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

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- corrections and removals reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health. In addition, the FDA may order a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death.

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

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

- warning letters or untitled letters that require corrective action;
- fines and civil penalties;
- unanticipated expenditures;
- delays in or refusal to grant requests for 510(k) clearance or pre market approval of new products or modified products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries;
- suspension or withdrawal of FDA clearance or approval;
- product recall, detention or seizure;
- 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 may be subject to regulation under additional healthcare laws by numerous regulatory and enforcement authorities in the United States, in addition to the FDA. These laws include, without limitation, state and federal anti kickback, false claims, physician sunshine, and patient data privacy and security laws and regulations, including but not limited to those described below.

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

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

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

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

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 $11,181.00 and $22,363.00 for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the federal FCA is a civil statute, FCA violations may also implicate various federal criminal statutes.

In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud, known as "qui tam", or whistleblower, lawsuits. Because the complaint is initially filed under seal, the action may be pending for some time before the

defendant is even aware of the action. If the government intervenes and is ultimately successful in obtaining redress in the matter, or if the plaintiff succeeds in obtaining redress without the government's involvement, then the plaintiff will receive a percentage of the recovery. Qui tam actions have increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a false claim action, pay fines or be excluded from Medicare, Medicaid or other federal or state healthcare programs as a result of an investigation arising out of such action.

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

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

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

The Administrative Simplification provisions of HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, including the Final HIPAA Omnibus Rule published on January 25, 2013, mandate, among other things, that certain types of entities and individuals adopt 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. Additionally, HITECH mandates the reporting of certain breaches of health information to the Department of Health and Human Services, affected individuals and if the breach is large enough, the media.

Even when HIPAA does not apply, according to the U.S. Federal Trade Commission, or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

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 and private litigation. For example, California recently

enacted legislation – the California Consumer Privacy Act, or CCPA, which goes into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Legislators have stated that they intend to propose amendments to the CCPA before it goes into effect, and the California Attorney General will issue clarifying regulations. Although the law includes limited exceptions, including for certain information collected as part of clinical trials as specified in the law, it may regulate or impact our processing of personal information depending on the context. It remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted.

Physician Payments Sunshine Act. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, PPACA, imposed, among other things, new annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, for certain payments and "transfers of value" provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately, and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an additional aggregate of $1 million per year for "knowing failures," for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission. We are required to report detailed payment data and submit legal attestation to the accuracy of such data by March 31st of each calendar year. Additionally, on October 25, 2018, President Trump signed into law the "Substance Use-Disorder Prevention that Promoted Opioid Recovery and Treatment for Patients and Communities Act." This law, in part (under a provision entitled "Fighting the Opioid Epidemic with Sunshine"), extends the reporting and transparency requirements for physicians in the Physician Payments Sunshine Act, to payments and transfers of value to physician assistants, nurse practitioners, and other mid-level practitioners (with reporting requirements going into effect in 2022 for payments and transfers of value made in 2021).

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

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

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

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

International Regulation. We are approved to sell the miraDry System in over 40 international markets outside of North America. International sales of medical devices are subject to local government regulations, which may vary substantially from country to country. We may evaluate international expansion opportunities in the future for Breast Products. 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 Breast Products.

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

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

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

There have been a number of legislative and regulatory proposals to change the healthcare system, reduce the costs of healthcare and change medical reimbursement policies. Doctors, clinics, hospitals and other users of our products may decline to purchase our products to the extent there is uncertainty regarding coverage from government or commercial payors. Further proposed legislation, regulation and policy changes affecting third-party reimbursement are likely. Among other things, Congress has in the past proposed changes to and the repeal of the Patient Protection and Affordable Care and Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the Affordable Care Act), and lawsuits have been brought challenging aspects of the law at various points. There have been repeated recent attempts by Congress to repeal or replace the Affordable Care Act, or ACA. Some of the provisions of the ACA have yet to be implemented, and there have been legal and political challenges to certain aspects of the ACA. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal and replace all or part of the ACA. While Congress has previously been successful at passing comprehensive repeal legislation through both Chambers of Congress, it had then been vetoed by former President Obama; however full repeal legislation is unlikely in the current political climate. Furthermore, the Tax Cuts and Jobs Act passed in December of 2017 included a provision that would repeal one of the primary pillars of the law, the

ACA's individual mandate penalty that essentially assessed a monetary penalty or fine on certain individuals who fail to maintain qualifying health coverage for all or part of a year. Congress may consider other legislation to repeal or replace elements of the ACA on a provision-by-provision basis. More recently, the United States District Court for the Northern District of Texas struck down the ACA, deeming it unconstitutional given that Congress repealed the individual mandate in 2017. This decision has been stayed pending outcome of an appeal to the Fifth Circuit Court of Appeals. Although there is no immediate impact on the ACA, we will continue to evaluate the effect that the ACA and its possible repeal and replacement, or potential total revocation by the Supreme Court of the United States, has on our business.

The ACA had also imposed, among other things, a federal excise tax of 2.3% on certain entities that manufacture or import medical devices for sale in the United States. This tax had previously been suspended, and on January 22, 2018 both the House and Senate struck a short-term Continuing Resolution to fund the federal government, H.R. 195, which included a two-year suspension on the medical device excise tax. This two-year delay is retroactively applied starting December 31, 2017, and will officially extend through January 1, 2020. The future of this provision beyond that point is uncertain, as there may be additional attempts to fully repeal the provision.

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

Intellectual Property and Proprietary Rights

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

Our Breast Products trademark portfolio consists of 10 registered U.S. trademarks. Our miraDry trademark portfolio consists of 96 worldwide registered trademarks and 3 pending trademark applications.

Our Breast Products patent portfolio consists of 2 pending U.S. patent application, as well as several in-licensed patent rights. Our miraDry patent portfolio is comprised of 21 granted or allowed U.S. patents, 95 granted or allowed foreign counterpart patents, 6 pending or published U.S. patent applications, and 27 pending or published foreign counterpart patent applications.

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

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

Employees

As of December 31, 2018, we had 259 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.

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 and purchase of miraDry procedures. We believe that aesthetic procedures are subject to seasonal fluctuation due to patients planning their procedures leading up to the summer season and in the period around the winter holiday season.

Corporate Information

We incorporated in Delaware on August 29, 2003 under the name Juliet Medical, Inc. and subsequently changed our name to Sientra, Inc. in April 2007. Our principal executive offices are located at 420 South Fairview Avenue,

Suite 200, Santa Barbara, California, 93117, and our telephone number is (805) 562 3500. Our website is located at www.sientra.com, and our investor relations website is located at http://investors.sientra.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, reports on Form 8-K and our Proxy Statements are available through our investor relations website, free of charge, as soon as reasonably possible after we file them with the SEC.

Item 1A. Risk Factors

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

Risks Relating to Our Business and Our Industry

We 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, 2018, we had an accumulated deficit of $362.1 million. To date, we have financed our operations primarily through sales of preferred stock, borrowings under our term loans, sales of our products since 2012, our initial public offering and follow-on public offerings of our common stock. We have devoted substantially all of our resources to the acquisition and clinical development of our products, the commercial launch of our products, the development of a sales and marketing team and the assembly of a management team to manage our business.

For the year ended December 31, 2018, our net loss was $82.6 million. The extent of our future operating losses and the timing of profitability are uncertain, especially in light of our inventory supply issues. We will need to generate significant sales to achieve profitability, and we might not be able to do so. Even if we do generate significant sales, we might not be able to achieve, sustain or increase profitability on a quarterly or annual basis in the future. If our sales grow more slowly than we have forecasted, or if our operating expenses exceed our forecasts, our financial performance and results of operations will be adversely affected.

We may not successfully integrate newly acquired businesses into our business operations or realize the benefits of partnerships with other companies, acquisitions of complementary products or technologies or other strategic alternatives.

We have completed a series of business and product acquisitions including our acquisition of miraDry and our product acquisitions, including BIOCORNEUM and our tissue expanders portfolio. As a result of these acquisitions, we have undergone substantial changes to our business and product offerings in a short period of time. In addition, in the future, we may consider other 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.

Integrating the business practice and operations of a new business with that of our own is a complex, costly and time-consuming process, which requires significant management attention and resources. The integration process may disrupt our existing operations and, if implemented ineffectively, would preclude realization of the full benefits expected by us. Our failure to meet the challenges involved in successfully integrating our acquisitions in order to realize the anticipated benefits may cause an interruption of, or a loss of momentum in, our operating activities and could adversely affect our results of operations. Potential difficulties, costs and delays we may encounter as part of the integration process may include:

- distracting management from day to day operations;
- potential incompatibility of corporate cultures;

- an inability to achieve synergies as planned;
- risks associated with the assumption of contingent or other liabilities of acquisition targets;

- adverse effects on existing business relationships with suppliers or customers;
- inheriting and uncovering previously unknown issues, problems and costs from the acquired company;
- uncertainties associated with entering new markets in which we have limited or no experience;
- increased legal and accounting costs relating to the partnership or acquisition or compliance with regulatory matters;
- delays between our expenditures to acquire new products, technologies or businesses and the generation of net sales from those acquired products, technologies or businesses;
- realization of assets and settlement of liabilities at amounts equal to estimated fair value as of the acquisition date of any acquisition or disposition;
- costs and delays in implementing common systems and procedures (including technology, compliance programs, financial systems, distribution and general business operations, among others); and
- increased difficulties in managing our business due to the addition of international locations.

Any one or all of these factors may increase operating costs or lower anticipated financial performance. Many of these factors are also outside of our control. In addition, even if new business operations are integrated successfully, we may not realize the full benefits of the acquisition, including the synergies, cost savings or sales or growth opportunities that we expect or within the anticipated time frame. Additional unanticipated costs may be incurred in the integration of the businesses. All of these factors could decrease or delay the expected accretive effect of the transaction, and negatively impact the price of our common stock. The failure to integrate the business operations of miraDry or any acquired business successfully would have a material adverse effect on our business, financial condition and results of operations.

In addition to integration related issues, the acquisition of miraDry has significantly increased the size of our business, augmenting a number of the risks included in these risk factors. Future success depends, in part, upon our ability to manage this expanded business, which will pose substantial challenges for management. There can be no assurance that we will be successful realizing the expected benefits from this acquisition.

We depend on a positive reaction from our Plastic Surgeons and their patients, and on an adequate supply of our products, to successfully re-establish our market position and achieve profitability.

Our Breast Products segment has historically accounted for substantially all of our net sales and we expect our Breast Products to continue to be a significant portion of our net sales.

We depend on a continued positive reception from our Plastic Surgeon customers and their patients to be able to reestablish the market position we had prior to the voluntary suspension of our Breast Products manufactured by Silimed. Additionally, our re-entry into the market has required us to effectively and responsibly educate accounts on the results of our testing and reconfirm our strong clinical data, while providing the same high levels of customer service to which our Plastic Surgeons are accustomed. Our plastic surgery consultants are working diligently to solidify the confidence and support of all our Plastic Surgeons; however, if we are not successful in re-establishing and maintaining these relationships or competing effectively in this market, our sales revenues, market share and financial performance will be affected negatively.

Any inability to manage inventory supply issues, an inadequacy of current inventory levels, the potential loss of market acceptance of our Breast Products, or any adverse rulings by regulatory authorities, any adverse publicity or other adverse events relating to us or our Breast Products, or the introduction of competitive products by our competitors and other third parties, would adversely affect our business, financial condition and results of operations.

If the market acceptance for the miraDry System, which has a limited commercial history, fails to grow significantly, our business and future prospects will be harmed.

Commercial sales of the miraDry System commenced in the United States in 2012. We expect that the net sales we generate from our miraDry System and bioTips will represent high margin sales (on a gross margin basis) and account for a substantial amount of our net sales for the next several years, with high margin consumables comprising a sizable percentage of our miraDry segment's net sales. Accordingly, our success depends on the acceptance among physicians and patients of the miraDry procedure as a preferred treatment for being sweat-bothered. Although we have received FDA clearance to market the miraDry procedure for the treatment of primary axillary hyperhidrosis, odor and permanent hair reduction in the United States and are approved or are otherwise free to market the miraDry procedure for the treatment of primary ancillary hyperhidrosis in adults in over 40 international markets, the degree of market acceptance of the miraDry procedure by physicians and patients is unproven. We believe that market acceptance of the miraDry procedure will depend on many factors, including:

- the perceived advantages or disadvantages of the miraDry System compared to other products and procedures;
- the safety and efficacy of the miraDry System relative to other products and alternative procedures;
- the price of the miraDry System relative to other products and alternative procedures;
- our success in expanding our sales and marketing organization;
- the effectiveness of our marketing, advertising, and commercialization initiatives;
- the development and publication of long-term clinical data in peer-reviewed journals supporting the long term efficacy of the miraDry procedure;
- our ability to obtain regulatory clearance to market miraDry for additional treatment indications in the United States and other international markets;
- education of physicians, especially general practitioners and dermatologists, regarding alternative procedures for sweat-bothered patients through key opinion leaders and product demonstrations at conferences, physician offices and webinars; and
- the success of patient education through direct-to-consumer marketing campaigns that utilize social media outlets and testimonials.

We cannot guarantee that the miraDry System will achieve broad market acceptance among physicians and patients. We expect to derive a substantial portion of sales from the miraDry Systems and the sale of our consumable bioTip products, which represent higher margin products within our product portfolio. As a result, any failure of this product to achieve meaningful market acceptance will harm our business, sales, profitability and future prospects.

We rely on sole suppliers to manufacture some of our products, including our breast implants and our scar management, tissue expander and bioTips products, and any production problems or inability to meet our demand could adversely affect our business prospects.

We rely on sole suppliers to manufacture certain of our products or the components used therein, and the loss of any such supplier or any disruption in operations, production problems or inability to meet our supply demands of any such supplier could have a material adverse and severe effect on our business, financial condition and results of operations. Additionally, there can be no guarantees that we would be able to replace or transition to alternative suppliers on a timely basis or at all, if needed. If we are required to replace any of our sole suppliers, or transition to alternative suppliers, it may adversely impact our operations.

For example, we have entered into a definitive manufacturing agreement with Vesta and have qualified Vesta as our sole manufacturer for sourcing our breast implants. In January 2018, the FDA granted approval of the site-change PMA supplement for Vesta to manufacture our silicone gel breast implants. In support of the move to the Vesta manufacturing facility, we also implemented new manufacturing process improvements which, in consultation with the FDA, required three (3) additional submissions. These submissions were approved by the FDA on January 10, 2018, January 19, 2018 and April 17, 2018. With these approvals, we have re-launched our breast implant business and intend to continue to scale our supply of implants by increasing the quantity of products manufactured by Vesta. If Vesta is unable to scale its manufacturing operations to meet our requirements in any future period, or if there are any delays or disruptions in manufacturing or delivering the implants, we may not be able to achieve our anticipated sales levels and our net sales and business prospects could suffer significantly. In addition, if Vesta were to terminate or otherwise fail to perform under the definitive manufacturing agreement, or if the FDA were to determine that Vesta does not meet its strict regulatory requirements in the future, we would need to identify and qualify another alternate manufacturer, which would require a significant amount of time and resources and result in a supply interruption.

There are numerous risks in relying on sole suppliers to manufacture our products, which, individually or in the aggregate, could have a material adverse and severe effect on our business, financial condition and results of operations.

Direct-to-consumer marketing and social media effort may expose us to additional regulatory scrutiny.

Our efforts to promote our products via direct-to-consumer marketing and social media initiatives may subject us to additional scrutiny of our practices of effective communication of risk information, benefits or claims, under the oversight of the FDA, FTC, or both.

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

Our reliance on any third-party manufacturer, including Vesta, Formulated Solutions, LLC, or Formulated Solutions, which supplies our BIOCORNEUM scar management products, SiMatrix, a Vesta subsidiary that supplies the tissue expanders, Healthcare Technology International which supplies bioTips for our miraDry System or any other third-party manufacturer we procure and qualify for the manufacture of our Breast Products or miraDry Products involves a number of risks. Changes that our manufacturers may make outside the purview of our direct control, or other mistakes and mishandling of our products, can have an impact on our processes and quality, as well as the successful delivery of our products. Additionally, if any third-party manufacturer becomes unable or unwilling to supply our products, we may not be able to find an alternate supplier in a timely manner. For example, there are only a few suppliers of medical-grade silicone available, and if these suppliers become unable or unwilling to supply medical-grade silicone to Vesta, Formulated Solutions, SiMatrix or any other manufacturer that we may engage with, an alternate supply of medical-grade silicone may not be able to be found in a timely manner. Our existing manufacturing contracts will also expire, and there can be no assurance that our contracting counterparties will agree to continue to manufacture and supply our products or they may impose increased pricing terms if the contract is renegotiated or renewed.

Some of the additional risks with relying on third-party manufacturers and suppliers include:

- our products may not be manufactured in accordance with agreed upon specifications or in compliance with regulatory requirements or cGMP, or the manufacturing facilities may not be able to maintain compliance with regulatory requirements or cGMP, which could negatively affect the safety or efficacy of our products or cause delays in shipments of our products;
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- we may not be able to timely respond to unanticipated changes in customer orders, and if orders do not match forecasts, we may have excess or inadequate inventory of materials and components;
- our products may be mishandled while in production or in preparation for transit;
- we are subject to transportation and import and export risk, particularly given the global nature of our supply chain;

- the third-party manufacturer may discontinue manufacturing and supplying products to us for risk management reasons;
- the third-party manufacturer may lose access to critical services and components, resulting in an interruption in the manufacturing or shipment of our products;
- the third-party manufacturer may encounter financial or other hardships unrelated to us and our demand for products, which could inhibit our ability to fulfill our orders;
- there may be delays in analytical results or failure of analytical techniques that we depend on for quality control and release of products;
- natural disasters, labor disputes, financial distress, lack of raw material supply, issues with facilities and equipment or other forms of disruption to business operations affecting our manufacturer or its suppliers may occur;
- latent defects may become apparent after products have been released and which may result in a recall of such products; and
- there are inherent risks if we contract with manufacturers located outside of the United States, including the risks of economic change, recession, labor strikes or disruptions, political turmoil, new or changing tariffs or trade barriers, new or different restrictions on importing or exporting, civil unrest, infrastructure failure, cultural differences in doing business, lack of contract enforceability, lack of protection for intellectual property, war and terrorism.

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

We have 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;
- enhance our existing products and develop new products;
- obtain regulatory clearance or approval to enhance our existing products and commercialize new products;
- perform clinical trials with respect to our existing products and any new products; and
- attract, retain and motivate qualified personnel in various areas of our business.

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

If we fail to compete effectively against our competitors, some 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. For example, our Breast Products competitors, Mentor, a wholly owned subsidiary of Johnson & Johnson, and Allergan are well-capitalized global pharmaceutical companies that have been the market leaders for many years and have the majority share of the breast implant market in the United States. These competitors also enjoy several competitive advantages over us, including:

- greater financial and human resources for sales, marketing and product development;
- established relationships with health care providers and third-party payors;
- established reputations and name recognition among health care providers and other key opinion leaders in the plastic surgery industry;
- in some cases, an established base of long-time customers;
- greater financial resources and economies-of-scale to put additional pricing pressure on competing products;
- 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.

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

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

On March 25-26, 2019, the FDA plans to convene a meeting of the General and Plastic Surgery Devices Panel at the FDA's Headquarters in Silver Spring, Maryland, to discuss a range of topics concerning the benefit-risk profile of breast implants, This two-day public meeting will include presentations, recommendations, and discussion on the following topics: breast implant associated anaplastic large cell lymphoma (BIA-ALCL); systemic symptoms reported in patients receiving breast implants; the use of registries for breast implant surveillance; magnetic resonance imaging (MRI) screening for silent rupture of silicone gel filled breast implants; the use of surgical mesh in breast procedures such as breast reconstruction and mastopexy; the use of real-world data and patient perspectives in regulatory decision making; and best practices for informed consent discussions between patients and clinicians.

We anticipate that data and information about our products, as well as those of other breast implant manufacturers, will be discussed at this panel meeting.

Among the long-term health risks of breast implants which are being studied and followed, health regulators believe there is an association between breast implants and a rare form of lymphoma called anaplastic large-cell lymphoma.

In January 2011, the FDA issued a Safety Communication indicating that there was a possible association between saline and silicone gel breast implants and anaplastic large-cell lymphoma, or BIA-ALCL. Since our FDA approval in 2012, Sientra's breast-implant product labeling, which is approved by the FDA, has been required to contain a description of BIA-ALCL as a possible outcome. Since its report in January 2011, the FDA has continued to gather information about BIA-ALCL in women with breast implants through the review of medical device reports, review of medical literature, and collaboration with international regulators, scientific experts, ASPS, ASAPS, ISAPS, and other organizations.

As of August 23, 2017, the FDA updated its recommendations on BIA-ALCL and subsequently requested all breast implant manufacturers to revise their physician and patient labeling with the most up-to-date information. The FDA has continued to monitor these matters, and on February 6, 2019 issued a "Letter to Health Care Providers" and a public statement detailing updated medical device report (MDR) data involving BIA-ALCL, and stating that the data and published information reviewed to date suggest that patients with breast implants have an an increased risk of BIA-ALCL. The FDA states: "Over time, we have strengthened our understanding of this condition. In 2016, the World Health Organization designated breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) as a rare T-cell lymphoma that can develop following breast implants. The exact number of cases remains difficult to determine due to significant limitations in world-wide reporting and lack of global implant sales data. At this time, most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces rather than those with smooth surfaces." The FDA noted it does not recommend prophylactic breast implant removal in a patient without symptoms or other abnormality.

On March 25-26, 2019, the FDA plans to convene a meeting of the General and Plastic Surgery Devices Panel to discuss a range of topics concerning the benefit-risk profile of breast implants, including BIA-ALCL.

Further studies or clinical experience may indicate that breast implants, including our products, expose individuals to a more substantial risk of developing BIA-ALCL or other unexpected complications than currently anticipated. As a

result, we may be exposed to increased regulatory scrutiny, negative publicity and lawsuits from any individual who may develop BIA-ALCL after using our products, any of which could have a significant negative impact on our results of operations or financial condition. Moreover, if long-term results and clinical experience indicate that our products cause unexpected or serious complications, we could be subject to mandatory product recalls, suspension or withdrawal of regulatory clearances and approvals and significant legal liability.

In some instances in our advertising and promotion, we may make claims regarding our product as compared to competing products, which may subject us to heightened regulatory scrutiny, enforcement risk, and litigation risks.

The FDA applies a heightened level of scrutiny to comparative claims when applying its statutory standards for advertising and promotion, including with regard to its requirement that promotional labeling be truthful and not misleading. There is potential for differing interpretations of whether certain communications are consistent with a product's FDA-required labeling, and FDA will evaluate communications on a fact-specific basis.

In addition, making comparative claims may draw concerns from our competitors. Where a company makes a claim in advertising or promotion that its product is superior to the product of a competitor (or that the competitor's product is inferior), this creates a risk of a lawsuit by the competitor under federal and state false advertising or unfair and deceptive trade practices law, and possibly also state libel law. Such a suit may seek injunctive relief against further advertising, a court order directing corrective advertising, and compensatory and punitive damages where permitted by law.

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 train Plastic Surgeons on the safe and appropriate use of our breast 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.

If we are unable to continue to enhance our existing product offerings 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 may involve additional clinical trials 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.

Laws impacting the U.S. healthcare system are subject to a great deal of uncertainty, which may result in adverse consequences to our business.

There have been a number of legislative and regulatory proposals to change the healthcare system, reduce the costs of healthcare and change medical reimbursement policies. Doctors, clinics, hospitals and other users of our products may decline to purchase our products to the extent there is uncertainty regarding coverage from government or commercial

payors. Further proposed legislation, regulation and policy changes affecting third-party reimbursement are likely. Among other things, Congress has in the past proposed changes to and the repeal of the Patient Protection and Affordable Care and Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the Affordable Care Act), and lawsuits have been brought challenging aspects of the law at various points. There have been repeated attempts by Congress to repeal or replace the Affordable Care Act, or ACA. Some of the provisions of the ACA have yet to be implemented, and there have been legal and political challenges to certain aspects of the ACA. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal and replace all or part of the ACA. While Congress has previously been successful at

passing comprehensive repeal legislation through both Chambers of Congress, it had then been vetoed by former President Obama; however full repeal legislation is unlikely in the current political climate. Furthermore, the Tax Cuts and Jobs Act passed in December of 2017 included a provision that would repeal one of the primary pillars of the law, the ACA's individual mandate penalty that essentially assessed a monetary penalty or fine on certain individuals who fail to maintain qualifying health coverage for all or part of a year. Congress may consider other legislation to repeal or replace elements of the ACA on a provision-by-provision basis. We are unable to predict what legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future at the state or federal level, or what effect such legislation or regulation may have on us. Denial of coverage and reimbursement of our products, or the revocation or changes to coverage and reimbursement policies, could have a material adverse effect on our business, results of operations and financial condition. More recently, the United States District Court for the Northern District of Texas struck down the ACA, deeming it unconstitutional given that Congress repealed the individual mandate in 2017. This decision has been stayed pending outcome of an appeal to the Fifth Circuit Court of Appeals. Although there is no immediate impact on the ACA, we will continue to evaluate the effect that the ACA and its possible repeal and replacement, or potential total revocation by the Supreme Court of the United States, has on our business. Financial arrangements and incentives that may impact healthcare decision-making continue to be a subject of attention for Congress and health regulators. For example, the federal Eliminating Kickbacks in Recovery Act of 2018 (EKRA) notably in some instances (relating to recovery centers, clinical treatment facilities, and clinical laboratories) applies to services payable by commercial insurers and self-pay patients, as opposed to only services for which payment is available from government payors.

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

We are subject to the risks arising from adverse changes in general economic and market conditions, or political actions including new or increased trade protection policies such as tariffs, particularly in China, where certain of our miraDry products are manufactured. Certain elective procedures, such as breast augmentation, are typically not covered by insurance. Adverse changes in the economy or a "trade war" may cause consumers to reassess their spending choices and reduce the demand for these surgeries and other procedures and could have an adverse effect on consumer spending. This shift could have an adverse effect on our net sales and profitability. 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.

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

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

We 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 the substantial inventory levels we like to maintain, we are subject to the risk that a

substantial portion of our inventory becomes obsolete. The materialization of any of these risks may have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory. Additionally, our ability to find an alternate supplier in a timely manner, may affect our ability to maintain the level of inventory supply we require to protect ourselves from supply interruptions that could have an unfavorable impact on our net sales.

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

Our principal offices are located in Santa Barbara, California. Substantially all of our operations are conducted at this location, including customer service, development and management and administrative functions. Substantially all of our inventory of Breast Products is held at a second location in Santa Barbara, California, and we manufacture, distribute, and service our miraDry Systems at a third location in Santa Clara, 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.

Cyberattacks and other security breaches could compromise our proprietary information which could harm our business and reputation.

In the ordinary course of our business, we generate, collect and store proprietary information, including intellectual property and business information. The secure storage, maintenance, and transmission of and access to this information is critical to our operations, business strategy, and reputation. Computer hackers may attempt to penetrate our computer systems or our third party IT service providers' systems and, if successful, misappropriate our proprietary information. In addition, an employee, contractor, or other third-party with whom we do business may attempt to circumvent our security measures in order to obtain such information, and may purposefully or inadvertently cause a breach involving such information. While we will continue to implement additional protective measures to reduce the risk of and detect cyberattacks, these incidents are becoming more sophisticated and frequent, and the techniques used in such attacks evolve rapidly and are difficult to detect. Despite our cybersecurity measures, our information technology networks and infrastructure may still be vulnerable to unpermitted access by hackers or other breaches, or employee error or malfeasance. Any such compromise of our, or our third party IT service providers' data security and access to, or public disclosure or loss of, confidential business or proprietary intellectual property information could disrupt our operations, damage our reputation, provide our competitors with valuable information, and subject us to additional costs which could adversely affect our business.

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 certain other facilities are located in Santa Barbara, California, which in the past has experienced both severe earthquakes and wildfires. 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 could have a material adverse effect on our business.

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

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

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

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

We are dependent upon the continued services of key personnel, including members of our executive management team who have extensive experience in our industry. The loss of any one of these individuals could disrupt our operations or our strategic plans. Additionally, our future success will depend on, among other things, our ability to continue to hire and retain the necessary qualified sales, marketing and managerial personnel, for whom we compete with numerous other companies, academic institutions and organizations. If we lose key employees, if we are unable to attract or retain other qualified personnel, or if our management team is not able to effectively manage us through these events, our business, financial condition, and results of operations may be adversely affected.

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

As of December 31, 2018, we had approximately 259 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 are subject to political, economic and regulatory risks associated with doing business outside of the United States.

As a result of our acquisition of miraDry, we face new risks inherent in conducting business internationally, including compliance with international and U.S. laws and regulations that apply to international operations. We are able to market and sell the miraDry System in over 40 international markets outside of North America, including countries in Asia, Europe, the Middle East and South America. In addition, we may seek to market and sell the miraDry System in

additional countries, as well as seek approval to market and sell our breast products in international markets, in the future. These laws, regulations policies and standards are complex, and there is a risk that some provisions may be breached by us, for example through fraudulent or negligent behavior of individual employees, our failure to comply with certain formal documentation requirements, or otherwise. Compliance with existing laws, regulations, policies and standards, the adoption of new laws, regulations, policies or standards, changes in the interpretation of existing laws, regulations, policies or standards, changes in the regulation of our

activities by a government or standards body and/or rulings in court, regulatory, administrative or other proceedings relating to such laws, regulations, policies or standards, including, among others, those affecting manufacturing practices, competitive business practices, the use of our products, protection of intellectual property, trade and trade protection, including tariffs, foreign currency, investments or loans, taxation, export control, privacy and data protection, environmental protection, health and safety, labor and employment, human rights, corporate governance, public disclosure or business conduct could have an adverse effect on our business and results of operations.

Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, requirements to obtain export licenses, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, our business and our operating results.

International trade disputes could result in tariffs and other protectionist measures that could adversely affect the Company's business. Tariffs could increase the cost of the Company's products and raw materials that go into making them. These increased costs could adversely impact the gross margin that the Company earns on its products. Tariffs could also make the Company's products more expensive for customers, which could make the Company's products less competitive and reduce consumer demand. Countries may also adopt other protectionist measures that could limit the Company's ability to offer its products and services. Political uncertainty surrounding international trade disputes and protectionist measures could also have a negative effect on consumer confidence and spending, which could adversely affect the Company's business.

In addition to the foregoing, engaging in international business inherently involves a number of other difficulties and risks, including:

- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability or sanctions in areas in which we operate;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;
- regulations related to customs and import/export matters;
- tax issues, including tax law changes and compliance with other tax laws;
- compliance with complex transfer pricing regulations administered by taxing authorities in various jurisdictions resulting from our intercompany arrangements, if any;
- complying with laws, rules and regulations relating to the manufacturing, marketing, distribution and sale of products in the jurisdictions in which we do or will operate;
- operating under regulations in jurisdictions related to obtaining eligibility for government or private payor reimbursement for our products at the wholesale/retail level;
- difficulties and costs of staffing and managing foreign operations, including cultural and language differences and additional employment regulations, union workforce negotiations and potential disputes in the jurisdictions in which we operate;
- difficulties associated with compliance with a variety of laws and regulations governing international trade, including the Foreign Corrupt Practices Act;
- difficulties protecting or procuring intellectual property rights; and
- fluctuations in foreign currency exchange rates.

These factors or any combination of these factors could have a material adverse effect on our results of operations and financial condition.

Risks Related to Our Financial Results

Our debt obligations could impair our financial condition and limit our operating flexibility.

Our indebtedness under our credit agreements with MidCap Financial Trust, or the Credit Agreements, and our other financial obligations could:

- impair our ability to obtain financing or additional debt in the future for working capital, capital expenditures, acquisitions or general corporate purposes;
- impair our ability to access capital and credit markets on terms that are favorable to us;
- have a material adverse effect on us if we fail to comply with financial and affirmative and restrictive covenants in our Credit Agreements and an event of default occurs as a result of a failure that is not cured or waived;
- require us to dedicate a portion of our cash flow for interest payments on our indebtedness and other financial obligations, thereby reducing the availability of our cash flow to fund working capital and capital expenditures; and
- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate.

There is no guarantee that we will be able to pay the principal and interest under the Credit Agreements or that future working capital, borrowings or equity financing will be available to repay or refinance any amounts outstanding under the Credit Agreements. Our obligations under the Credit Agreements are secured by a perfected security interest in all of our tangible and intangible assets (including our intellectual property assets), except for certain customary excluded property and all of our and our subsidiaries capital stock, with certain limited exceptions. 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 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 availability of any alternative manufacturing sources to supply our silicone gel breast implants and certain other products;
- our ability to integrate and achieve the anticipated benefits of our acquisitions of miraDry, BIOCORNEUM and our tissue expander portfolio;
- the impact of the buying patterns of patients and seasonal cycles in consumer spending;
- our ability to drive increased sales of breast implant products, miraDry Systems and bioTips;
- our ability to establish and maintain an effective and dedicated sales organization;

- pricing pressure applicable to our products, including adverse third-party coverage and reimbursement outcomes;
- results of clinical research and trials on our existing products;
- the impact of the past regulatory inquiries of Silimed on our brand and reputation;
- timing of our research and development activities and initiatives;
- the mix of our products sold due to different profit margins among our products and sales channels;
- 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.

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

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

As of December 31, 2018, we had federal net operating loss carryforwards, or NOLs, of approximately $305 million available to reduce future taxable income, which begin expiring in 2027, if not utilized to offset taxable income. In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. In general, an “ownership change” occurs if there is a cumulative change in our ownership by “5% shareholders” that exceeds 50 percentage points over a rolling three-year period. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we undergo one or more ownership changes in connection with future transactions in our stock, our ability to utilize NOLs could be further limited by Section 382 of the Code. In addition, the deduction for NOLs generated after 2017 is limited to 80% of our taxable income. As a result of these limitations, we may not be able to utilize a material portion of the NOLs reflected on our consolidated balance sheet. Our deferred tax assets for net operating loss carryforwards have been offset by a full valuation allowance in our financial statements.

If the goodwill we have recorded in connection with acquisitions become impaired, our earnings and capital could be reduced.

In accordance with GAAP, we record assets acquired and liabilities assumed at their fair value with the excess of the purchase consideration over the net assets acquired resulting in the recognition of goodwill. As a result, acquisitions, such as our acquisition of miraDry, typically result in recording goodwill. We perform a goodwill evaluation at least annually to test for goodwill impairment. As part of our testing, we first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If we determine the fair value of a reporting unit is less than its carrying amount using these qualitative factors, we then compare the fair value of goodwill with its carrying amount to measure any impairment loss. Adverse changes in our business, including a deviation from our expected growth rate and performance, a significant decline in future operating cash flows, or a significant change in our stock price or market capitalization may significantly affect the fair value of our goodwill and may trigger additional impairment losses, which could be materially adverse to our operating results and financial position. For example, if future operating performance of our miraDry segment was to fall below our current expectations, we could be required to recognize a non-cash charge to operating earnings to impair the related goodwill or other intangible assets.

We cannot provide assurance that we will not be required to take an impairment charge in the future. Any impairment charge would have an adverse effect on our results of stockholders' equity and financial results and could cause a decline in our stock price.

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.

Our results of operations and financial position could be negatively impacted if there are adverse changes in tax laws and regulations.

We could be adversely affected in the future by changes in applicable tax laws, regulations, or administrative interpretations thereof. On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act, which provides for significant changes in the U.S. Internal Revenue Code of 1986, as amended. The Tax Cuts and Jobs Act contains provisions with separate effective dates but is generally effective for taxable years beginning after December 31, 2017. This change to the U.S. tax system, as well as a change to the tax system in a jurisdiction where we have significant operations, or a change in tax law in other jurisdictions where we do business, could have a material and adverse effect on our business and on the results of our operations. We expect that the ultimate impact of the Tax Cuts and Jobs Act on our reported results in 2018 and beyond will not be material. However, the actual impact of the Tax Cuts and Jobs Act may differ from our expectations and estimates, possibly materially, due to, among other things, changes in interpretations and assumptions we have made, guidance that may be issued, and other actions we may take as a result of the Tax Cuts and Jobs Act different from that presently contemplated.

Risks Related to Our Intellectual Property and Potential Litigation

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

Our success depends in part on our ability to protect our intellectual property rights. We rely on a combination of trademarks, trade secrets, confidential information, copyrights, patent rights and other intellectual property rights to protect our intellectual property. In addition, to protect our trade secrets, confidential information and other intellectual property rights, we have entered into confidentiality agreements with third parties, and confidential information and invention assignment agreements with employees, consultants and advisors. However, these agreements may not provide sufficient protection or adequate remedies for violation of our rights in the event of

unauthorized use or disclosure of confidential and proprietary information. Without additional protection under the patent or other intellectual property laws, such unauthorized use or disclosure may enable competitors to duplicate or surpass our technological achievements. Moreover, the laws of certain foreign countries do not recognize intellectual property rights or protect them to the same extent as do the laws of the United States. Failure to protect our proprietary rights could seriously impair our competitive position.

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

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

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

Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, negatively impact shareholder value and harm our reputation. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages (which may be increased up to three times of awarded damages) and/or substantial royalties and could be prevented from selling our products unless we obtain a license or

are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations and financial condition.

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

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

As a supplier of medical devices, we are and may be subject to warranty or product liability claims alleging that the use of our products has resulted in adverse health effects or other litigation in the ordinary course of business that may require us to make significant expenditures to defend these claims or pay damage awards. The breast implant industry has a particularly significant history of product liability litigation. The risks of litigation exist even with respect to products that have received or in the future may receive regulatory approval for commercial sale, such as our Breast Products. In addition, historically our silicone gel breast implants were 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 ten years of implantation. In April 2018, we announced our Platinum20 product replacement and limited warranty program, which we believe provides an industry-leading program of no-charge replacement implants for covered rupture events that occur during the lifetime of the patient, and no-charge replacement implants for other covered events that occur within twenty years of the implant procedure, as well as financial assistance for certain qualifying events that occur within twenty years of the implant procedure. If we experience an increase in warranty claims following the launch of our Platinum20 warranty in excess of our expectations, or if our replacement costs associated with warranty claims increase significantly, we will incur liabilities for potential warranty claims that may be greater than we expect. An increase in the frequency of warranty claims or amount of warranty costs may harm our reputation and could have a material

adverse effect on our business, results of operations and financial condition.

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

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

We hold a number of insurance policies, including product liability insurance, directors' and officers' liability insurance, general liability insurance, property insurance, employment practices, cyber, 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 healthcare regulation, and if we fail to comply with applicable regulations, we could suffer severe criminal or civil sanctions or be required to restructure our operations, any of which could adversely affect our business, financial condition and operating results.

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

- the federal Anti-Kickback Statute, which applies to our business activities, including our marketing practices, educational programs, pricing policies and relationships with healthcare providers, by prohibiting, among other things, knowingly and willfully soliciting, receiving, offering or providing any remuneration (including any bribe, kickback or rebate) directly or indirectly, overtly or covertly, in cash or in kind, intended to induce or in return for the purchase or recommendation of any good, facility, item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare or Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to commit a violation. Rather, if "one purpose" of the remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. In addition, following passage of the PPACA violations of the federal Anti-Kickback Statute became per se violations of the False Claims Act;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government payors that are false or fraudulent, or making a false statement to decrease or conceal an obligation to pay or transmit money or property to the federal government, and which may apply to entities that provide coding and billing advice to customers;
- HIPAA, and its implementing regulations, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by HITECH, also imposes certain regulatory and contractual requirements on certain types of people and entities subject to the law and their business associates regarding the privacy, security, breach reporting and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act, enacted under the PPACA, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to make annual reports to the Centers for Medicare & Medicaid Services, or CMS, regarding any "transfers of value" provided to physicians and teaching hospitals. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an additional aggregate of $1 million per year for "knowing failures," for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission. We are required to report detailed payment data and submit legal attestation to the accuracy of such data by March 31st of each calendar year; additionally, on October 25, 2018, President Trump signed into law the "Substance Use-Disorder Prevention that Promoted Opioid Recovery and Treatment for Patients and Communities Act" which in part (under a provision entitled "Fighting the Opioid Epidemic with Sunshine") extends the reporting and transparency requirements for physicians in the Physician Payments Sunshine Act to physician assistants, nurse practitioners, and other mid-level practitioners (with reporting requirements going into effect in 2022 for payments made in 2021).
- 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 and may receive stock awards as compensation for services provided, could be subject to challenge under one or more of such laws. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and/or criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, exclusion from governmental health care programs, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

We recently settled a securities class action lawsuit and have reached a settlement agreement with the SEC. If we are subject to additional claims, our insurance may not be sufficient to cover additional expenses incurred.

In May 2017, we settled a class action lawsuit which named the Company and certain of its officers as defendants for allegedly false and misleading statements concerning the Company's business, operations, and prospects in connection with the Company's September 2015 common stock offering, or the 2015 offering. In connection with the settlement, we received $9.3 million in insurance proceeds to pay the settlement amount.

In March 2018, we reached an agreement-in-principle with the Staff of the Division of Enforcement, or the Staff, of the SEC to settle, without admitting or denying, charges arising out of the SEC's investigation into alleged false and misleading statements or omissions made in connection with the 2015 offering. Those charges include alleged violations of Section 10 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Rule 10b-5 promulgated thereunder, and Sections 17(a)(1)-(3) of the Securities Act. On September 19, 2018, the SEC issued an order approving the terms of the settlement agreement.

We may, in the future, be subject to regulatory claims, including claims for violations of the federal securities laws, rules and regulations relating to our 2015 offering, and may also need to defend claims against our current or former directors and officers. If that occurs, we may be required to pay a monetary settlement or judgment and we may not have sufficient insurance coverage remaining to cover the costs of any such claims or any related potential indemnification obligations to our current or former directors and officers. Moreover, even if these claims against us are not successful, the defense of such claims could result in substantial costs and significant adverse impact on our reputation and divert management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

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

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

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

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

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

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

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory authority. The FDA or other regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or other regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be

jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or other regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

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. We completed and submitted the Final Report to FDA for our 10-year pivotal study in March 2018. Clinical data is ongoing for our second or "new enrollment" post-approval study. Failure to conduct 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;
- withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products; and/or
- in the most serious cases, criminal penalties.

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

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

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

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;

- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or pre-market approval of new products or modified products;
- withdrawing 510(k) clearances or pre-market approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

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

Our ability to market the miraDry System in the United States is limited to the treatment of sweat, odor and hair in the underarm, and if we want to expand our marketing claims, we will need to obtain additional FDA clearances or approvals, which may not be granted.

We currently only have FDA clearance to market the miraDry System in the United States for the treatment of primary hyperhidrosis of the axilla, or the underarm, and for permanent hair reduction procedures in the axilla. This clearance restricts our ability to market or advertise the miraDry System for other specific body areas, and other conditions, which could limit physician adoption and patient demand for the miraDry System. We believe that future applications using the miraDry System could be used to treat other body areas, such as the feet and hands, where patients experience sweat-bothered symptoms. Developing and promoting these new treatment applications for our miraDry System is an element of our growth strategy, but we cannot predict when or if we will receive the clearances required to implement these additional products and applications. In addition, we will be required to conduct additional clinical trials or studies to support our applications, which may be time-consuming and expensive, and may produce results that do not result in submission of, or FDA clearances for, new treatment applications. In the event that we do not obtain additional FDA clearances, our ability to promote the miraDry System in the United States will be limited. Because we anticipate that sales in the United States will continue to be a significant portion of our business for the foreseeable future, ongoing restrictions on our ability to market the miraDry System in the United States could harm our business and limit our net sales growth.

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

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

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

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

In the United States, our silicone gel breast implants are marketed pursuant to a PMA order issued by the FDA in March 2012, and our tissue expanders and miraDry System 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. For example, on March 14, 2017, we announced that we had submitted a PMA supplement to the FDA for the manufacturing of our PMA-approved breast implants by Vesta for which we received final approval on April 17, 2018. Certain changes to a PMA-approved device do not require submission and approval of a new PMA or PMA supplement and may only require notice to FDA in a PMA 30-Day Notice, Special PMA Supplement – Changes Being Effected or PMA Annual Report. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have modified some of our 510(k) cleared products, and have determined based on our review of the applicable FDA guidance that in certain instances the changes did not require new 510(k) clearances or PMA approvals. If the FDA disagrees with our determination and requires us to seek new 510(k) clearances or PMA approvals for modifications to our previously cleared or approved products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. Furthermore, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. Delays in receipt or failure to receive approvals, the loss of previously received approvals, or the failure to comply with any other existing or future regulatory requirements, could reduce our sales, profitability and future growth prospects.

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

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious injury or death. Manufacturers may also, under their own initiative, recall a product if any material deficiency in a device is found or withdraw a product to improve device performance or for other reasons. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Similar regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert management attention and financial resources and could cause the price of our stock to decline, expose us to product liability or other claims and harm our reputation with customers. Such events could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. A recall involving our silicone gel breast implants could be particularly harmful to our business, financial and operating results. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA or similar foreign governmental authorities. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA or foreign governmental authorities. If the FDA or foreign governmental authorities disagree with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers

and negatively affect our sales. In addition, the FDA or a foreign governmental authority could take enforcement action for failing to report the recalls when they were conducted.

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

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

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

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

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

Our educational and promotional activities and training methods must comply with FDA and other applicable laws, including the prohibition of the promotion of a medical device for a use that has not been cleared or approved by the FDA. Use of a device outside of its cleared or approved indications is known as "off-label" use. Physicians may use our products off-label in their professional medical judgment, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our educational and promotional activities or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of warning letters, untitled letters, fines, penalties, injunctions, or seizures, which could have an adverse impact on our reputation and financial results. It is also possible that other federal, state or foreign enforcement authorities may take action if they consider our educational and promotional activities or training methods to constitute promotion of an off-label

use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products could be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. It is also possible that other federal, state or foreign enforcement authorities might take action, such as federal prosecution under the federal civil False Claims Act, if they consider

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

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

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

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

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

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

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

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

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 of our products, any of which could have a material adverse effect on our business, results of operations and financial condition.

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

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

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

We are not currently directly subject to 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 receive confidential and personal information from our customers which may be directly subject to HIPAA. We also occasionally encounter hospital customers that require 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 private litigation, and any resulting liability could adversely affect our financial condition.

In addition, even when HIPAA does not apply, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the FTCA, 15 U.S.C. § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

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 and private litigation. For example, California recently enacted legislation – the California Consumer Privacy Act, or CCPA, which goes into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Legislators have stated that they intend to propose amendments to the CCPA before it goes into effect, and the California Attorney General will issue clarifying regulations. Although the law includes limited exceptions, including for certain information collected as part of clinical trials as specified in the law, it may regulate or impact our processing of personal information depending on the context. It remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted.

An adverse outcome of a sales and use tax or value-added tax (VAT) 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 also sell internationally and some sales may be subject to value-added tax. We may be audited by the taxing authorities of one or more jurisdictions 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. In recent years, the stock markets generally have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors may significantly affect the market price of our common stock, regardless of our actual operating performance.

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

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

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

As of March 4, 2019, our executive officers, directors and principal stockholders beneficially owned approximately 23% of our outstanding voting stock. As a result, these stockholders have the ability to influence us through their ownership position and may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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

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

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

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

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

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

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

For as long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to utilize the provision exempting us from the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting. The process of becoming fully compliant with Section 404 may divert internal resources and will take a significant amount of time and effort to complete, and may result in additional deficiencies and material weaknesses being identified by us or our independent registered public accounting firm. We may experience higher than anticipated operating expenses, as well as increased independent

registered public accounting firm fees during the implementation of any required changes and thereafter. Completing documentation of our internal control system and financial processes,

remediation of control deficiencies and management testing of internal controls will require substantial effort by us. If our internal control over financial reporting or our related disclosure controls and procedures are not effective, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that our officers, directors or the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock.

Certain holders of shares of our common stock are entitled to certain rights, subject to some conditions, with respect to the registration of their shares under the Securities Act.

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

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

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock. Information regarding our equity securities is provided in this Annual Report in “Notes to Consolidated Financial Statements, Note 9.”

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

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

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;

- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;

- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

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

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

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

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our headquarters located in Santa Barbara, California is approximately 20,000 square feet. The term of the lease for our headquarters expires in February 2020. We also lease warehouse spaces located in Santa Barbara, California, which is approximately 10,000 square feet, and a space used for research and development in Carpinteria, California, which is approximately 5,000 square feet. These leases terms expire in January 2022 and December 2021, respectively. 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.

Our miraDry facilities are located in Santa Clara, California, where we lease and occupy approximately 29,000 square feet of office, manufacturing and research and development space. The current term of our Santa Clara lease expires in July 2024.

Item 3. Legal Proceedings

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

certain legal proceedings is provided in this Annual Report in “Notes to Consolidated Financial Statements, Note 11(b).”

SEC Settlement

In March 2018, we reached an Agreement-in-Principle, or the Agreement-in-Principle, with the Staff of the Division of Enforcement, or the Staff, of the U.S. Securities and Exchange Commission, or the SEC, to settle, without admitting or denying, charges arising out of the SEC's investigation into alleged false and misleading statements or omissions made in connection with its follow-on public offering, or the Offering, that closed on September 23, 2015. Those charges include alleged violations of Section 10 of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder, and Sections 17(a)(1)-(3) of the Securities Act of 1933, as amended. The Staff previously informed the Company on March 1, 2018 that it was considering bringing charges against the Company related to the Offering.

On September 19, 2018, the SEC issued an order, or the Order, approving the terms of the Agreement-in-Principle and fully and finally disposes of the investigation of the Company by the SEC without any monetary component as previously disclosed. It also contains an order prohibiting future violations of the securities laws.

Neither the Company nor any current officers or directors admitted or denied or were required to admit or deny the allegations. The SEC does not allege that either the Company or any current officers or directors acted with an intent to deceive investors.

Item 4. Mine Safety Disclosures

Not applicable.

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.

Holders of Record

As of March 4, 2019 there were approximately 14 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. In addition, our ability to pay dividends is currently restricted by the terms of our credit agreements with MidCap Financial Trust.

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.

Sales of Unregistered Securities

None.

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, 2018.

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, 2018, 2017 and 2016 and as of December 31, 2018 and 2017 from our financial statements, which are included elsewhere in this Annual Report on Form 10 K. The consolidated statement of operations data for the years ended December 31, 2015 and 2014, and the consolidated balance sheet data as of December 31, 2016, 2015 and 2014, were derived from the audited financial statements that are not included in this Annual Report on Form 10-K. Historical results are not necessarily indicative of the results to be expected in future periods.

	Year Ended December 31,				
	2018	2017	2016	2015	2014
Statement of operations data					
Net sales	$68,126	$36,542	$20,734	$38,106	$44,733
Gross profit	41,304	22,371	13,854	27,452	33,233
Net loss	(82,627)	(64,028)	(40,166)	(41,230)	(5,811)
Net loss per share					
Basic and diluted	$(3.25)	$(3.34)	$(2.20)	$(2.61)	$(2.28)
Weighted average shares					
Basic and diluted	25,402,241	19,159,057	18,233,177	15,770,972	2,545,371

	As of December 31,				
	2018	2017	2016	2015	2014
Balance sheet data					
Working capital	$71,982	$5,218	$72,484	$118,609	$103,151
Total assets	168,359	92,213	114,283	140,805	139,078
Long-term debt, excluding current position	27,883	—	—	—	21,671
Stockholders' equity	66,878	27,623	83,617	118,871	95,639

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

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

Overview

We are a medical aesthetics company committed to making a difference in patients' lives by enhancing their body image, growing their self esteem and restoring their confidence. We were founded to provide greater choices to board certified plastic surgeons and patients in need of medical aesthetics products. We have developed a broad portfolio of products with technologically differentiated characteristics, supported by independent laboratory testing and strong clinical trial outcomes. We sell our breast implants and breast tissue expanders, or Breast Products, exclusively to board certified and board admissible plastic surgeons and tailor our customer service offerings to their specific needs, which we believe helps secure their loyalty and confidence.

On June 11, 2017, we entered into a Merger Agreement with miraDry (formerly Miramar Labs) pursuant to which we commenced a tender offer to purchase all of the outstanding shares of miraDry's common stock. Pursuant to the transaction, which closed on July 25, 2017 we added the miraDry System, the only FDA cleared device to reduce underarm sweat, odor and hair of all colors to our aesthetics portfolio. Following our acquisition of miraDry in July 2017, we began selling the miraDry System and bioTips. As a result of the miraDry acquisition, we determined that we will conduct our business in two operating segments: Breast Products and miraDry. The Breast Products segment focuses on sales of our breast implants, tissue expanders and scar management products under the brands Sientra, AlloX2, Dermaspan, Softspan and BIOCORNEUM. The miraDry segment focuses on sales of the miraDry System, consisting of a console and a handheld device which uses consumable single-use bioTips.

We sell both our Breast Products and miraDry products in the U.S. through a direct sales organization, which as of December 31, 2018, consisted of 103 employees, including 86 sales representatives and 17 sales managers. Additionally, we also sell our miraDry System in several international markets where we leverage a combination of distributor relationships and direct sales efforts. As of December 31, 2018, our international operations were supported by 6 sales representatives, as well as a number of consultants supporting both direct sales efforts and distributer relationships.

Breast Products Segment

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

Our breast implants were approved by the FDA in 2012, based on data we collected from our long term clinical trial of our breast implants in 1,788 women across 36 investigational sites in the United States, which included 3,506 implants (approximately 53% of which were smooth and 47% of which were textured). Our clinical trial is the largest prospective, long term safety and effectiveness pivotal study of breast implants in the United States and includes the largest magnetic resonance imaging, or MRI, cohort with 571 patients. The MRI cohort is a subset of study patients that underwent regular MRI screenings in addition to the other aspects of the clinical trial protocol prior to FDA approval. Post-approval, all patients in the long-term clinical trial are subject to serial MRI screenings as part of the clinical protocol. The clinical data we collected over a ten year follow up period demonstrated rupture

rates, capsular contracture rates and reoperation rates that were comparable to or better than those of our competitors, at similar time points. In addition to our pivotal study, our clinical data is supported by our Continued Access Study of 2,497 women in the United States. We have also commissioned a number of bench studies run by independent laboratories that we believe further demonstrate the advantages of our breast implants over those of our competitors.

On August 9, 2016, we announced our collaboration with Vesta Intermediate Funding, Inc., or Vesta, a Lubrizol Lifesciences company, pursuant to which we worked with Vesta to establish a dedicated manufacturing facility for our breast implants. On March 14, 2017, we announced that we had executed a definitive manufacturing agreement with Vesta for the manufacture and supply of our breast implants and that we had submitted a site-change pre-market approval, or PMA, supplement to the FDA for the manufacturing of our PMA-approved breast implants by Vesta. Vesta began manufacturing our breast products in October 2017 in order to build our inventory pending FDA approval of the PMA supplement. On January 30, 2018, we announced that the FDA granted approval of the PMA supplement for our contract manufacturer, Vesta, to manufacture our silicone gel breast implants. In support of the move to the Vesta manufacturing facility, we also implemented new manufacturing process improvements which, in consultation with the FDA, required three (3) additional submissions. These submissions were approved by the FDA on January 10, 2018, January 19, 2018 and April 17, 2018. With these latest approvals, we re-launched our breast implant business in April 2018 and intend to continue to scale implant supply.

In addition, we offer BIOCORNEUM, an advanced silicone scar treatment, directly to physicians and the AlloX2, and Dermaspan lines of breast tissue expanders, as well as the Softspan line of general tissue expanders.

We sell our silicone gel breast implants and tissue expanders exclusively to Plastic Surgeons. We seek to provide Plastic Surgeons with differentiated services, including enhanced customer service offerings and a twenty year limited warranty that provides patients with 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 the industry’s first policy of no charge replacement implants to patients who experience covered capsular contracture, double capsule and late-forming seroma events within twenty years of the initial implant procedure.

miraDry Segment

In July 2017, we completed our acquisition of miraDry, following which we began selling the miraDry System, the only FDA cleared device to reduce underarm sweat, odor and hair of all colors through the precise and non-surgical delivery of microwave energy to the region where sweat glands reside. The energy generates heat at the dermal-fat interface which results in destruction of the sweat glands. At the same time, a continuous hydro-ceramic cooling system protects the superficial dermis and keeps the heat focused at the dermal-fat interface where the sweat glands reside. Because sweat glands do not regenerate after the procedure, we believe the results are lasting. Microwaves are the ideal technology as the energy can be focused directly at the dermal-fat interface where the glands reside.

The miraDry System has been cleared by the FDA as indicated for use in the treatment of primary axillary hyperhidrosis, or a condition characterized by abnormal sweating in excess of that required for regulation of body temperature, plus unwanted underarm hair removal, and permanent reduction of underarm hair of all colors for Fitzpatrick skin types I – IV. Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime. When used for the treatment of primary axillary hyperhidrosis, the miraDry System may reduce underarm odor. In addition, the miraDry System received CE mark approval for the treatment of primary axillary hyperhidrosis and approval in several other countries.

The miraDry System provides patients with a non-surgical and durable procedure to selectively destroy underarm sweat glands for both severely hyperhidrotic patients and those that are bothered by their underarm sweat. The

miraDry System is clinically proven to reduce sweat in one or more procedures of approximately 60-minutes, allowing most patients to achieve immediately noticeable and durable results without the pain, expense, downtime, or repeat visits associated with surgical and minimally-invasive procedures. The sweat glands in the treated area are destroyed through targeted heating of the tissue, and because the body does not regenerate sweat glands, we believe the results will be lasting, although some patients may need to repeat the miraDry procedure to achieve the lasting results.

The miraDry System consists of a console and a handheld device which uses consumable single-use bioTips. The miraDry procedure is not technique-dependent, does not require significant training or skill for the treatment provider, and the user-interface guides the provider through each step of the procedure for each treatment. We sell our miraDry System and consumable single-use bioTips only to physicians, consisting of dermatologists, plastic surgeons, aesthetic specialists and physicians specializing in the treatment of hyperhidrosis. Aesthetic specialists are physicians who elect to offer aesthetic procedures as a significant part of their practices but are generally not board-certified dermatologists or plastic surgeons. Physicians can market the miraDry procedure as a premium, highly-differentiated, non-surgical sweat reduction procedure. We are approved to sell the miraDry System in over 40 international markets outside of North America, including countries in Asia, Europe, the Middle East and South America.

Components of Operating Results

Net Sales

We recognize revenue on breast implants and tissue expanders, net of sales discounts and estimated returns, as the customer has a standard six-month window to return purchased breast implants and tissue expanders. Our Breast Products segment net sales include sales of silicone gel breast implants, tissue expanders and BIOCORNEUM. We defer the value of our service warranty revenue and recognize it once all performance obligations have been met. Net sales for our miraDry segment for the years ended December 2018 and 2017 include net sales of the miraDry System and consumable bioTips, as a result of the acquisition of miraDry on July 25, 2017.

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 and purchase of miraDry procedures. We believe that aesthetic procedures are subject to seasonal fluctuation due to patients planning their procedures leading up to the summer season and in the period around the winter holiday season.

Cost of Goods Sold and Gross Margin

Cost of goods sold consists primarily of costs of finished products purchased from our third party manufacturers, reserve for product assurance warranties, inventory fair market value adjustment, royalty costs, and warehouse and other related costs. With the acquisition of miraDry, cost of goods sold also consists of raw material, labor, overhead, and variable manufacturing costs associated with the manufacturing of the miraDry Systems and bioTips.

With respect to our supplier contracts, all our products and raw materials are manufactured under contracts with fixed unit costs.

We provide an assurance and service warranty on our silicone gel breast implants and a standard warranty on our miraDry Systems, handpieces and bioTips. The estimated warranty costs are recorded at the time of sale. Costs related to our service warranty are recorded when expense is incurred related to meeting our performance obligations. In addition, the inventory fair market value associated with purchase accounting adjustments and royalty costs related to both the SSP and miraDry acquisitions were recorded at the time of sale.

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

Sales and Marketing Expenses

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

Research and Development Expenses

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

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

General and Administrative Expenses

Our general and administrative, or G&A, expenses primarily consist of salaries, bonuses, benefits, incentive compensation and stock-based compensation for our executive, financial, legal, business development and administrative functions. Other G&A expenses include contingent consideration fair market value adjustments, outside legal counsel and litigation expenses, independent auditors and other outside consultants, corporate insurance, facilities and information technologies expenses.

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

Other Income (Expense), net

Other income (expense), net primarily consists of interest income, interest expense, changes in the fair value of common stock warrants and amortization of issuance costs associated with our Credit Agreements.

Income Taxes

Income tax expense consists of an estimate for income taxes based on the projected income tax expense for the year ended December 31, 2018. We operate in several tax jurisdictions and are subject to taxes in each jurisdiction in which we conduct business. To date, we have incurred cumulative net losses and maintain a full valuation allowance on our net deferred tax assets due to the uncertainty surrounding realization of such assets. However, as a result of the BIOCORNEUM and tissue expander portfolio acquisitions, we have deferred tax liabilities associated with indefinite-lived intangible assets that cannot be considered sources of income to support the realization of the deferred tax assets. The end result is a tax expense which is reduced by the indefinite life benefits of IRC section 163(j), NOL carryovers, and CA R&D Credits that can be used within the applicable limitations.

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 the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

We generate revenue primarily through the sale and delivery of promised goods or services to customers and recognize revenue when control is transferred to customers, in an amount that reflects the consideration we expect to be entitled to in exchange for the goods or services. Performance obligations typically include the delivery of promised products, such as breast implants, tissue expanders, BIOCORNEUM, miraDry Systems and bioTips, along with service-type warranties and deliverables under certain marketing programs. Other deliverables are sometimes promised, but are ancillary and insignificant in the context of the contract as a whole. Sales prices are documented in the executed sales contract, purchase order or order acknowledgement prior to the transfer of control to the customer. Customers may enter into a separate extended service agreement to purchase an extended warranty for miraDry products from us whereby the payment is due at the inception of the agreement. Typical payment terms are 30 days for Breast Products and direct sales of consumable miraDry products, and tend to be longer for capital sales of miraDry Systems and sales to miraDry distributors, but do not extend beyond one year. For delivery of promised products, control transfers and revenue is recognized upon shipment, unless the contractual arrangement requires transfer of control when products reach their destination, for which revenue is recognized once the product arrives at its destination. Revenue for extended service agreements are recognized ratably over the term of the agreements.

We announced our Platinum20 Limited Warranty Program, or Platinum20, in April 2018 on all OPUS breast implants implanted in the United States or Puerto Rico on or after May 1, 2018. Platinum20 provides for financial assistance for revision surgeries and no-charge contralateral replacement implants upon the occurrence of certain qualifying events. We consider Platinum20 to have an assurance warranty component and a service warranty component. The assurance component is recorded as a warranty liability at the time of sale. We consider the service warranty component as an additional performance obligation and defer revenue at the time of sale based on the relative estimated selling price, by estimating a standalone selling price using the expected cost plus margin approach for the performance obligation. Inputs into the expected cost plus margin approach include historical incidence rates, estimated replacement costs, estimated financial assistance payouts and an estimated margin. The liability for unsatisfied performance obligations under the service warranty as of December 31, 2018, was $0.5 million, of which $0.2 million is considered a short-term obligation and is included in “accrued and other current liabilities” and $0.3 million is considered a long-term obligation and is included in “warranty reserve and other long-term liabilities” on the consolidated balance sheet. The performance obligation is satisfied at the time that Platinum20 benefits are provided and are expected to be satisfied over the following 6 to 24 month period for financial assistance and 20 years for product replacement. Revenue recognized for the service warranty performance obligations for the year ended December 31, 2018 was immaterial.

We also leverage a distributor network for selling the miraDry System internationally. We recognize revenue when control of the goods or services is transferred to the distributors. Standard terms in these agreements do not allow for trial periods, right of return, refunds, payment contingent on obtaining financing or other terms that could impact the customer’s payment obligation. Contract liabilities are included in “accrued and other current liabilities” in the consolidated balance sheet.

A portion of our revenue is generated from the sale of consigned inventory of breast implants maintained at doctor, hospital, and clinic locations. For these products, revenue is recognized at the time we are notified by the customer that the product has been implanted, not when the consigned products are delivered to the customer’s location.

For Breast Products, with the exception of the Company's BIOCORNEUM scar management products, we allow for the return of products from customers within six months after the original sale, which is accounted for as variable consideration. Reserves are established for anticipated sales returns based on the expected amount calculated with historical experience, recent gross sales and any notification of pending returns. The estimated sales return is recorded as a reduction of revenue and as a sales return liability in the same period revenue is recognized. 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. We have established an allowance for sales returns of $6.0 million and $3.9 million as of December 31,

2018 and December 31, 2017, respectively, recorded as “sales return liability” on the consolidated balance sheet under Topic 606 as of December 31, 2018 and recorded in “accounts receivable, net of allowances,” at December 31, 2017 on the consolidated balance sheet.

Arrangements with Multiple Performance Obligations

We have determined that the delivery of each unit of product in the our revenue contracts with customers is a separate performance obligation. Our revenue contracts may include multiple products or services, each of which is considered a separate performance obligation. For such arrangements, we allocate revenue to each performance obligation based on its relative standalone selling price. We generally determine standalone selling prices based on observable prices or using an expected cost plus margin approach when an observable price is not available. We invoice customers once products are shipped or delivered to customers depending on the negotiated shipping terms.

We defer the value of the service warranty revenue and recognize it once the performance obligations have been met.

Practical Expedients and Policy Election

We generally expense sales commissions when incurred because the amortization period would have been one year or less. These costs are recorded within sales and marketing expenses.

We do not adjust accounts receivable for the effects of any significant financing components as customer payment terms are shorter than one year.

We have elected to account for shipping and handling activities performed after a customer obtains control of the products as activities to fulfill the promise to transfer the products to the customer. Shipping and handling activities are largely provided to customers free of charge for the Breast Products segment. The associated costs were $1.3 million, $0.9 million and $0.6 million for the years ended December 31, 2018, 2017 and 2016, respectively. These costs are viewed as part of our marketing programs and are recorded as a component of sales and marketing expense in the consolidated statement of operations as an accounting policy election. For the miraDry segment, shipping and handling charges are typically billed to customers and recorded as revenue. The shipping and handling costs incurred are recorded as a component of cost of goods sold in the consolidated statement of operations. The associated costs were $0.4 million, and $35,000 for the years ended December 31, 2018 and 2017 from the acquisition date of July 25, 2017, respectively.

Goodwill Impairment Testing

Goodwill represents the excess of the purchase price over the fair value of net assets of purchased businesses. Goodwill is not amortized, but instead subject to impairment tests on at least an annual basis and whenever circumstances suggest that goodwill may be impaired. Our annual test for impairment is performed as of October 1 of each fiscal year, pursuant to which we make a qualitative assessment of whether it is more likely than not that a reporting unit’s fair value is less than its carrying amount. If we conclude that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, we will recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit’s fair value. After the acquisition of miraDry, management began evaluating the Company as two reporting units: Breast Products and miraDry.

The fair value analysis of goodwill utilizes the income approach and market approach, which requires the use of estimates about a reporting unit's future revenues and free cash flows, market multiples, enterprise value, control risk premiums, discount rates, terminal value and enterprise value to determine the estimated fair value. Our future revenues and free cash flow assumptions are determined based upon actual results giving effect to management's expected changes in operating results in future years. Our market multiples, enterprise value, control risk premiums, discount rates and terminal value are based upon market participant assumptions using a defined peer group. Changes in these assumptions can materially affect these estimates. Thus, to the extent the market changes, discount rates increase significantly or we do not meet our projected performance, we could recognize impairments, and such impairments could be material.

We performed our annual goodwill impairment test on October 1, 2018 for our Breast Products and miraDry reporting units. The miraDry reporting unit had a negative carrying value and $7.6 million of allocated goodwill. We performed a quantitative assessment and determined the fair value was greater than the carrying value. For the Breast Products reporting unit, we performed a qualitative analysis and determined fair value was likely greater than carrying value. For the years ended December 31, 2018, 2017 and 2016 we did not record any goodwill impairment charges.

Warranty Reserve

We offer a product replacement and limited warranty program for the our silicone gel breast implants, and a product warranty for the our miraDry Systems and consumable bioTips, which we consider to be assurance-type warranties. For silicone get breast implant surgeries occurring prior to May 1, 2018, we provide lifetime replacement implants and up to $3,600 in financial assistance for revision surgeries, for covered rupture events that occur within ten years of the surgery date. We introduced our Platinum20 Limited Warranty Program in May 2018, covering OPUS silicone get breast implants implanted in the United States or Puerto Rico on or after May 1, 2018. The assurance component is related to the lifetime no-charge contralateral replacement implants and up to $5,000 in financial assistance for revision surgeries, for covered rupture events that occur within twenty years of the surgery date. Under the miraDry warranty, we provide a standard product warranty for the miraDry System and bioTips.

We recorded expense for the accrual of warranties in the amounts of $0.3 million, $0.2 million and $0.1 million, for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018 and 2017, we held total warranty liabilities of $1.4 million and $1.6 million, respectively.

Stock Based Compensation

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

We estimate the fair value of our stock based awards to employees and directors using the Black Scholes option pricing model. The grant date fair value of a stock based award is recognized as an expense over the requisite service period of the award on a straight line basis. In addition, we use the Monte-Carlo simulation option-pricing model to determine the fair value of market-based awards. The Monte-Carlo simulation option-pricing model uses the same input assumptions as the Black-Scholes model; however, it also further incorporates into the fair-value determination the possibility that the market condition may not be satisfied. Compensation costs related to these awards are recognized regardless of whether the market condition is satisfied, provided that the requisite service has been provided.

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

We recorded total non cash stock based compensation expense of $13.8 million, $6.8 million and $3.2 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had total unrecognized compensation costs of $1.0 million related to unvested stock options. These costs are expected to be recognized over a weighted average period of 1.33 years. As of December 31, 2018, we had total unrecognized compensation costs of $19.1 million related to unvested restricted stock units, or RSUs. These costs are expected to be recognized over a weighted average period of 2.10 years.

The following table represents stock-based compensation expense included in operating expenses in the accompanying consolidated statement of operations for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	December 31,		
	2018	2017	2016
Operating Expenses			
Sales and marketing	$4,878	$1,368	$1,000
Research and development	1,710	645	344
General and administrative	7,236	4,753	1,892
Total	$13,824	$6,766	$3,236

Acquisitions

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

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

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

Acquisition-related deferred and contingent consideration associated with a business combination is initially recognized at fair value and then remeasured each reporting period, with changes in fair value recorded in general and administrative expense. We use the Monte-Carlo Simulation model to estimate the fair value of contingent

consideration, which requires input assumptions about the likelihood of achieving specified milestone criteria, projections of future financial performance, and assumed discount rates. Changes in the fair value of the acquisition-related contingent consideration obligations result from several factors including changes in discount periods and rates, changes in the timing and amount of revenue estimates and changes in probability assumptions with respect to the likelihood of achieving specified milestone criteria. These estimates involve inherent uncertainties and the application of management's judgment. If factors change and different assumptions are used, our contingent consideration fair value expense could be materially different in the future.

Recent Accounting Pronouncements

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

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

The following table sets forth our results of operations for the years ended December 31, 2018 and 2017:

	Year Ended December 31,	
	2018	2017
	(In thousands)	
Statement of operations data		
Net sales	$68,126	$36,542
Cost of goods sold	26,822	14,171
Gross profit	41,304	22,371
Operating expenses		
Sales and marketing	67,715	33,911
Research and development	10,945	9,813
General and administrative	42,418	31,537
Legal settlement	—	10,000
Total operating expenses	121,078	85,261
Loss from operations	(79,774)	(62,890)
Other income (expense), net		
Interest income	532	172
Interest expense	(3,428)	(1,232)
Other income (expense), net	39	(95)
Total other income (expense), net	(2,857)	(1,155)
Loss before income taxes	(82,631)	(64,045)
Income tax benefit	(4)	(17)
Net loss	$(82,627)	$(64,028)

Net Sales

Net sales increased $31.6 million, or 86.4%, to $68.1 million for the year ended December 31, 2018, as compared to $36.5 million for the year ended December 31, 2017. Net sales of our Breast Products segment increased $5.5 million to $37.0 million for the year ended December 31, 2018, as compared to $31.5 million for the year ended December 31, 2017. The increase was driven primarily by an increase in sales of our Allox2 and Dermaspan breast tissue expanders and our breast implants. Net sales of our miraDry segment increased $26.1 million to $31.1 million for the year ended December 31, 2018, as compared to $5.1 for the year ended December 31, 2017, due to a higher volume of miraDry System and bioTip sales and the inclusion of 12 months of activity in 2018 versus approximately five months of activity in 2017.

As of December 31, 2018, our sales organization included 109 employees, including 103 U.S. employees and 6 international employees, as compared to 90 employees as of December 31, 2017. As of December 31, 2018, our international sales organization also included a number of consultants supporting both direct sales efforts and distributor relationships.

Cost of Goods Sold and Gross Margin

Cost of goods sold increased $12.7 million, or 89.3%, to $26.8 million for the year ended December 31, 2018, as compared to $14.2 million for the year ended December 31, 2017. The increase was primarily due to an increase in net sales and the acquisition of miraDry on July 25, 2017. Cost of goods sold for our miraDry segment increased $12.9 million to $15.6 million for the year ended December 31, 2018, as compared to $2.7 million for the year ended December 31, 2017, due to an increase in sales and the inclusion of a year of activity in 2018 versus approximately five months of activity in 2017.

The gross margins for the years ended December 31, 2018 and 2017 were 60.6% and 61.2%, respectively. The decrease for the year ended December 31, 2018 was primarily due to the inclusion of miraDry which carries a lower margin.

Sales and Marketing Expenses

Sales and marketing expenses increased $33.8 million, or 99.7%, to $67.7 million for the year ended December 31, 2018, as compared to $33.9 million for the year ended December 31, 2017. The increase is primarily due to the addition of miraDry, higher employee-related costs as a result of increased sales and headcount, and an increase in marketing initiatives. Sales and marketing expense for our miraDry segment increased $27.5 million to $32.9 million for the year ended December 31, 2018, as compared to $5.4 million for the year ended December 31, 2017, due to the inclusion of a year of activity in 2018 versus approximately five months of activity in 2017.

Research and Development Expenses

Research and development expenses increased $1.1 million, or 11.5%, to $10.9 million for the year ended December 31, 2018, as compared to $9.8 million for the year ended December 31, 2017. The increase was primarily due to the addition of miraDry. Research and development expense for our miraDry segment increased $1.1 million to $2.0 million for the year ended December 31, 2018, as compared to $0.9 million for the year ended December 31, 2017, due to the inclusion of a year of activity in 2018 versus approximately five months of activity in 2017.

General and Administrative Expenses

G&A expenses increased $10.9 million, or 34.5%, to $42.4 million for the year ended December 31, 2018, as compared to $31.5 million for the year ended December 31, 2017. The increase was primarily due to the addition of miraDry, an increase in payroll and related expenses, stock-based compensation, consulting expenses, contingent consideration fair value adjustments and bad debt expense, offset by a decrease in legal expenses. G&A expenses for our miraDry segment increased $5.0 million to $7.3 million for the year ended December 31, 2018, as compared to $2.2 million for the year ended December 31, 2017, due to the inclusion of a year of activity in 2018 versus approximately five months of activity in 2017.

Legal Settlement Expenses

We had no legal settlement expenses for the year ended December 31, 2018. The $10.0 million expense for the year ended December 31, 2017 was related to the settlement of the Silimed Litigation in 2017.

Other Income (Expense), net

Other income (expense), net for the year ended December 31, 2018 and 2017 was primarily associated with interest income, interest expense, expenses related to warrants and amortization of debt issuance costs associated with Credit and Loan Agreements.

Income Tax (Benefit) Expense

Income tax benefit for the years ended December 31, 2018 and 2017 was $4,000 and $17,000, respectively. The income tax benefit was due to the tax effect of rate changes under the Tax Cuts and Jobs Act.

Comparison of the Years Ended December 31, 2017 and 2016

The following table sets forth our results of operations for the years ended December 31, 2017 and 2016:

	Year Ended December 31,	
	2017	2016
	(In thousands)	
Statement of operations data		
Net sales	$36,542	$20,734
Cost of goods sold	14,171	6,880
Gross profit	22,371	13,854
Operating expenses		
Sales and marketing	33,911	20,607
Research and development	9,813	9,704
General and administrative	31,537	21,959
Legal settlement	10,000	1,618
Total operating expenses	85,261	53,888
Loss from operations	(62,890)	(40,034)
Other income (expense), net		
Interest income	172	63
Interest expense	(1,232)	(98)
Other income (expense), net	(95)	(36)
Total other income (expense), net	(1,155)	(71)
Loss before income taxes	(64,045)	(40,105)
Income tax (benefit) expense	(17)	61
Net loss	$(64,028)	$(40,166)

Net Sales

Net sales increased $15.8 million, or 76.2%, to $36.5 million for the year ended December 31, 2017, as compared to $20.7 million for the year ended December 31, 2016. Net sales of our Breast Products segment increased $10.8 million to $31.5 million for the year ended December 31, 2017, as compared to $20.7 million for the year ended December 31, 2017. The increase was a result of the controlled re-entry to market designed to optimize our supply of breast implant inventory after the voluntary hold on the sale and implanting of all Sientra devices manufactured by Silimed between October 9, 2015 and March 1, 2016. Net sales of our Breast Products segment for the year ended December 31, 2017 also included sales of the tissue expander portfolio we acquired from SSP as of November 2016 and the integration of our scar management products after our acquisition of BIOCORNEUM in March 2016. The acquisition of miraDry contributed $5.1 million of net sales since the acquisition on July 25, 2017.

As of December 31, 2017, our sales organization included 90 employees, including 83 U.S. employees and 7 international employees, as compared to 43 employees as of December 31, 2016. The increase is primarily attributed to the acquisition of miraDry.

Cost of Goods Sold and Gross Margin

Cost of goods sold increased $7.3 million, or 106.0%, to $14.2 million for the year ended December 31, 2017, as compared to $6.9 million for the year ended December 31, 2016. This increase was due to an increase in sales volume of the Breast Products segment and a $2.3 million reserve of excess and obsolete inventory in 2017, mainly related to breast products that were not expected to be sold prior to expiration in 2018. In addition, the acquisition of miraDry increased cost of goods by $2.7 million since the acquisition on July 25, 2017.

The gross margins for the years ended December 31, 2017 and 2016 were 61.2% and 66.8%, respectively. The decrease for the year ended December 31, 2017 was primarily due to the inclusion of miraDry which carries a lower margin and an increase in excess and obsolete inventory reserves. The increase in inventory reserves resulted from the timing and recognition of products anticipated to expire prior to being sold and discontinuation of certain product lines.

Sales and Marketing Expenses

Sales and marketing expenses increased $13.3 million, or 64.6%, to $33.9 million for the year ended December 31, 2017, as compared to $20.6 million for the year ended December 31, 2016. The increase is primarily due to the increase in employee related costs as a result of increased sales and headcount. The acquisition of miraDry increased sales and marketing expenses by $5.4 million since the acquisition on July 25, 2017.

Research and Development Expenses

R&D expenses increased $0.1 million, or 1.1%, to $9.8 million for the year ended December 31, 2017, as compared to $9.7 million for the year ended December 31, 2016. The acquisition of miraDry increased research and development expenses by $0.9 million since the acquisition on July 25, 2017.

General and Administrative Expenses

G&A expenses increased $9.5 million, or 43.6%, to $31.5 million for the year ended December 31, 2017, as compared to $22.0 million for the year ended December 31, 2016. The increase consisted primarily of an increase in employee related costs, an increase in acquisition related costs, an increase in amortization and change in fair market value of contingent consideration related to acquisitions. The acquisition of miraDry increased general and administrative expenses by $2.2 million since the acquisition on July 25, 2017.

Legal Settlement Expenses

Legal settlement expenses were $10.0 million for the year ended December 31, 2017 for the settlement of the Silimed Litigation. Legal settlement expenses were $1.6 million for the year ended December 31, 2016 for the settlement of the Class Action Shareholder Litigation which was comprised of a loss contingency of approximately $10.9 million, net of expected insurance proceeds of approximately $9.4 million.

Other Income (Expense), net

Total other income (expense), net for the year ended December 31, 2017 was primarily associated with expenses related to the change in fair value of warrants, interest expense and amortization of issuance costs associated with our Credit Agreements. Total other income (expense), net for the year ended December 31, 2016 was primarily associated with interest income on cash held in a money market account, interest paid on inventory payable and expense recognized for the change in fair value of warrants.

Income Tax (Benefit) Expense

Income tax benefit was $17,000 for the year ended December 31, 2017, as compared to expense of $0.1 million for the year ended December 31, 2016. Income tax expense is primarily associated with a deferred tax liability associated with indefinite lived intangibles from acquisitions that cannot offset the deferred tax asset. The income tax benefit for 2017 is due to measuring the December 31, 2017 deferred tax liability using the future decreased federal corporate income tax rate under the Tax Cuts and Jobs Act.

Liquidity and Capital Resources

Since our inception, we have incurred significant net operating losses and anticipate that our losses will continue in the near term. We expect our operating expenses will continue to grow as we expand our operations. We will need to generate significant net sales to achieve profitability. To date, we have funded our operations primarily with proceeds from the sales of preferred stock, borrowings under our term loans, sales of our products since 2012, and the proceeds from the sale of our common stock in public offerings.

On March 13, 2017, we entered into the SVB Loan Agreement. Under the terms of the SVB Loan Agreement, SVB made available to us a $15.0 million Revolving Line of Credit and a $5.0 million term loan. On July 25, 2017, we repaid in full our outstanding indebtedness under the SVB Loan Agreement and the agreement was terminated and replaced with the Credit Agreements with MidCap.

On July 25, 2017, we borrowed $25.0 million pursuant to the Term Loan Credit Agreement with MidCap and the other lenders party thereto. We used the proceeds (i) to repay in full our then-existing indebtedness under the SVB Loan Agreement, which totaled approximately $5.0 million, (ii) to pay fees and expenses in connection with the foregoing and (iii) for general corporate purposes. The Term Loan Credit Agreement provides for (i) the Closing Date Term Loan, (ii) until March 31, 2018, an additional $10.0 million term loan facility subject to the satisfaction of certain conditions, including FDA certification of the manufacturing facility operated by Vesta and (iii) an additional $5.0 million term loan facility subject to the satisfaction of certain conditions, including evidence that the Company's Net Revenue (as defined in the Term Loan Credit Agreement) for the past 12 months was greater than or equal to $75.0 million. On April 18, 2018, we amended the Term Loan Credit Agreement with MidCap pursuant to which MidCap agreed to adjust the date by which we must obtain FDA approval of our PMA supplement in order to access the March 2018 Term Loan until April 30, 2018. Upon FDA approval in April 2018, the $10.0 million March 2018 Term Loan was funded. In addition, on July 25, 2017, we also entered into a Revolving Credit Agreement with MidCap and the other lenders party thereto. The amount available to be drawn under the Revolving Credit Agreement is based on a Borrowing Base equal to 85% of the net collectible value of eligible accounts receivable plus 40% of eligible finished goods inventory, provided that availability from eligible finished goods inventory does not exceed 20% of the Borrowing Base. We may make (subject to the applicable borrowing base at the time) and repay borrowings from time to time under the Revolving Credit Agreement until the maturity of the facility on December 1, 2021.

See Note 5 to the consolidated financial statements for a full description of our long-term debt and revolving line of credit.

In February 2018, we entered into an At-The-Market Equity Offering Sales Agreement with Stifel, Nicolaus & Company, Incorporated, or Stifel, as sales agent pursuant to which we may sell, from time to time, through Stifel shares of our common stock having an aggregate gross offering price of up to $50 million. As of December 31, 2018, we have not sold any common stock pursuant to the sales agreement.

On May 7, 2018, we completed an underwritten follow-on public offering in which we sold 7,407,408 shares of common stock at $13.50 per share, as well as 1,111,111 additional shares of common stock pursuant to the full exercise of the over-allotment option granted to the underwriters. Net proceeds to the Company were approximately $107.6 million after deducting underwriting discounts and commissions of $6.9 million and offering expenses of approximately $0.5 million.

As of December 31, 2018, we had $86.9 million in cash and cash equivalents. Our historical cash outflows have primarily been associated with research and development activities, activities relating to commercialization and increases in working capital, including the expansion of our sales force and marketing programs. In addition, we have used cash to fund the acquisitions of miraDry, BIOCORNEUM and the tissue expander portfolio.

To fund our ongoing operating and capital needs, we may need to raise additional equity or debt capital. We believe we have sufficient capital resources to continue as a going concern through the next twelve months.

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Cash Flows

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

	Year Ended December 31,		
	2018	2017	2016
Net cash (used in) provided by:			
Operating activities	$(56,190)	$(45,916)	$(34,430)
Investing activities	(855)	(20,319)	(12,835)
Financing activities	117,356	25,611	1,676
Net change in cash and cash equivalents	$60,311	$(40,624)	$(45,589)

Cash used in operating activities

Net cash used in operating activities was $56.2 million, $45.9 million and $34.4 million during the years ended December 31, 2018, 2017 and 2016, respectively. The $10.3 million increase in cash used in operating activities between the years ended December 31, 2018 and 2017 was primarily associated with an $18.6 million increase in net loss, an increase in accounts receivable due to the timing of sales and collections, an increase in inventory following the FDA's approval of our manufacturing site-change supplement and three PMA submissions in January and April 2018 in connection with the Vesta facility as compared to the year ended December 31, 2017, partially offset by an increase in accounts payable and accrued and other liabilities due to the timing of payments, and an increase in stock based compensation as compared to the year ended December 31, 2017. The $11.5 million increase in cash used in operating activities between the years ended December 31, 2017 and 2016 was primarily associated with a $23.8 million increase in net loss, offset by the timing of the receipt of the $9.4 million Class Action Shareholder Litigation insurance receivable.

Cash used in investing activities

Net cash used in investing activities was $0.9 million, $20.3 million and $12.8 million during the years ended December 31, 2018, 2017 and 2016, respectively. The decrease in cash used in investing activities between the year ended December 31, 2018 and 2017 was due to a decrease in business acquisitions. The increase in cash used in investing activities of $7.5 million between the years ended December 31, 2017 and 2016 was primarily due to $18.4 million for the acquisition of miraDry in July 2017.

Cash provided by financing activities

Net cash provided by financing activities was $117.4 million, $25.6 million and $1.7 million for the years ended December 31, 2018, 2017, and 2016, respectively. The increase in cash provided by financing activities of $91.8 million between the years ended December 31, 2018, and 2017 was primarily the result of proceeds from the public follow-on offering and proceeds from borrowings under the Credit Agreements for the year ended December 31, 2018. The increase in cash provided by financing activities of $23.9 million between the years ended December 31, 2017 and 2016 was primarily the result of borrowing under the Term Loan.

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

- the ability of the Vesta facility to meet capacity to meet customer requirements;
- net sales generated by our Breast Products and miraDry segments, and any other future products that we may develop and commercialize;
- costs associated with expanding our sales force and marketing programs;
- cost associated with developing and commercializing our proposed products or technologies;

- expenses we incur in connection with potential litigation or governmental investigations;
- cost of obtaining and maintaining regulatory clearance or approval for our current or future products;
- cost of ongoing compliance with regulatory requirements, including compliance with Sarbanes-Oxley;
- anticipated or unanticipated capital expenditures; and
- unanticipated G&A expenses.

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

- support of our sales and marketing efforts related to our current and future products;
- new product acquisition and development efforts;
- facilities expansion needs; and
- 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 credit facilities. Additional capital, if needed, may not be available on satisfactory terms, if at all. Furthermore, any additional equity financing may be dilutive to stockholders, and debt financing, if available, may include restrictive covenants. For a discussion of other factors that may impact our future liquidity and capital funding requirements, see "Risk Factors — Risks Related to Our Financial Results."

Off Balance Sheet Arrangements

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

Item 7A. Quantitative and Qualitative Disclosures about Market Risks

As of December 31, 2018, we had $86.9 million in cash and cash equivalents. We generally hold our cash in checking accounts and interest-bearing money market accounts. Our exposure to market risk related to interest rate sensitivity is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents.

Item 8. Financial Statements and Supplementary Data

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

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of 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 this evaluation, the Company's principal executive officer and principal financial officer have concluded that, as of December 31, 2018, the Company's disclosure controls and procedures were effective.

Management's Annual Report on Internal Control over Financial Reporting

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

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

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

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

As of December 31, 2018, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control – Integrated Framework (2013), or the COSO 2013 Framework. Based on this assessment, management concluded that as of December 31, 2018, our internal control over financial reporting was effective based on those criteria.

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

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the year ended December 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

On March 12, 2019, the Company entered into an amendment (the "Nugent Amendment") to the Employment Agreement, dated November 12, 2015 (as amended, the "Nugent Employment Agreement"), with Jeffrey M. Nugent, the Company's Chief Executive Officer. The Nugent Amendment provides that the Company shall provide Mr. Nugent with a one-time payment of $300,000, payable on or before December 31, 2019, for Mr. Nugent's relocation to Santa Barbara county (the "Relocation Payment"). If Mr. Nugent resigns without good reason or is terminated for cause (each as defined in the Nugent Employment Agreement) within twelve months of March 12, 2019, Mr. Nugent shall repay the Relocation Payment.

On March 12, 2019, the Company entered into an amendment (the "Sullivan Amendment") to the Second Amended and Restated Strategic Advisory Consulting Agreement (the "Sullivan Agreement") with Keith J. Sullivan, a member of the Company's Board of Directors. The Sullivan Amendment extends the term of the Sullivan Agreement to December 31, 2019. In addition, the Sullivan Agreement provides that Mr. Sullivan will receive a grant of 40,000 restricted stock units vesting in equal quarterly installments beginning on the first business day following the quarter ending March 31, 2019. In addition, Mr. Sullivan will receive an additional grant of 20,000 performance-based restricted stock units, the vesting of which is contingent upon the achievement of certain revenue targets for miraDry as set forth by the Board of Directors or the Compensation Committee.

On March 12, 2019, the Company entered into a Strategic Advisory Consulting Agreement (the "Schaison Agreement") with Philippe A. Schaison, a member of the Company's Board of Directors. The Schaison Agreement provides that Mr. Schaison will provide strategic advisory services to the Company (the "Services") for a term ending December 31, 2019 (the "Term") which may be extended by mutual written consent. As compensation for the Services, Mr. Schaison will receive total compensation of no more than $115,000 for the Term, payable in monthly installments of $11,500.

As previously disclosed, on February 4, 2019 (the "Separation Date"), Patrick F. Williams, the Company's former Senior Vice President and General Manager of miraDry, ceased to be employed by the Company, following which he will continue to provide consulting services. On March 12, 2019, the Company entered into a Confidential Settlement, Release and Consulting Agreement with Mr. Williams (the "Williams Agreement"). Pursuant to the Williams Agreement, in exchange for a general release of all claims, the Company will (1) pay Mr. Williams, in accordance with the Company's regular payroll cycle, an amount equal to twelve months of his base salary in effect on the Separation Date, or $374,500, (2) make a lump sum payment of $231,253.75, equal to Mr. Williams' bonus for 2018 and 2019 prorated through the Separation Date and (3) reimburse Mr. Williams for COBRA premiums until the earlier of (1) twelve months following the Separation Date (2) the date Mr. Williams is eligible for group health insurance coverage through a new employer or (3) the date Mr. Williams ceases to be eligible for COBRA continuation coverage for any reason. In addition, the Williams Agreement provides that Mr. Williams will continue to provide consulting services (the "Services") for twelve months following the Separation Date. As consideration for the Services, the Company will continue the vesting of Mr. Williams' outstanding stock options and restricted stock units and accelerated the vesting of the 15,000 restricted stock units subject to performance-based criteria at the end of the consulting period.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

Incorporated by reference from the information in our Proxy Statement for our 2019 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 2019 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 2019 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 2019 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 2019 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.

PART IV

Item 15. Exhibits, Financial Statements and Schedule

(a)(1) Financial Statements.
The response to this portion of Item 15 is 15 is appended to this report beginning on page F 1 below.

(a)(2) Financial Statement Schedule.
All schedules have been omitted because they are not required or because the required information is given in the Financial Statements or Notes thereto.

(a)(3) Exhibits.
List of Exhibits required by Item 601 of Regulation S-K. See Item 15(b) below.

(b)

Exhibit Number	Exhibit Description	Incorporated by Reference Form	SEC File No.	Exhibit	Filing	Filed Herewith
2.1	Agreement and Plan of Merger, dated as of June 11, 2017, by and among Sientra, Inc., Desert Acquisition Corporation and Miramar Labs, Inc.	8-K	001-36709	2.1	June 12, 2017	
2.2	Amendment No.1 to Agreement and Plan of Merger, dated as of June 25, 2017 by and among Sientra, Inc., Desert Acquisition Corporation and Miramar Labs, Inc.	8-K	001-36709	2.1	June 26, 2017	
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	S-1/A	333-198837	3.2	October 20, 2014	
3.2	Amended and Restated Bylaws of the Registrant.	S-1/A	333-198837	3.4	October 20, 2014	
4.1	Form of Common Stock Certificate of the Registrant.	S-1/A	333-198837	4.1	October 20, 2014	
4.2	Conversion and Amendment Agreement by and among the Registrant and certain of its stockholders, dated October 10, 2014.	S-1/A	333-198837	4.11	October 20, 2014	

Exhibit Number	Exhibit Description	Incorporated by Reference Form	SEC File No.	Exhibit	Filing	Filed Herewith
4.3	Amended and Restated Investor Rights Agreement, dated March 28, 2012, by and among Sientra, Inc., and the investors and stockholders party thereto.	S-1	333-198837	4.2	September, 19 2014	
4.4	Warrant to Purchase Stock issued to Oxford Finance LLC, dated January 17, 2013.	S-1	333-198837	4.3	September, 19 2014	
4.5	Warrant to Purchase Stock issued to Oxford Finance LLC, dated January 17, 2013.	S-1	333-198837	4.4	September, 19 2014	
4.6	Warrant to Purchase Stock issued to Oxford Finance LLC, dated August 1, 2013.	S-1	333-198837	4.5	September, 19 2014	
4.7	Warrant to Purchase Stock issued to Oxford Finance LLC, dated August 1, 2013.	S-1	333-198837	4.6	September, 19 2014	
4.8	Warrant to Purchase Stock issued to Oxford Finance LLC, dated December 13, 2013.	S-1	333-198837	4.7	September, 19 2014	
4.9	Warrant to Purchase Stock issued to Oxford Finance LLC, dated December 13, 2013.	S-1	333-198837	4.8	September, 19 2014	
10.1#	Form of Indemnity Agreement by and between Sientra, Inc. and its directors and officers.	S-1	333-198837	10.1	September, 19 2014	
10.2#	2007 Equity Incentive Plan, as amended, and forms of award agreements thereunder.	S-1	333-198837	10.2	September, 19 2014	
10.3#	2014 Equity Incentive Plan and forms of award agreements thereunder.	S-1/A	333-198837	10.3	October 20, 2014	
10.4#	2014 Non-Employee Director Compensation Policy.	S-1	333-198837	10.4	September, 19 2014	
10.5#	2014 Employee Stock Purchase Plan.	S-1/A	333-198837	10.5	October 20, 2014	
10.6	Multi-Purpose Commercial Building Lease, dated March 28, 2014, by and between Sientra, Inc. and Fairview Business Center, L.P.	S-1	333-198837	10.6	September, 19 2014	

Exhibit Number	Exhibit Description	Incorporated by Reference Form	SEC File No.	Exhibit	Filing	Filed Herewith
10.7#	Amended and Restated Employment Agreement by and between Sientra, Inc. and Charles Huiner, dated September 22, 2016.	10-Q	001-36709	10.1	November 9, 2016	
10.8#	Employment Agreement by and between Sientra, Inc. and Patrick F. Williams, dated October 26, 2016.	10-Q	001-36709	10.3	November 9, 2016	
10.9#	Employment Agreement by and between Sientra, Inc. and Jeffrey Nugent, dated November 12, 2015.	10-Q	001-36709	10.3	November 16, 2015	
10.10#	Amendment to Amended and Restated Employment Agreement by and between Sientra, Inc. and Charles Huiner, dated February 7, 2017.	10-K	001-36709	10.16	March 14, 2017	
10.11#	Amendment No. 2 to Amended and Restated Employment Agreement by and between Sientra, Inc. and Charles Huiner, dated March 10, 2017.	10-K	001-36709	10.17	March 14, 2017	
10.12#	Sientra, Inc. Inducement Plan and forms of award agreements thereunder.	10-K	001-36709	10.20	March 10, 2016	
10.13+	Manufacturing Agreement by and between the Registrant and Vesta Intermediate Funding, Inc., a Lubrizol LifeSciences Company, dated March 10, 2017.	10-Q	001-36709	10.1	May 9, 2017	
10.14	Loan and Security Agreement by and between the Registrant and Silicon Valley Bank, dated March 13, 2017.	10-Q	001-36709	10.2	May 9, 2017	
10.15#	Amendment to Employment Agreement by and between the Registrant and Jeffrey M. Nugent, dated May 8, 2017.	10-Q	001-36709	10.3	May 9, 2017	

Exhibit Number	Exhibit Description	Incorporated by Reference Form	SEC File No.	Exhibit	Filing	Filed Herewith
10.16	Credit and Security Agreement (Revolving Loan) by and between the Registrant and the other borrowers thereto and Midcap Financial Trust and the additional lenders thereto, dated July 25, 2017.	10-Q	001-36709	10.1	August 9, 2017	
10.17	Credit and Security Agreement (Term Loan) by and between the Registrant and the other borrowers thereto and Midcap Financial Trust and the additional lenders thereto, dated July 25, 2017.	10-Q	001-36709	10.2	August 9, 2017	
10.18#	Amended and Restated Consulting Agreement by and between Registrant and Keith J. Sullivan, dated August 4, 2017.	10-Q	001-36709	10.3	August 9, 2017	
10.19	Assignment and License Agreement, dated December 31, 2008, by and between Miramar Labs, Inc. and The Foundry, Inc.	S-1	333-214121	10.8	October 14, 2016	
10.20	Assignment and License Clarification Letter, dated June 10, 2010, by and between Miramar Labs, Inc. and The Foundry, LLC.	S-1	333-214121	10.9	October 14, 2016	
10.21	Asset Purchase Agreement, dated January 18, 2008, by and between Miramar Labs, Inc. and Jan Wallace.	S-1	333-214121	10.10	October 14, 2016	
10.22	Lease Agreement, dated December 16, 2013, by and between Miramar Labs, Inc. and DWF III Walsh Bowers, LLC.	S-1	333-214121	10.15	October 14, 2016	
10.23+	Supply Agreement dated, November 13, 2014, by and between Miramar Labs, Inc. and Broadband Wireless, LLC.	S-1	333-214121	10.23	October 14, 2016	
10.24+	Contract Manufacturing Service Agreement dated, November 6, 2012, by and between Miramar Labs, Inc. and Healthcare Technology International Limited.	S-1	333-214121	10.24	October 14, 2016	

Exhibit Number	Exhibit Description	Incorporated by Reference Form	SEC File No.	Exhibit	Filing	Filed Herewith
10.25	At-The-Market Equity Offering Sales Agreement, dated February 20, 2018, by and between Sientra, Inc. and Stifel, Nicolaus & Company, Incorporated.	8-K	001-36709	10.1	February 20, 2018	
10.26#	Strategic Advisory Consulting Agreement, dated March 9, 2018, by and between Sientra, Inc., and Philippe A. Schaison.	10-K	001-36709	10.31	March 13, 2018	
10.27#	Second Amended and Restated Consulting Agreement by and between Registrant and Keith J. Sullivan, dated March 9, 2018.	10-K	001-36709	10.32	March 13, 2018	
10.28#	Second Amendment to Employment Agreement by and between Registrant and Jeffrey M. Nugent, dated March 13, 2018.	10-K	001-36709	10.33	March 13, 2018	
10.29#	Amendment No. 1 to Credit and Security Agreement (Term Loan), dated April 18, 2018, by and among Sientra, Inc., miraDry Holdings, Inc., miraDry, Inc., MidCap Financial Trust and certain other financial institutions as lenders.	8-K	001-36709	10.1	April 20, 2018	
10.30#	Employment Agreement, effective August 8, 2018, by and between Sientra, Inc. and Paul Little.	10-Q	001-36709	10.3	August 7, 2018	
10.31#	First Amendment to Employment Agreement, effective August 8, 2018, by and between Sientra, Inc. and Patrick F. Williams.	10-Q	001-36709	10.4	August 7, 2018	
10.32#	First Amendment to Second Amended and Restated Consulting Agreement, effective August 6, 2018, by and between Sientra, Inc. and Keith J. Sullivan.	10-Q	001-36709	10.5	August 7, 2018	

Exhibit Number	Exhibit Description	Incorporated by Reference Form	SEC File No.	Exhibit	Filing	Filed Herewith
10.33	Order Instituting Cease-and-Desist Proceedings Pursuant to Section 8A of the Securities Act of 1933 and Section 21c of the Securities Exchange Act of 1934, Making Findings, and Imposing a Cease-And-Desist Order dated September 19, 2018.	8-K	001-36709	10.1	September 20, 2018	
10.34	First Amendment to the Lease, effective October 9, 2018, by and between miraDry, Inc. and IPX Walsh Bowers Investors, L.P.	10-Q	001-36709	10.5	November 6, 2018	
10.35#	Third Amendment to Employment Agreement, dated March 12, 2019, by and between Sientra, Inc. and Jeffrey M. Nugent.					X
10.36#	Second Amendment to Second Amended and Restated Consulting Agreement, effective March 12, 2019, by and between Sientra, Inc. and Keith J. Sullivan.					X
10.37#	Strategic Advisory Consulting Agreement, dated March 12, 2019, by and between Sientra, Inc., and Philippe A. Schaison.					X
10.38#	Confidential Settlement, Release and Consulting Agreement, dated March 12, 2019, by and between Sientra, Inc. and Patrick F. Williams.					X
21.1	List of significant subsidiaries of the registrant.					X
23.1	Consent of KPMG LLP, an independent registered public accounting firm.					X
24.1	Power of Attorney (included in signature page to this Annual Report on Form 10-K).					X

Exhibit Number	Exhibit Description	Incorporated by Reference Form	SEC File No.	Exhibit	Filing	Filed Herewith
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a 14(a) or Rule 15d 14(a) of the Securities Exchange Act of 1934, as amended.					X
32.1	Certification of Principal Executive Officer pursuant to Rule 13a 14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.					X
32.2	Certification of Principal Financial Officer pursuant to Rule 13a 14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant Section 906 of the Sarbanes Oxley Act of 2002.					X
101.INS*	XBRL Instance Document.					
101.SCH*	XBRL Taxonomy Extension Schema Document.					
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.					
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.					
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.					
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.					

+Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

#Indicates management contract or compensatory plan, contract, or agreement.

* XBRL (Extensible Business Reporting Language) information is furnished and not filed herewith, is not a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, and otherwise is not subject to liability under these sections.

Item 16. Form 10-K Summary

None.

Sientra, Inc.

INDEX TO FINANCIAL STATEMENTS AND FINANCIAL STATEMENT SCHEDULE

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors

Sientra, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Sientra, Inc. and subsidiaries (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2018, and the related notes and financial statement schedule II (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

(signed) KPMG LLP

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

Los Angeles, California

March 14, 2019

Sientra, Inc.

Consolidated Balance Sheets

(in thousands, except per share and share amounts)

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 86,899	$ 26,588
Accounts receivable, net of allowances of $2,428 and $4,816 at December 31, 2018 and December 31, 2017, respectively	22,527	6,569
Inventories, net	24,085	20,896
Prepaid expenses and other current assets	2,612	1,512
Total current assets	136,123	55,565
Property and equipment, net	2,536	4,763
Goodwill	12,507	12,507
Other intangible assets, net	16,495	18,803
Other assets	698	575
Total assets	$ 168,359	$ 92,213
Liabilities and Stockholders' Equity		
Current liabilities:		
Current portion of long-term debt	$ 6,866	$ 24,639
Accounts payable	13,184	5,811
Accrued and other current liabilities	27,697	13,474
Legal settlement payable	410	1,000
Customer deposits	9,936	5,423
Sales return liability	6,048	—
Total current liabilities	64,141	50,347
Long-term debt	27,883	—
Deferred and contingent consideration	6,481	12,597
Warranty reserve and other long-term liabilities	2,976	1,646
Total liabilities	101,481	64,590
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.01 par value – Authorized 10,000,000 shares; none issued or outstanding	—	—
Common stock, $0.01 par value — Authorized 200,000,000 shares; issued 28,701,494 and 19,474,702 and outstanding 28,628,767 and 19,401,975 shares at December 31, 2018 and December 31, 2017 respectively	286	194
Additional paid-in capital	428,949	307,159
Treasury stock, at cost (72,727 shares at December 31, 2018 and December 31, 2017)	(260)	(260)
Accumulated deficit	(362,097)	(279,470)
Total stockholders' equity	66,878	27,623
Total liabilities and stockholders' equity	$ 168,359	$ 92,213

See accompanying notes to the consolidated financial statements.

Sientra, Inc.

Consolidated Statements of Operations

(in thousands, except per share and share amounts)

	Year Ended December 31,		
	2018	2017	2016
Net sales	$68,126	$36,542	$20,734
Cost of goods sold	26,822	14,171	6,880
Gross profit	41,304	22,371	13,854
Operating expenses:			
Sales and marketing	67,715	33,911	20,607
Research and development	10,945	9,813	9,704
General and administrative	42,418	31,537	21,959
Legal settlement	—	10,000	1,618
Total operating expenses	121,078	85,261	53,888
Loss from operations	(79,774)	(62,890)	(40,034)
Other income (expense), net:			
Interest income	532	172	63
Interest expense	(3,428)	(1,232)	(98)
Other income (expense), net	39	(95)	(36)
Total other income (expense), net	(2,857)	(1,155)	(71)
Loss before income taxes	(82,631)	(64,045)	(40,105)
Income tax (benefit) expense	(4)	(17)	61
Net loss	$(82,627)	$(64,028)	$(40,166)
Basic and diluted net loss per share attributable to common stockholders	$(3.25)	$(3.34)	$(2.20)
Weighted average outstanding common shares used for net loss per share attributable to common stockholders:			
Basic and diluted	25,402,241	19,159,057	18,233,177

See accompanying notes to the consolidated financial statements.

Sientra, Inc.

Consolidated Statements of Stockholders' Equity

(in thousands, except per share and share amounts)

	Preferred stock		Common stock		Treasury stock		Additional paid-in	Accumulated	Total stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	capital	deficit	equity
Balances at December 31, 2015	—	$ —	18,066,143						