Sientra, Inc.
Form S-1/A
October 10, 2014

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As filed with the Securities and Exchange Commission on October 9, 2014

Registration No. 333-198837

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1
TO

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Sientra, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**3842**	**20-5551000**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

420 South Fairview Avenue, Suite 200
Santa Barbara, CA 93117
(805) 562-3500

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Hani Zeini
Founder, President and Chief Executive Officer
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Santa Barbara, CA 93117
(805) 562-3500

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price[1]	Amount of registration fee[2][3]
Common Stock, $0.01 par value per share	$86,250,000	$11,109

(1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended. Includes the offering price of additional shares that the underwriters have the option to purchase.

(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

(3) Previously paid.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment that specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the Securities and Exchange Commission declares our registration statement effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated October 9, 2014

Shares

SIENTRA, INC.

Common Stock

$ per share

Sientra, Inc. is offering shares.

We anticipate that the initial public offering price will be between $ and $ per share.

This is our initial public offering and no public market currently exists for our shares.

Proposed trading symbol: "SIEN."

This investment involves risk. See "Risk Factors" beginning on page 13.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, and as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

	Per Share	Total
Public offering price	$	$
Underwriting discount[1]	$	$
Proceeds to Sientra, Inc., before expenses	$	$

(1) See "Underwriting" for additional information regarding underwriting compensation.

We have granted to the underwriters an option to purchase up to additional shares of common stock from us at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to investors on or about , 2014.

Piper Jaffray **Stifel**

Leerink Partners **William Blair**

The date of this prospectus is , 2014.

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You should rely only on the information contained in this prospectus or any related free writing prospectus we may authorize to be delivered to you. We have not, and the underwriters have not, authorized any other person to provide you with different information. We and the underwriters take no responsibility for, and can provide no assurances as to the reliability of, any information that others may give you. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any state where the offer or sale is not permitted. The information in this prospectus is only accurate as of the date of this prospectus, regardless of the time or delivery of this prospectus and any sale of our common stock.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to the registration statement of which this prospectus is a part were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreement, and should not be deemed to be a representation, warranty or covenant made to you or for your benefit. Moreover, such representations, warranties or covenants were accurate only as of the date they were made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

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Trademarks

Our trademark portfolio contains five registered U.S. trademarks, including Sientra®, Simplicity is Beauty®, Sientra Simplicity is Beauty®, Anatomical Controlled® and ACX®, and six Canadian trademark applications. This prospectus contains additional trademarks and trade names of others, which are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the ® and symbols, but such references should not be construed as any indicator that we will not assert, to the fullest extent under applicable law, our rights thereto.

Investors Outside of the United States

Neither we nor any of the underwriters have taken any action that would permit this offering or the possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of shares of our common stock and the distribution of this prospectus outside of the United States.

Market and Industry Data and Forecasts

Certain market and industry data and forecasts included in this prospectus were obtained from independent market research, industry publications and surveys, governmental agencies and publicly available information. Industry surveys, publications and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We believe the data from such third-party sources to be reliable. However, we have not independently verified any of such data and cannot guarantee its accuracy or completeness. Similarly, internal market research and industry forecasts, which we believe to be reliable based upon our management's knowledge of the market and the industry, have not been verified by any independent sources. While we are not aware of any misstatements regarding the market or industry data presented herein, our estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under the heading "Risk Factors," "Special Note Regarding Forward-Looking Statements" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this prospectus.

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PROSPECTUS SUMMARY

This prospectus summary provides an overview of certain information appearing elsewhere in this prospectus. This prospectus summary is not complete and does not contain all of the information that you should consider before making a decision to invest in our common stock. You are encouraged to carefully read this entire prospectus, including the information provided under the headings "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes, before investing in our common stock. Unless otherwise stated in this prospectus, references to "Sientra," "we," "us," "our" or "the Company" refer to Sientra, Inc.

Overview

We are a medical aesthetics company committed to making a difference in patients' lives by enhancing their body image, growing their self-esteem and restoring their confidence. We were founded to provide greater choice to board-certified plastic surgeons and patients in need of medical aesthetics products. We have developed a broad portfolio of products with technologically differentiated characteristics, supported by independent laboratory testing and strong clinical trial outcomes. We sell our breast implants and breast tissue expanders, or Breast Products, exclusively to board-certified and board-admissible plastic surgeons and tailor our customer service offerings to their specific needs, which we believe helps secure their loyalty and confidence. These advantages have allowed us to increase our market share each year since we entered the market in 2012.

Our primary products are silicone gel breast implants for use in breast augmentation and breast reconstruction procedures, which we offer in over 120 variations of shapes, sizes and textures. Our breast implants are primarily used in elective procedures which are generally performed on a cash-pay basis. Many of our breast implants incorporate one or more differentiated technologies, including a proprietary high-strength, cohesive silicone gel and proprietary texturing branded TRUE Texture. Our breast implants offer a desired balance between strength, shape retention and softness due to the high-strength, cohesive silicone gel used in our manufacturing process. TRUE Texture provides texturing on the implant shell that is designed to reduce the incidence of malposition, rotation and capsular contracture, 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. We also offer breast tissue expanders and a range of other aesthetic and specialty products. We do not have any patents or patent applications, but rely on trade secrets, proprietary know-how and regulatory barriers to protect our products and technologies.

Our breast implants were approved by the U.S. Food and Drug Administration, or FDA, in 2012, based on data we collected from our ongoing, long-term clinical trial of our breast implants in 1,788 women across 36 investigational sites in the United States. Our clinical trial is the largest prospective, long-term safety and effectiveness pivotal study of breast implant patients in the United States. The clinical data we collected over a five-year follow-up period demonstrated rupture rates, capsular contracture rates and reoperation rates that were comparable to or better than those of our competitors, based on our competitors' published six-year data. In addition to our pivotal study, our clinical data is supported by our Continued Access Study of 2,497 women in the United States. We have also commissioned a number of bench trials run by independent laboratories that we believe further demonstrate the advantages of our breast implants over those of our competitors.

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

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industry. According to the American Society of Plastic Surgeons, or ASPS, there are approximately 6,400 board-certified plastic surgeons in the United States. We seek to provide Plastic Surgeons with differentiated services, including enhanced customer service offerings, a ten-year limited warranty that is the best-in-the-industry based on providing patients with the largest cash reimbursement for certain out-of-pocket costs related to revision surgeries in a covered event; a lifetime no-charge implant replacement program for covered ruptures; and our industry-first CapCon Care Program, or C3 Program, through which we offer no-charge replacement implants to breast augmentation patients who experience capsular contracture within the first five years after implantation with our smooth or textured breast implants.

Breast augmentation surgery remains the leading aesthetic surgical procedure by dollars and number of procedures in the United States. Based on the number of procedures reported by either the American Society for Aesthetic Plastic Surgery, or ASAPS, or by ASPS, and our estimates of average selling price, implant mix and implants per procedure, we estimate that the U.S. market for breast implants and breast tissue expanders exceeded $600 million in 2013. Based on data from ASAPS and ASPS, between 1997 and 2013, the number of breast augmentation and breast reconstruction procedures has grown at a compound annual growth rate of approximately 7.3% and 4.4%, respectively.

We commenced sales of our breast implants in the United States in the second quarter of 2012. Our net sales were $35.2 million for the year ended December 31, 2013, as compared to $10.4 million for the year ended December 31, 2012. Our net sales were $21.9 million for the six months ended June 30, 2014, as compared to $17.9 million for the six months ended June 30, 2013. Our net loss was $19.1 million for the year ended December 31, 2013, as compared to $23.4 million for the year ended December 31, 2012. Our net loss was $1.2 million for the six months ended June 30, 2014, as compared to $9.6 million for the six months ended June 30, 2013. Our accumulated deficit as of June 30, 2014 was $129.4 million.

Our Market

The overall market for medical aesthetic procedures is significant, and awareness and acceptance of these procedures is growing in the United States. According to ASAPS, in 2013, consumers in the United States spent approximately $12.4 billion on aesthetic procedures overall, including both surgical and non-invasive cosmetic treatments. Of this amount, more than $7.2 billion was spent on aesthetic surgical procedures.

Breast augmentation surgery remains the leading aesthetic surgical procedure by dollars and number of procedures in the United States. According to ASAPS, over 313,000 primary breast augmentation procedures and 55,000 revision augmentation procedures were performed in the United States in 2013. These procedures provide cosmetic solutions generally to enhance breast size and shape, correct breast asymmetries or help restore fullness after breastfeeding. For breast reconstruction, ASPS estimates that approximately 96,000 procedures were performed in the United States in 2013. These procedures are a surgical solution generally used to restore a breast to near normal shape and appearance following a mastectomy and typically utilize a breast tissue expander prior to implantation of a breast implant. Based on the number of procedures reported by ASAPS and by ASPS, and our estimates of average selling price, implant mix and implants per procedure, we estimate that the U.S. market for breast implants and breast tissue expanders exceeded $600 million in 2013. Based on data from ASAPS and ASPS, between 1997 and 2013, the number of breast augmentation and breast reconstruction procedures has grown at a compound annual growth rate of approximately 7.3% and 4.4%, respectively.

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Our Opportunity

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

For more than 20 years prior to the FDA approval of our breast implants in 2012, only two companies manufactured and distributed breast implants in the United States. We believe that this market concentration is largely a result of the considerable costs and risks associated with the lengthy regulatory approval process required by the FDA, which has created a significant barrier to entry in the U.S. breast implant market. All new breast implants require pre-market approval, or PMA, from the FDA before they may be marketed in the United States. The PMA application process is lengthy and uncertain, and the PMA application must be supported by valid scientific evidence, which typically requires long-term follow-up of a large number of enrolled patients, as well as extensive technical, pre-clinical, clinical and manufacturing data to demonstrate safety and effectiveness. At present, we are not aware of any ongoing clinical studies in the United States for silicone breast implants other than those post-approval studies being performed by us and our two U.S. competitors. We believe that in the near term, it is likely that the companies currently providing silicone breast implants in the United States will continue to be the only companies servicing the U.S. silicone breast implant market.

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

Our Competitive Strengths

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

Differentiated silicone gel and texturing technologies. We incorporate differentiated technologies into our breast implants, including a proprietary high-strength, cohesive silicone gel and proprietary texturing branded TRUE Texture. Our breast implants offer a desired balance between strength, shape retention and softness due to the high-strength, cohesive silicone gel used in our manufacturing process. In addition, TRUE Texture technology provides texturing on the implant shell that is designed to reduce the incidence of malposition, rotation and capsular contracture. We do not have any patents or patent applications, but rely on trade secrets, proprietary know-how and regulatory barriers to protect our products and technologies.

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

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Innovative services that deliver an improved customer experience. Our customer service offerings are intended to accommodate and anticipate the needs of Plastic Surgeons so that they can focus on providing better services to their patients. We provide a ten-year limited warranty that is the best-in-the-industry based on providing patients with the largest cash reimbursement for certain out-of-pocket costs related to revision surgeries in a covered event; a lifetime no-charge implant replacement program for covered ruptures; and our industry-first C3 Program through which we offer no-charge replacement implants to breast augmentation patients who experience capsular contracture within the first five years after implantation with our smooth or textured breast implants. We also offer specialized educational initiatives and a streamlined ordering, shipping and billing process.

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

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 collectively have more than 125 years of medical aesthetics industry experience.

Our Strategy

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

Create awareness of our differentiated technologies, products and services with Plastic Surgeons and consumers. To date, we have focused most of our marketing efforts on Plastic Surgeons to promote and create awareness of the benefits of our products. We believe that investing in expanded marketing initiatives will have a positive impact on our business. We offer educational initiatives exclusively to Plastic Surgeons through our Sientra Education Forum. We also plan to expand our recent initiative to educate consumers considering breast augmentation or breast reconstruction about our technologies, products and services to drive adoption of our products.

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

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

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

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

Selectively pursue acquisitions. We may selectively pursue domestic and international acquisitions of businesses or technologies that may allow us to leverage our relationships with Plastic Surgeons and our existing commercial infrastructure to provide us with new or complementary products or technologies, and allow us to compete in new geographic markets or market segments or to increase our market share.

Recent Developments

Our financial results for the three and nine months ended September 30, 2014 are not yet finalized. However, the following information reflects our preliminary expectations with respect to such results based on information currently available to management.

We expect to report that our net sales for the three months ended September 30, 2014 will be between approximately $10.3 million and $10.6 million, representing an increase of 29% to 33%, as compared to approximately $8.0 million for the three months ended September 30, 2013. Additionally, we expect to report that our net sales for the nine months ended September 30, 2014 will be between approximately $32.3 million and $32.6 million, representing an increase of 24% to 26%, as compared to approximately $25.9 million for the nine months ended September 30, 2013. These estimated increases in our net sales from the same periods in the prior year are primarily driven by sales of our Breast Products in the United States resulting from increased commercialization activities, including the expansion of our sales organization, increased marketing activities and greater familiarity with our products and customer service offerings by Plastic Surgeons. As of September 30, 2014, our sales organization included 42 employees, as compared to 36 employees as of September 30, 2013.

We expect to report that our cost of goods sold for the three months ended September 30, 2014 will be between approximately $2.8 million and $3.0 million, as compared to approximately $2.0 million for the three months ended September 30, 2013. Additionally, we expect to report that our cost of goods sold for the nine months ended September 30, 2014 will be between approximately $8.3 million and $8.5 million, as compared to approximately $6.4 million for the nine months ended September 30, 2013. These estimated increases in our cost of goods sold from the same periods in the prior year are primarily due to an increase in sales volume. Our gross margin for the three and nine months ended September 30, 2014 is expected to decrease, as compared to the same periods in the prior year, primarily due to manufacturing price increases, targeted pricing programs and an increase in overhead related to warehouse operations.

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We expect to report that our operating expenses for the three months ended September 30, 2014 will be between approximately $8.5 million and $8.8 million, as compared to approximately $12.2 million for the three months ended September 30, 2013. Additionally, we expect to report that our operating expenses for the nine months ended September 30, 2014 will be between approximately $27.7 million and $28.0 million, as compared to approximately $35.0 million for the nine months ended September 30, 2013. These estimated decreases in our operating expenses from the same periods in the prior year are primarily due to a decrease in expenses related to the Mentor litigation and the Grader Street arbitration, partially offset by an increase in employee related expense for the sales department, an increase in marketing costs and expenses related to the federal excise tax and accounting costs.

We expect to report that other (expense) income, net for the three months ended September 30, 2014 will be approximately ($0.7) million, as compared to approximately ($0.3) million for the three months ended September 30, 2013. Additionally, we expect to report that other (expense) income, net for the nine months ended September 30, 2014 will be approximately $0.7 million, as compared to approximately ($0.7) million for the nine months ended September 30, 2013. Other (expense) income, net for the three months ended September 30, 2014 is primarily associated with interest expense on our term loans. Other (expense) income, net for the nine months ended September 30, 2014 is primarily associated with income from recovery of costs associated with the Mentor litigation of approximately $2.4 million, partially offset by interest expense on our terms loans of approximately $1.5 million. Other (expense) income, net for the three and nine months ended September 30, 2013 was primarily associated with interest expense on our term loans.

These preliminary estimates are the responsibility of management, reflect management's estimates based solely upon information available to it as of the date of this prospectus and are not a comprehensive statement of our financial results for the three and nine months ended September 30, 2014 and 2013. In addition, our independent registered public accounting firm, KPMG LLP, has not audited, reviewed or performed any procedures with respect to these preliminary financial estimates or the accounting treatment thereof and does not express an opinion or any other form of assurance with respect thereto. We expect to complete our unaudited financial statements for the quarter ended September 30, 2014 subsequent to the completion of this offering. It is possible that we or our independent registered public accounting firm may identify items that require us to make adjustments to the financial information set forth above and those changes could be material.

The ranges for the preliminary estimated financial results described above constitute forward-looking statements. Actual results may vary materially from the information contained in these forward-looking statements based on a number of factors, including those discussed under the heading "Risk Factors" and "Special Note Regarding Forward-Looking Statements." Accordingly, you should not place undue reliance upon this preliminary information. The preliminary information should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus.

Risks Related to Our Business and Our Industry

Our business is subject to numerous risks and uncertainties of which you should be aware before you decide to invest in our common stock. These risks may prevent us from achieving our business objectives, and may adversely affect our business, financial condition, results of operations and

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prospects. These risks are discussed in greater detail in the section entitled "Risk Factors" beginning on page 13 of this prospectus, including the following:

- we have incurred significant net operating losses since inception and cannot assure you that we will achieve profitability;
- our future profitability depends on the success of our Breast Products;
- we rely on a foreign, sole source, third-party to manufacture and supply our silicone gel breast implants, tissue expanders and other products;
- there are inherent risks in contracting with manufacturers located outside of the United States such as in Brazil;
- various factors outside our direct control may adversely affect manufacturing and supply of our breast implants, tissue expanders and other products;
- we have a limited operating history and may face difficulties encountered by companies early in their commercialization in competitive and rapidly evolving markets;
- if we fail to compete effectively against our competitors, many of whom have greater resources than we have, our net sales and operating results may be negatively affected;
- pricing pressure from customers and our competitors may impact our ability to sell our products at prices necessary to support our current business strategies;
- the long-term (defined as 10 years or more) safety of our products has not fully been established and our breast implants are currently under study in our PMA and post-approval studies, which could reveal unanticipated complications;
- we are subject to extensive federal and state regulation, and if we fail to comply with applicable regulations, we could suffer severe criminal or civil sanctions or be required to restructure our operations, any of which could adversely affect our business, financial condition and operating results;
- 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;
- any negative publicity concerning our products could harm our business and reputation and negatively impact our financial results; and
- other factors set forth under "Risk Factors" in this prospectus.

Corporate Information

We were incorporated in Delaware in August 2003 as Juliet Medical, Inc. and 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 *www.sientra.com*. The information on our website or accessible through our website is not incorporated by reference into this prospectus, and you should not consider information contained on our website or accessible through our website to be a part of this prospectus or in deciding whether to purchase our common stock.

Implications of Being an Emerging Growth Company

As a company with less than $1.0 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting

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requirements and is relieved of certain other significant requirements that are otherwise generally applicable to public companies. As an emerging growth company:

- we are permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- 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;
- 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.

We may take advantage of these provisions until the last day of the fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, our annual gross revenue equals or exceeds $1.0 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We may choose to take advantage of some but not all of these reduced burdens. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from our competitors that are public companies, or other public companies in which you have made an investment.

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.

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The Offering

Shares of common stock offered by us	shares.
Shares of common stock to be outstanding immediately after this offering	shares (or shares if the underwriters exercise in full their option to purchase additional shares).
Option to purchase additional shares	We have granted the underwriters an option to purchase up to additional shares of common stock from us. The underwriters can exercise this option at any time within 30 days from the date of this prospectus.
Use of proceeds	We estimate that we will receive net proceeds from this offering of approximately $ million, or $ million if the underwriters exercise in full their option to purchase additional shares, based on an assumed initial public offering price of $ per share, the mid-point of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discount and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering to expand our sales force and marketing programs, to fund research and development activities and for working capital and other general corporate purposes. We may also use a portion of the net proceeds to acquire or invest in complementary products, technologies or businesses; however, we currently have no agreements or commitments to complete any such transaction. For additional information, see "Use of Proceeds."
Risk factors	Investing in our common stock involves risks. See the section entitled "Risk Factors" beginning on page 13 of this prospectus and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Proposed NYSE symbol	"SIEN."

The number of shares of our common stock to be outstanding immediately after this offering is based upon 25,168,801 shares of common stock outstanding as of June 30, 2014, and excludes:

- 131,210 shares of common stock issuable upon exercise of outstanding warrants as of June 30, 2014, at a weighted average exercise price of $5.335 per share;
- 4,308,486 shares of common stock issuable upon exercise of outstanding options to purchase shares of common stock under our 2007 Equity Incentive Plan, or the 2007 Plan, at a weighted average exercise price of $1.27 per share;

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190,500 shares of common stock issuable upon exercise of outstanding options granted on July 22, 2014 to purchase shares of common stock under the 2007 Plan at an exercise price of $4.82 per share;

shares of common stock reserved for future grant or issuance under our 2014 Equity Incentive Plan, or the 2014 Plan, which will become effective upon the execution and delivery of the underwriting agreement for this offering; and

shares of common stock reserved for future grant or issuance under our 2014 Employee Stock Purchase Plan, or the ESPP, which will become effective upon the execution and delivery of the underwriting agreement for this offering.

Except as otherwise indicated or the context otherwise requires, the information in this prospectus assumes:

no exercise of the underwriters' option to purchase additional shares;

the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws upon the closing of this offering;

no exercise of the outstanding warrants or options described above;

the automatic conversion of all outstanding shares of our preferred stock as of June 30, 2014 into an aggregate of 24,593,087 shares of our common stock in connection with the closing of this offering; and

a for reverse stock split of our common stock to be effected prior to the closing of this offering.

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Summary Financial Data

The following tables set forth our summary financial data for the periods and as of the dates indicated. We derived the summary statement of operations data presented below for the years ended December 31, 2012 and 2013 from our audited financial statements included elsewhere in this prospectus. We derived the summary statement of operations data presented below for the six months ended June 30, 2013 and 2014 and the summary balance sheet data as of June 30, 2014 from our unaudited financial statements included elsewhere in this prospectus. In the opinion of management, the unaudited financial statements reflect all adjustments, consisting of normal recurring adjustments, necessary for a fair statement of our results for those periods. Our historical results are not necessarily indicative of future operating results and our interim results are not necessarily indicative of results for a full year or any future period.

You should read the summary financial data presented below in conjunction with the information included under the headings "Selected Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus.

	Year Ended December 31,		Six Months Ended June 30,	
	2012	2013	2013	2014
			(Unaudited)	
	(In thousands, except per share and share amounts)			
Statement of operations data:				
Net sales	$ 10,447	$ 35,171	$ 17,940	$ 21,947
Cost of goods sold	2,352	8,592	4,384	5,455
Gross profit	8,095	26,579	13,556	16,492
Operating expenses:				
Sales and marketing	17,919	22,229	10,797	11,863
Research and development	3,670	4,479	2,166	2,305
General and administrative	9,938	18,078	9,768	4,908
Total operating expenses	31,527	44,786	22,731	19,076
Loss from operations	(23,432)	(18,207)	(9,175)	(2,584)
Other (expense) income, net:				
Interest expense		(872)	(380)	(842)
Other (expense) income, net	(1)	(46)	(20)	2,264
Total other (expense) income, net	(1)	(918)	(400)	1,422
Loss before income taxes	(23,433)	(19,125)	(9,575)	(1,162)
Income taxes				

Net loss	$ (23,433)	$ (19,125)	$ (9,575)	(1,162)
Per share data:				
Basic and diluted net loss per share attributable to common stockholders[1]	$ (30.91)	$ (29.91)	$ (13.45)	(2.03)
Weighted average outstanding common shares used for net loss per share attributable to common stockholders:				
Basic and diluted[1]	758,023	639,419	712,059	572,823
Pro forma net loss per share:				
Basic and diluted (unaudited)[1]		$ (0.76)		$ (0.05)
Weighted average outstanding common shares used in computing pro forma net loss per share attributable to common stockholders:				
Basic and diluted (unaudited)[1]		25,232,506		25,165,910

(1) See Notes 3(d) and 3(u) to our financial statements appearing elsewhere in this prospectus for an explanation of the method used to calculate the basic and diluted net loss per share and pro forma net loss per share and the number of shares used in the computation of the per share amounts.

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	As of June 30, 2014 (Unaudited) (In thousands)		
	Actual	Pro Forma[1]	Pro Forma As Adjusted[2][3]
Balance sheet data (at end of period):			
Cash and cash equivalents	$ 21,637	$ 21,637	
Working capital	33,773	33,773	
Total assets	63,397	63,397	
Long-term debt	25,177	25,177	
Convertible preferred stock	150,456		
Total stockholders' (deficit) equity	(127,627)	22,829	

(1) Pro forma amounts reflect the automatic conversion of all our outstanding shares of preferred stock as of June 30, 2014 into an aggregate of 24,593,087 shares of our common stock in connection with the closing of this offering.

(2) Pro forma as adjusted amounts further adjusts the pro forma amounts to reflect the sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share, the mid-point of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discount and commissions and estimated offering expenses payable by us.

(3) A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the mid-point of the price range set forth on the cover page of this prospectus, would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately $ million, assuming the number of shares offered by us as stated on the cover of this prospectus remains unchanged and after deducting the estimated underwriting discount and commissions and estimated offering expenses payable by us. Similarly, a 1,000,000 share increase (decrease) in the number of shares offered by us, as set forth on the cover of this prospectus, would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately $ million, at the assumed initial public offering price of $ per share, the mid-point of the price range set forth on the cover of this prospectus, and after deducting the estimated underwriting discount and commissions and estimated offering expenses payable by us. The pro forma information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of our initial public offering determined at pricing.

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RISK FACTORS

An investment in our common stock involves risks. You should consider carefully the risks described below, together with all of the other information included in this prospectus, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before investing in our common stock. If any of the events contemplated in following risks actually occur, our business, financial condition, operating results and prospects could suffer. In that case, the trading price of our common stock may decline and you might lose all or part of your investment.

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 June 30, 2014, we had an accumulated deficit of $129.4 million. To date, we have financed our operations primarily through sales of preferred stock, borrowings under our term loans and, since 2012, sales of our products. We have devoted substantially all of our resources to the acquisition and clinical development of our products, the commercial launch of our products, the development of a sales and marketing team and the assembly of a management team to manage our business.

We commenced sales of our breast implants in the second quarter of 2012. For the year ended December 31, 2013, our gross profit was $26.6 million. However, although we have achieved a positive gross profit, we still operate at a substantial net loss. The extent of our future net operating losses and the timing of profitability are uncertain, especially in light of the recent commercialization of our silicone gel breast implants, which makes forecasting our sales more difficult. We will need to generate significant sales to achieve profitability, and we might not be able to do so. Even if we do generate significant sales, we might not be able to achieve, sustain or increase profitability on a quarterly or annual basis in the future. If our sales grow more slowly than we have forecasted, or if our operating expenses exceed our forecasts, our financial performance and results of operations will be adversely affected.

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

Sales of our Breast Products accounted for 98% and 97% of our net sales for the year ended December 31, 2013 and for the six months ended June 30, 2014, respectively. We expect our net sales to continue to be based primarily on sales of our Breast Products. Any product liability lawsuits, introduction of competitive products by our competitors and other third parties, the loss of market acceptance of our Breast Products, adverse rulings by regulatory authorities, adverse publicity or other adverse events relating to us or our Breast Products may significantly impact our sales and profitability, which would adversely affect our business, financial condition and results of operations.

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

We rely on Silimed Industria de Implantes Ltda. (formerly, Silimed-Silicone e Instrumental Medico-Cirugio e Hospitalar Ltda.), or Silimed, our sole source, third-party manufacturer located in Brazil, to manufacture and supply our silicone gel breast implants, tissue expanders and other products, and Silimed relies on Applied Silicone Corporation, or ASC, its sole source, third-party supplier of medical-grade silicone based in Santa Paula, California. If ASC becomes unable or willing to supply medical-grade silicone to Silimed or if Silimed becomes unable or unwilling to manufacture and supply our silicone gel breast implants, tissue expanders and other products, we will not be able to replace ASC

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

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

- our products may not be manufactured in accordance with agreed upon specifications or in compliance with regulatory requirements, or its manufacturing facilities may not be able to maintain compliance with regulatory requirements, which could negatively affect the safety or efficacy of our products or cause delays in shipments of our products;
- we may not be able to timely respond to unanticipated changes in customer orders, and if orders do not match forecasts, we may have excess or inadequate inventory of materials and components;
- we may be subject to price fluctuations when a supply contract is renegotiated or if our existing contract is not renewed;
- our agreement with Silimed does not permit us to sell the products we obtain from Silimed in any country other than the United States and Canada;
- we, Silimed or ASC may lose access to critical services and components, resulting in an interruption in the manufacture or shipment of our products;
- Silimed may not be able to find an alternate supplier in a timely manner if the medical-grade silicone becomes unavailable from ASC or we may not be able to find an alternate supplier in a timely manner if the products become unavailable from Silimed;
- we may be required to obtain regulatory approvals related to any change in our supply chain;
- ASC may wish to discontinue manufacturing and supplying products to Silimed for risk management reasons;
- Silimed may wish to discontinue manufacturing and supplying products to us for risk management reasons; and
- Silimed or ASC may encounter financial or other hardships unrelated to our demand for products, which could inhibit its ability to fulfill our orders and meet our requirements.

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

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

Silimed is our sole source, third-party manufacturer and its manufacturing plant is located in Brazil. There are inherent risks in contracting with manufacturers located outside of the United States such as in Brazil, including the risks of economic change, recession, labor strikes or disruptions, political turmoil, new or changing tariffs or trade barriers, new or different restrictions on importing or exporting, civil unrest, infrastructure failure, cultural differences in doing business, lack of contract enforceability, lack of protection for intellectual property, war and terrorism. If any of these risks were to materialize, we and Silimed would both be materially adversely affected and our business, financial condition and results of operations would suffer.

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

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

- failure of our manufacturer to follow Good Manufacturing Practices, or cGMP, requirements or mishandling of our products while in production or in preparation for transit;
- transportation and import and export risk, particularly given the global nature of our supply chain;
- delays in analytical results or failure of analytical techniques that we depend on for quality control and release of products;
- natural disasters, labor disputes, financial distress, lack of raw material supply, issues with facilities and equipment or other forms of disruption to business operations affecting our manufacturer or its suppliers; and
- latent defects that may become apparent after products have been released and which may result in a recall of such products.

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

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

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

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

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

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

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

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

- greater financial and human resources for sales, marketing and product development;
- established relationships with health care providers and third-party payors;
- established reputations and name recognition among health care providers and other key opinion leaders in the plastic surgery industry;
- in some cases, an established base of long-time customers;
- products supported by long-term clinical data;
- larger and more established distribution networks;

- greater ability to cross-sell products; and
- more experience in conducting research and development, manufacturing, performing clinical trials and obtaining regulatory approval or clearance.

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

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

Our 2012 entry into the U.S. breast implant market represented a significant expansion of the breast implant choices and technologies available in the United States. As a result of our entry into the U.S. breast implant market, our competitors intensified competitive pricing pressure for traditional round-shaped breast implants. If we are not successful in convincing customers or third-party payors of the differentiation of the gel technology used in our implants and selection of shapes and products as compared to our competitors' products, third-party payors may not cover or adequately reimburse our products and customers may choose our competitors' products. Additionally, as more competitors introduce anatomically-shaped products that compete with ours, we may face additional pricing pressure that will impact our future results.

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

We currently market our silicone gel breast implants in the United States. These products have received pre-market approval from the FDA. However, there could still be unanticipated complications or unforeseen health consequences of being implanted with our silicone gel breast implants over the long-term (defined as 10 years or more). Additionally, we compare our five-year data to our competitors' six-year data in some cases in this prospectus, and our longer term data may change due to an increase in such complications or consequences over time. Further, future studies or clinical experience may indicate that treatment with our products is not differentiated to treatment with competitive products. Such results could slow the adoption of our products and significantly reduce our sales, which could prevent us from achieving our forecasted sales targets or achieving or sustaining profitability. Moreover, if long-term results and experience indicate that our products cause unexpected or serious complications, we could be subject to mandatory product recalls, suspension or withdrawal of FDA clearance or approval and significant legal liability.

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

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

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

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

There is a learning process involved for Plastic Surgeons to become proficient in the use of our anatomically-shaped products. It is critical to the success of our commercialization efforts to train a sufficient number of Plastic Surgeons and provide them with adequate instruction in the appropriate use of our products via preceptorships and additional demonstration surgeries. This training process

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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.

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

We need to maintain substantial levels of inventory to protect ourselves from supply interruptions, provide our customers with a wide range of shapes and sizes of our breast implants, and account for the high return rates we experience as Plastic Surgeons typically order our products in multiple sizes for a single surgery and then return what they do not use. As a result of our substantial inventory levels, we are subject to the risk that a substantial portion of our inventory becomes obsolete, which could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory.

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

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

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

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

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

Our principal offices are located in Santa Barbara, California. Substantially all of our operations are conducted at this location, including customer and technical support, development and management and administrative functions. In addition, substantially all of our inventory of finished goods is held at

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a second location in Santa Barbara, California. Despite our efforts to safeguard our facilities, including acquiring insurance, adopting health and safety protocols and utilizing off-site storage of computer data, vandalism, terrorism or a natural or other disaster, such as an earthquake, fire or flood, could damage or destroy our inventory of finished goods, cause substantial delays in our operations, result in the loss of key information and cause us to incur additional expenses. Our insurance may not cover our losses in any particular case. In addition, regardless of the level of insurance coverage, damage to our facilities may have a material adverse effect on our business, financial condition and operating results.

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

The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage sales and marketing data, accounting and financial functions, inventory, product development tasks, clinical data, and customer service and technical support functions. Our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, computer viruses or hackers, power losses, and computer system or data network failures. In addition, a variety of our software systems are cloud-based data management applications hosted by third-party service providers whose security and information technology systems are subject to similar risks.

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

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

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

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

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

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

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

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

As of June 30, 2014, we had approximately 94 full-time employees. Our management and personnel, and the systems and facilities we currently have in place, may not be adequate to support future growth. Effectively executing our growth strategy requires that we increase net sales through sales and marketing activities, recruit and retain additional employees and continue to improve our operational, financial and management controls, reporting systems and procedures. If we are not able to effectively expand our organization in these ways, we may not be able to successfully execute our growth strategy, and our business, financial condition and results of operations may suffer.

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

From time to time, we may consider opportunities to partner with or acquire other businesses, products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base or advance our business strategies. Potential partnerships or acquisitions involve numerous risks, including:

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

We currently have no commitments with respect to any partnership or acquisition. We do not know if we will be able to identify partnerships or acquisitions we deem suitable, whether we will be able to successfully complete any such partnerships or acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any partnered or acquired products or technologies. Our potential

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inability to integrate any partnered or acquired products or technologies effectively or realize anticipated synergies may adversely affect our business, financial condition and results of operations.

Risks Related to Our Financial Results and Need for Financing

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

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

- the impact of the buying patterns of patients and seasonal cycles in consumer spending;
- our ability to drive increased sales of anatomically-shaped breast implants products;
- our ability to establish and maintain an effective and dedicated sales organization;
- pricing pressure applicable to our products, including adverse third-party coverage and reimbursement outcomes;
- results of clinical research and trials on our existing products;
- timing of our research and development activities and initiatives;
- the mix of our products sold due to different profit margins among our products;
- timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;
- the ability of our suppliers to timely provide us with an adequate supply of products;
- the evolving product offerings of our competitors;
- regulatory approvals and legislative changes affecting the products we may offer or those of our competitors;
- increased labor and related costs;
- interruption in the manufacturing or distribution of our products;
- the effect of competing technological, industry and market developments;

- changes in our ability to obtain regulatory clearance or approval for our products; and
- our ability to expand the geographic reach of our sales and marketing efforts.

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

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

As of June 30, 2014, we had $21.6 million in cash and cash equivalents. We believe that our available cash on hand and proceeds from this offering will be sufficient to satisfy our liquidity requirements for at least the next 18 months. However, the continued growth of our business, including the expansion of our sales force and marketing programs, and research and development activities, will significantly increase our expenses. In addition, the amount of our future product sales is difficult to predict, especially in light of the recent commercialization of our silicone gel breast implants, and actual sales may not be in line with our forecasts. As a result, we may be required to seek additional funds in the future. Our future capital requirements will depend on many factors, including:

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

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

If we are unable to raise additional capital, we may not be able to expand our sales force and marketing programs, enhance our current products or develop new products, take advantage of future opportunities, or respond to competitive pressures, changes in supplier relationships, or unanticipated changes in customer demand. Any of these events could adversely affect our ability to achieve our strategic objectives, which could have a material adverse effect on our business, financial condition and operating results.

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

Our term loan agreement with Oxford Finance LLC, or Oxford, contains certain restrictive covenants that limit our ability to transfer or dispose of certain assets, engage in new lines of business, change the composition of our management, merge with or acquire other companies, incur additional debt, create new liens and encumbrances, pay dividends or subordinated debt and enter into material transactions with affiliates, among others. We therefore may not be able to engage in any of the

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foregoing transactions unless we obtain the consent of the lender or terminate the term loan agreement. The term loan agreement also contains financial reporting requirements. There is no guarantee that we will be able to pay the principal and interest under the term loan agreement or that future working capital, borrowings or equity financing will be available to repay or refinance the amounts outstanding under the term loan agreement. In addition, we may enter into debt agreements in the future that may contain similar or more burdensome terms and covenants, including financial covenants.

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

As of December 31, 2013, we had federal net operating loss carryforwards, or NOLs, of approximately $96.9 million, which expire in various years beginning in 2027, if not utilized to offset taxable income. In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we undergo one or more ownership changes in connection with this offering or future transactions in our stock, our ability to utilize NOLs could be further limited by Section 382 of the Code. As a result of these limitations, we may not be able to utilize a material portion of the NOLs reflected on our balance sheet and for this reason, we have fully reserved against the value of our NOLs on our balance sheet.

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

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

Risks Related to Our Intellectual Property and Potential Litigation

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

Our success depends in part on our ability to protect our intellectual property rights. Our intellectual property portfolio consists of no patents or patent applications, and we do not currently plan to file for patent protection in the future, in the United States or elsewhere. We instead rely on trade secrets, proprietary know-how and regulatory barriers to protect our products and technologies and seek protection of our rights, in part, through confidentiality and proprietary information agreements. However, these agreements may not provide sufficient protection or adequate remedies for violation of our rights in the event of unauthorized use or disclosure of confidential and proprietary information. Without additional protection under the patent laws, such unauthorized use or disclosure may enable competitors to duplicate or surpass our technological achievements. Moreover, the laws of certain foreign countries do not recognize intellectual property rights or protect them to the same extent as do the laws of the United States. Failure to protect our proprietary rights could seriously impair our competitive position.

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

We rely on a license from our manufacturer for use of the Silimed trademark. In the event Silimed believes that our products do not meet its commercially reasonable quality expectations and we do not cure any deficiency within a commercially reasonable period of time to Silimed's reasonable satisfaction, Silimed may revoke our exclusive license to use the Silimed trademark. If such license is terminated, the inability to use that trademark could result in a loss of sales to us as a result of the goodwill associated with the Silimed trademark, and a competitor may use that trademark to capitalize on the goodwill associated with the Silimed trademark. Either of these outcomes could seriously impair our competitive position.

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

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

- stop making, selling or using products or technologies that allegedly infringe the asserted intellectual property;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others;
- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing;

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- 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 and harm our reputation. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages (which may be increased up to three times of awarded damages) and/or substantial royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations and financial condition.

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

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

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

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

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

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

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

We hold a number of insurance policies, including product liability insurance, directors' and officers' liability insurance, general liability insurance, property insurance and workers' compensation insurance. If the costs of maintaining adequate insurance coverage increase significantly in the future, our operating results could be materially adversely affected. Likewise, if any of our current insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. If we operate our business without insurance, we could be responsible for paying claims or judgments against us that would have otherwise been covered by insurance, which could adversely affect our results of operations or financial condition.

Risks Related to Our Legal and Regulatory Environment

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

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

- the federal Anti-Kickback Statute, which applies to our business activities, including our marketing practices, educational programs, pricing policies and relationships with healthcare providers, by prohibiting, among other things, knowingly and willfully soliciting, receiving, offering or providing any remuneration (including any bribe, kickback or rebate) directly or indirectly, overtly or covertly, in cash or in kind, intended to induce or return for the purchase or recommendation of any good, facility, item or service reimbursable, in whole or in part, under a federal healthcare program, such as the

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Medicare or Medicaid programs. A person or entity does not need to have actual knowledge of the Anti-Kickback Statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims laws;

federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, or FCA, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent, or making a false statement material to an obligation to pay or transmit money or property to the federal government, and which may apply to entities that provide coding and billing advice to customers;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and its implementing regulations, which created federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and, as amended by the Health Information Technology for Economic and Clinical Health Act, also imposes certain regulatory and contractual requirements regarding the privacy, security and transmission of individually identifiable health information;

federal "sunshine" requirements imposed by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or PPACA, on certain device manufacturers regarding any "transfers of value" provided to physicians and teaching hospitals. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1 million per year for "knowing failures," for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission. The period between August 1, 2013 and December 31, 2013 was the first reporting period, and manufacturers were required to report aggregate payment data by March 31, 2014, and were required to report detailed payment data and submit legal attestation to the accuracy of such data by June 30, 2014. Thereafter, manufacturers must submit reports by the 90th day of each subsequent calendar year; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be provided to healthcare providers and entities; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers and entities or marketing expenditures; and state laws governing the privacy and security of certain health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws, it is possible that some of our business activities, including our relationships with physicians and other health care providers and entities, some of whom recommend, purchase and/or prescribe our products, could be subject to challenge under one or more of such laws. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and/or criminal penalties, damages, fines, disgorgement, contractual

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damages, reputational harm, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

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

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

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

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

Before we can market or sell a new regulated product or a significant modification to an existing product in the United States, we must obtain either clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or FDCA, or an approval of a pre-market approval, or PMA, application unless the device is specifically exempt from pre-market review. In the 510(k) clearance process, the FDA must determine that a

proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices for which the 510(k) process cannot be used and that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. Modifications to products that are approved through a PMA application generally need FDA approval. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). The FDA's 510(k) clearance process usually takes from three to 12 months, but may last longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and

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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. For example, in 2011, the FDA announced a Plan of Action to modernize and improve the FDA's pre-market review of medical devices, and has implemented, and continues to implement, reforms intended to streamline the pre-market review process. In addition, as part of the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, Congress enacted several reforms entitled the Medical Device Regulatory Improvements and additional miscellaneous provisions which will further affect medical device regulation both pre- and post-approval. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products.

The FDA could also reclassify some or all of our products that are currently classified as Class II to Class III requiring additional controls, clinical studies and submission of a PMA for us to continue marketing and selling those products. Under new changes instituted by FDASIA, the FDA may now change the classification of a medical device by administrative order instead of by regulation. Although the revised process is simpler, the FDA must still publish a proposed order in the Federal Register, hold a device classification panel meeting and consider comments from affected stakeholders before issuing the reclassification order. We cannot guarantee that the FDA will not reclassify any of our Class II devices into Class III and require us to submit a PMA for FDA review and approval of the safety and effectiveness of our product. Any delay in, or failure to receive or maintain, clearance or approval for our products under development could prevent us from generating sales from these products or achieving profitability. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could dissuade some surgeons from using our products and adversely affect our reputation and the perceived safety and efficacy of our products.

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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 postmarketing studies. For example, we are required to continue to study and report clinical results to the FDA on our silicone gel breast implants. Failure to conduct this or other required studies in a timely manner could result in the revocation of the PMA approval or 510(k) clearance for the product that is subject to such a requirement and could also result in the recall or withdrawal of the product, which would prevent us from generating sales from that product in the United States.

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

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

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

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

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

untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;

unanticipated expenditures to address or defend such actions;

customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;

operating restrictions or partial suspension or total shutdown of production;

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- refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products;
- withdrawing 510(k) clearances or pre-market approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Any of the foregoing actions could have a material adverse effect on our reputation, business, financial condition and operating results. Furthermore, our manufacturer may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

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

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

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

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

In the United States, our silicone gel breast implants are marketed pursuant to a PMA order issued by the FDA in March 2012, and our tissue expanders are marketed pursuant to pre-market clearance under Section 510(k) of the FDCA. Any modifications to a PMA-approved or 510(k)-cleared device that could significantly affect its safety or effectiveness, including significant design and manufacturing changes, or that would constitute a major change in its intended use, manufacture, design, components, or technology requires a new 510(k) clearance or, possibly, approval of a new PMA application or PMA supplement. However, certain changes to a PMA-approved device do not require submission and approval of a new PMA or PMA supplement and may only require notice to FDA in a PMA 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.

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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 recordkeeping requirements for all firm-initiated medical device corrections and removals, and to report such corrective and removal actions to FDA if they are carried out in response to a risk to health and have not otherwise been reported under the medical device reporting regulations. In addition, in December of 2012, the FDA issued a draft guidance intended to assist the FDA and industry in distinguishing medical device recalls from product enhancements. Per the guidance, if any change or group of changes to a device addresses a violation of the FDCA, that change would generally constitute a medical device recall and require submission of a recall report to the FDA. Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our business, including our ability to market our products in the future.

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

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

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

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

Our educational and promotional activities and training methods must comply with FDA and other applicable laws, including the prohibition of the promotion of a medical device for a use that has not been cleared or approved by the FDA. Use of a device outside of its cleared or approved indications is known as "off-label" use. Physicians may use our products off-label in their professional medical judgment, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our educational and promotional activities or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of warning letters, untitled letters, fines, penalties, injunctions, or seizures, which could have an adverse impact on our reputation and financial results. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our educational and promotional activities or training methods to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products could be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, and the curtailment or restructuring of our operations. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us, and harm our reputation.

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

Maintaining and growing sales of our products when used in breast reconstruction procedures depends, in part, on the availability of coverage and adequate reimbursement from third-party payors, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs. Hospitals and other healthcare provider customers that purchase our products to use in breast reconstruction procedures typically bill various third-party payors to cover all or a portion of the costs and fees associated with the procedures in which our products are used, including the cost of the purchase of our products. Changes in the amount third-party payors are willing to reimburse our customers for breast reconstruction procedures using our products could create pricing pressures for us. We may be unable to sell our products on a profitable basis if third-party payors deny coverage or reduce their current levels of payment, or if our costs of production increase faster than increases in reimbursement levels.

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

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

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

Recent political, economic and regulatory influences are subjecting the health care industry to fundamental changes. The sales of our products depend, in part, on the availability of coverage and adequate reimbursement from third-party payors such as government health programs, private health insurers, health maintenance organizations and other health care-related organizations. Both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation and regulations designed to contain or reduce the cost of health care. Such legislation and regulations may result in decreased reimbursement for medical devices and/or the procedures in which they are used, which may further exacerbate industry-wide pressure to reduce the prices charged for medical devices. This could harm our ability to market and generate sales from our products.

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

Federal and state governments in the United States have recently enacted legislation to overhaul the nation's health care system. In March 2010, the PPACA was signed into law. While the goal of health

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care reform is to expand coverage to more individuals, it also involves increased government price controls, additional regulatory mandates and other measures designed to constrain medical costs. The PPACA substantially changes the way healthcare is financed by both governmental and private insurers, encourages improvements in the quality of healthcare items and services and significantly impacts the medical device industry. Among other things, the PPACA:

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

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

In the future there may continue to be additional proposals relating to the reform of the U.S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products, or the amount of reimbursement available for our products, and could limit the acceptance and availability of our products, any of which could have a material adverse effect on our business, results of operations and financial condition.

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

In order to market our products in Canada, we must obtain and maintain separate regulatory approvals and comply with numerous and varying regulatory requirements. We currently market our tissue expanders and facial implants in Canada, but are awaiting Health Canada's approval to market our breast implant products in Canada. Although we do not anticipate any additional nonclinical or clinical study requirements, we may be delayed in obtaining approval to sell our breast implants in Canada if we need to respond to requests for information from Health Canada during the review process, which remains ongoing. The time required to obtain regulatory approval in Canada may be longer than the time required to obtain FDA pre-market approval. The Canadian regulatory approval process includes many of the risks associated with obtaining FDA clearance and we may not obtain Canadian regulatory approval on a timely basis, if at all. FDA approval does not ensure approval by regulatory authorities in other countries, including Canada, and approval by one foreign regulatory

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authority does not ensure approval by regulatory authorities in other foreign countries. However, the failure to obtain clearance or approval in one jurisdiction may have a negative impact on our ability to obtain clearance or approval elsewhere. If we do not obtain or maintain necessary approvals to commercialize our products in Canada, it would negatively affect our overall market penetration.

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

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

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

We are not currently required to comply with HIPAA or HITECH because we are neither a Covered Entity nor a Business Associate (as that term is defined by HIPAA). However, in administering our warranties and complying with FDA required device tracking, we do regularly handle confidential and personal information similar to that which these laws seek to protect. We also occasionally encounter hospital customers who pressure us to sign Business Associate Agreements, or BAAs, although, to date, we have refused, given that we do not believe we are business associates to such Covered Entities under HIPAA or HITECH. If the law or regulations were to change or if we were to agree to sign a BAA, the costs of complying with the HIPAA standards are burdensome and could have a material adverse effect on our business. In addition, under such situations there would be significant risks and financial penalties for us if we were then found to have violated the laws and regulations that pertain to Covered Entities and Business Associates.

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

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

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

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

Risks Related to This Offering and Ownership of Our Common Stock

No public market for our common stock currently exists and an active trading market may not develop or be sustained following this offering.

Prior to this initial public offering, there has been no public market for our common stock. Although we intend to apply to list our common stock on the New York Stock Exchange, or NYSE, an active trading market may not develop or be sustained following the completion of this offering. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value or the trading price of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

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 initial public offering price for our common stock has been determined through our negotiations with the underwriters and may not be representative of the price that will prevail in the open market following the offering. Our stock price after the completion of this offering may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in this "Risk Factors" section of this prospectus and others such as:

- a slowdown in the medical device industry, the aesthetics industry or the general economy;
- actual or anticipated quarterly or annual variations in our results of operations or those of our competitors;
- changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;
- actual or anticipated changes in our growth rate relative to our competitors;
- changes in earnings estimates or recommendations by securities analysts;

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- fluctuations in the values of companies perceived by investors to be comparable to us;
- announcements by us or our competitors of new products or services, significant contracts, commercial relationships, capital commitments or acquisitions;
- competition from existing technologies and products or new technologies and products that may emerge;
- the entry into, modification or termination of agreements with our sales representatives or distributors;
- developments with respect to intellectual property rights;
- sales, or the anticipation of sales, of our common stock by us, our insiders or our other stockholders, including upon the expiration of contractual lock-up agreements;
- our ability to develop and market new and enhanced products on a timely basis;
- our commencement of, or involvement in, litigation;
- additions or departures of key management or technical personnel; and
- changes in laws or governmental regulations applicable to us.

In recent years, the stock markets generally have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors may significantly affect the market price of our common stock, regardless of our actual operating performance. These fluctuations may be even more pronounced in the trading market for our common stock shortly following this offering. If the market price of shares of our common stock after this offering does not ever exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment.

We could be subject to securities class action litigation.

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

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

After the completion of this offering, we do not anticipate declaring any cash dividends to holders of our common stock in the foreseeable future. In addition, our ability to pay cash dividends is currently prohibited by the terms of our existing loan agreement and may be prohibited by future loan agreements. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

Prior to this offering, as of June 30, 2014, our executive officers, directors and principal stockholders beneficially owned approximately 98.8% of our outstanding voting stock and, upon the closing of this offering, will hold approximately % of our outstanding voting stock (assuming no exercise of the underwriters' option to purchase additional shares), in each case based on the assumed initial public offering price of $ per share, the mid-point of the price range set forth on the cover page of this prospectus. Therefore, even after this offering, these stockholders have the ability to influence us through their ownership position and may be able to determine all matters requiring stockholder

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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.

Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.

The initial public offering price of our common stock is substantially higher than the net tangible book value per share of our common stock immediately prior to this offering. Therefore, if you purchase our common stock in this offering, you will incur an immediate dilution of $ in pro forma as adjusted net tangible book value per share as of June 30, 2014 from the price you paid, based on an assumed initial public offering price of $ per share, the mid-point of the range set forth on the cover page of this prospectus. In addition, new investors who purchase shares in this offering will contribute approximately % of the total amount of equity capital raised by us through the date of this offering, but will only own approximately % of the outstanding share capital and approximately % of the voting rights. In addition, we have issued options and warrants to acquire common stock at prices below the initial public offering price. To the extent outstanding options and warrants are ultimately exercised, there will be further dilution to investors who purchase shares in this offering. In addition, if the underwriters exercise their option to purchase additional shares or if we issue additional equity securities, investors purchasing shares in this offering will experience additional dilution. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. For a further description of the dilution that you will experience immediately after this offering, see "Dilution."

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 permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- 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.

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

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

As a public company, and increasingly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and the NYSE impose numerous requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Also, the Securities Exchange Act of 1934, as amended, or the Exchange Act, requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel will need to devote a substantial amount of time to compliance with these laws and regulations. These requirements have increased and will continue to increase our legal, accounting and financial compliance costs and have made and will continue to make some activities more time consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or our board committees or as executive officers.

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

Our internal control over financial reporting does not currently meet the standards required by Section 404 of the Sarbanes-Oxley Act, and failure to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could result in material misstatements of our annual or interim financial statements and have a material adverse effect on our business and share price.

We are not currently required to comply with Section 404 of the Sarbanes-Oxley Act, and are therefore not yet required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Upon becoming a public company, we will however be required to comply with certain of these rules, which will require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting commencing with our second annual report. This assessment will need to include the disclosure of any material weaknesses in our internal control over financial reporting identified by our management or our independent registered public accounting firm. A "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

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Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of our second annual report or the first annual report required to be filed with the SEC following the date we are