SIENTRA, INC.

FORM 10-Q
(Quarterly Report)

Filed 11/21/14 for the Period Ending 09/30/14

Address	420 SOUTH FAIRVIEW AVENUE SUITE 200 SANTA BARBARA, CA 93117
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Symbol	SIEN
SIC Code	3842 - Orthopedic, Prosthetic, and Surgical Appliances and Supplies
Fiscal Year	12/31

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

OR

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

For the transition period from to

Commission file number: 001-36709

SIENTRA, INC.
(Exact Name of Registrant as Specified in its Charter)

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

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

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

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

Indicate by check mark 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. (Check one):

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

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

As of November 3, 2014, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 14,912,613.

SIENTRA, INC.

FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2014

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PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

SIENTRA, INC.
Condensed Balance Sheets
(In thousands, except per share and share amounts)
(Unaudited)

	September 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 19,816	$ 9,722
Accounts receivable, net of allowances of $10,452 and $8,543 at September 30, 2014 and December 31, 2013, respectively	4,317	6,111
Inventories, net	19,247	21,533
Prepaid expenses and other current assets	3,782	884
Total current assets	47,162	38,250
Property and equipment, net	449	254
Goodwill	14,278	14,278
Other intangible assets, net	138	207
Other assets	248	177
Total assets	$ 62,275	$ 53,166
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Current portion of long-term debt	$ 1,487	$ —
Accounts payable	2,589	4,768
Accrued and other current liabilities	4,593	4,065
Customer deposits	7,258	4,908
Total current liabilities	15,927	13,741
Long-term debt, net of current portion	23,817	15,092
Warranty reserve and other long-term liabilities	985	550
Total liabilities	40,729	29,383
Commitments and contingencies (note 10)		
Convertible preferred stock, $0.01 par value — Authorized, issued and outstanding 24,593,087 shares at September 30, 2014 and December 31, 2013 (Liquidation preference of $151,000 as of September 30, 2014 and December 31, 2013)	150,456	150,456
Stockholders' deficit:		
Common stock, $0.01 par value — Authorized 30,200,000 shares; Issued 282,071 and 279,879 and outstanding 209,344 and 207,152 shares at September 30, 2014 and December 31, 2013, respectively	3	3
Additional paid-in capital	2,196	1,819
Treasury stock, at cost (72,727 shares at September 30, 2014 and December 31, 2013)	(260)	(260)
Accumulated deficit	(130,849)	(128,235)
Total stockholders' deficit	(128,910)	(126,673)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 62,275	$ 53,166

See accompanying notes to condensed financial statements.

SIENTRA, INC.
Condensed Statements of Operations
(In thousands, except per share and share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Net sales	$ 10,670	7,981	32,617	25,921
Cost of goods sold	2,832	1,968	8,287	6,352
Gross profit	7,838	6,013	24,330	19,569
Operating expenses:				
Sales and marketing	4,711	4,704	16,574	15,501
Research and development	1,246	1,234	3,551	3,400
General and administrative	2,634	6,304	7,542	16,072
Total operating expenses	8,591	12,242	27,667	34,973
Loss from operations	(753)	(6,229)	(3,337)	(15,404)
Other (expense) income, net:				
Interest expense	(665)	(232)	(1,507)	(612)
Other (expense) income, net:	(34)	(14)	2,230	(34)
Total other (expense) income, net	(699)	(246)	723	(646)
Loss before income taxes	(1,452)	(6,475)	(2,614)	(16,050)
Income taxes	—	—	—	—
Net loss	$ (1,452)	(6,475)	(2,614)	(16,050)
Basic and diluted net loss per share attributable to common stockholders	$ (6.94)	(31.45)	(12.53)	(66.58)
Weighted average outstanding common shares used for net loss per share attributable to common stockholders:				
Basic and diluted	209,344	205,901	208,648	241,057

See accompanying notes to condensed financial statements.

SIENTRA, INC.
Condensed Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2014	**2013**
Cash flows from operating activities:		
Net loss	$ (2,614)	$ (16,050)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	196	209
Provision for sales return reserve	1,973	3,186
(Recovery of) provision for doubtful accounts	(64)	—
Provision for warranties	363	300
Change in fair value of warrants	135	34
Non cash interest expense	350	137
Stock-based compensation expense	368	256
Changes in assets and liabilities:		
Accounts receivable	(115)	(6,925)
Prepaid expenses, other current assets and other assets	(1,035)	(258)
Inventories	2,285	(9,031)
Accounts payable	(2,815)	5,732
Accrued and other liabilities	169	(369)
Customer deposits	2,350	4,421
Net cash provided by (used in) operating activities	1,546	(18,358)
Cash flows from investing activities:		
Purchase of property and equipment	(320)	(60)
Contingent payment related to Silimed acquisition	—	(18,000)
Net cash used in investing activities	(320)	(18,060)
Cash flows from financing activities:		
Proceeds from exercise of stock options	9	10
Repurchase of common stock	—	(260)
Proceeds from issuance of long-term debt	10,000	10,000
Deferred financing costs	(148)	(108)
Deferred equity issuance costs	(993)	—
Net cash provided by financing activities	8,868	9,642
Net increase (decrease) in cash and cash equivalents	10,094	(26,776)
Cash and cash equivalents at:		
Beginning of period	9,722	39,208
End of period	$ 19,816	$ 12,432
Supplemental disclosure of cash flow information:		
Cash paid during the year for:		
Interest	$ 1,052	$ 410
Supplemental disclosure of noncash investing activities:		
Accrued deferred equity issuance costs	$ 818	$ —

See accompanying notes to condensed financial statements.

SIENTRA, INC.
Notes to the Condensed Financial Statements
(Unaudited)

1. Formation and Business of the Company

a. Formation

Sientra, Inc., or the Company, was incorporated in the State of Delaware on August 29, 2003 under the name Juliet Medical, Inc. and subsequently changed its name to Sientra, Inc. in April 2007. The Company acquired substantially all the assets of Silimed, Inc., or Silimed, on April 4, 2007. The purpose of the acquisition was to acquire the rights to the silicone breast implant clinical trials. Following this acquisition, the Company focused on completing the clinical trials to gain Food and Drug Administration, or FDA, approval to offer its silicone gel breast implants in the United States.

In March 2012, Sientra announced it had received approval from the FDA for its portfolio of silicone gel breast implants, and in the second quarter of 2012 the Company began commercialization efforts to sell its products in the United States. The Company, based in Santa Barbara, California, is a medical aesthetics company that focuses on serving board-certified plastic surgeons and offers a portfolio of silicone shaped and round breast implants, tissue expanders, and body contouring products.

b. Initial Public Offering

The Company completed an initial public offering, or IPO, of its common stock on November 3, 2014. See note 11, Subsequent Events for disclosures related to the IPO and other related transactions.

c. Reverse Stock Split

On October 10, 2014, the board of directors and stockholders approved an amendment to the Company's fourth amended and restated certificate of incorporation, which was filed on October 17, 2014, which effected a 1 for 2.75 reverse stock split of the Company's issued and outstanding shares of common stock. The par value of the common stock was not adjusted as a result of the reverse stock split. All issued and outstanding shares of common stock, stock options and warrants and the related per share amounts contained in the Company's condensed financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented. Also, as a result of the reverse stock split of the common stock, the conversion ratios for all of the Company's convertible preferred stock have been adjusted such that the preferred stock are now convertible into shares of common stock at a conversion rate of 2.75-to-1 instead of 1-to-1. The number of issued and outstanding shares of preferred stock and their related per share amounts have not been affected by the reverse stock split and therefore have not been adjusted in the Company's condensed financial statements. However, to the extent that the convertible preferred stock are presented on an as converted to common stock basis, such share and per share amounts contained in the Company's financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented.

2. Summary of Significant Accounting Policies

a. Basis of Presentation

The accompanying unaudited condensed financial statements in this Quarterly Report on Form 10-Q have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, and the rules and regulations of the U.S. Securities and Exchange Commission, or SEC. Accordingly, they do not include certain footnotes and financial presentations normally required under accounting principles generally accepted in the United States of America for complete financial reporting. The interim financial information is unaudited, but reflects all normal adjustments and accruals which are, in the opinion of management, considered necessary to provide a fair presentation for the interim periods presented. The accompanying condensed financial statements should be read in conjunction with the Company's audited financial statements and notes thereto included in the Company's final prospectus filed pursuant to Rule 424(b)(1) under the Securities and Exchange Act of 1933, as amended, relating to the Company's Registration Statement on Form S-1 (File No. 333-198837), filed with the SEC. The results for the three and nine months ended September 30, 2014 are not necessarily indicative of results to be expected for the year ending December 31, 2014, any other interim periods, or any future year or period.

b. Use of Estimates

The preparation of the condensed financial statements, in conformity with GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates.

c. Significant Accounting Policies

There have been no significant changes to the accounting policies during the three and nine months ended September 30, 2014, as compared to the significant accounting policies described in Note 3 of the "Notes to Financial Statements" in the Company's audited financial statements included in the final prospectus filed with the SEC on October 29, 2014 other than those listed below.

Deferred Equity Issuance Costs

Deferred equity issuance costs, primarily consisting of legal, accounting and other direct fees and costs relating to the IPO, are capitalized. The deferred equity issuance costs were offset against the IPO proceeds upon the closing of the offering in November 2014. As of September 30, 2014, there was $1,811 in deferred equity issuance costs capitalized in other current assets on the condensed balance sheet. There were no deferred equity issuance costs capitalized as of December 31, 2013.

d. Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued accounting standard update 2014-09, *Revenue from Contracts with Customers* . The standard was issued to provide a single framework that replaces existing industry and transaction specific US GAAP with a five step analysis of transactions to determine when and how revenue is recognized. This accounting standard updated will be effective for the Company beginning in fiscal year 2018. The Company is currently assessing the impact that the standard will have on the financial statements upon adoption of the guidance.

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

3. Fair Value of Financial Instruments

The Company has estimated the fair value of its financial instruments using the following methods and assumptions:

- Cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, and customer deposits are carried at cost, which approximates fair value because of the short term nature of those instruments.

- Long-term debt is included in the balance sheet at its amortized cost. The carrying value of the long-term debt approximates its fair value. The fair value of the Company's long-term debt was determined based on the relative timing of the instruments, all under substantially the same terms, including the issuance of each of the three tranches (tranche A, B, and C) drawn in 2013. In addition, tranches B and C were made available to the Company based on the Company meeting certain performance milestones. Furthermore, on June 30, 2014, the Company negotiated with Oxford Finance LLC, or Oxford, to amend the Loan and Security Agreement and raise an additional $10,000 in a fourth tranche (tranche D). The terms for tranche D were substantially the same as for the prior tranches (see Note 8). Based upon this, for December 31, 2013 and September 30, 2014, the Company has determined the carrying value closely approximates the fair value.

4. Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Observable inputs (other than Level 1 quoted prices) such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's common stock warrant liabilities are carried at fair value determined according to the fair value hierarchy described above. The Company has utilized an option pricing valuation model to determine the fair value of its outstanding common stock warrant liabilities. The inputs to the model include fair value of the common stock related to the warrant, exercise price of the warrant, expected term, expected volatility, risk-free interest rate and dividend yield. The Company determines the fair value per share of the underlying common stock by taking into consideration its most recent sale of its convertible preferred stock, the occurrence of the initial public offering, as well as additional factors that the Company deems relevant. The Company historically has been a private company and lacks company-specific historical and implied volatility information of its stock. Therefore, it estimates its expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrants. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. The Company has estimated a 0% dividend yield based on the expected dividend yield and the fact that the Company has never paid or declared dividends. As several significant inputs are not observable, the overall fair value measurement of the warrants is classified as Level 3.

The following tables present information about the Company's liabilities that are measured at fair value on a recurring basis as of September 30, 2014 and December 31, 2013 and indicate the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of September 30, 2014 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Liability for common stock warrants	$ —	—	335	335

	Fair Value Measurements as of December 31, 2013 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Liability for common stock warrants	$ —	—	90	90

The following table provides a rollforward of the aggregate fair values of the Company's common stock warrants for which fair value is determined by Level 3 inputs:

Balance, December 31, 2013	$ 90
Fair value of warrants upon issuance during 2014	110
Increase in fair value through September 30, 2014	135
Balance, September 30, 2014	335

5. Product Warranties

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

The Company accrued for warranties issued during the three months ended September 30, 2014 and 2013 in the amounts of $117 and $97, respectively, and accrued for warranties issued during the nine months ended September 30, 2014 and 2013 in the amounts of $363 and $300, respectively. As of September 30, 2014 and December 31, 2013, the Company held total warranty liabilities of $878 and $515, respectively.

6. Net Loss Per Share

Basic loss per share attributable to common stockholders is computed by dividing net loss by the weighted average number of common shares outstanding during each period. Diluted loss per common share is computed by dividing net loss available to common stockholders by the weighted average number of common shares and dilutive potential common share equivalents then outstanding, to the extent they are dilutive. Potential common shares consist of shares issuable upon the exercise of stock options and warrants (using the treasury stock method), and the weighted average conversion of the convertible preferred stock into shares of common stock (using the if-converted method). Dilutive loss per share is the same as basic loss per share for all periods presented because the effects of potentially dilutive items were anti-dilutive.

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Net loss	$ (1,452)	(6,475)	(2,614)	(16,050)
Weighted average common shares outstanding, basic and diluted	209,344	205,901	208,648	241,057
Net loss per share attributable to common stockholders	(6.94)	(31.45)	(12.53)	(66.58)

The Company excluded the following potentially dilutive securities, outstanding as of September 30, 2014 and 2013, from the computation of diluted net loss per share attributable to common stockholders for the three months and nine months ended September 30, 2014 and 2013 because they had an anti-dilutive impact due to the net loss attributable to common stockholders incurred for the periods.

	September 30,	
	2014	2013
Stock options to purchase common stock	1,631,922	1,409,408
Warrants for the purchase of common stock	47,710	20,446
Convertible preferred stock (as converted to common stock)	8,942,925	8,942,925
	10,622,557	10,372,779

7. Balance Sheet Components

a. Allowance for Sales Returns and Doubtful Accounts

The Company has established an allowance for sales returns of $10,243 and $8,270 as of September 30, 2014 and December 31, 2013, respectively, recorded net against accounts receivable in the balance sheet.

The Company has established an allowance for doubtful accounts of $209 and $273 as of September 30, 2014 and December 31, 2013, respectively, recorded net against accounts receivable in the balance sheet.

b. Property and Equipment

Property and equipment, net consist of the following:

	September 30, 2014	December 31, 2013
Leasehold improvements	$ 58	19
Computer equipment	202	183
Software	85	85
Office equipment	139	128
Furniture and fixtures	708	456
	1,192	871
Less accumulated depreciation and amortization	(743)	(617)
	$ 449	254

Depreciation expense for the three months ended September 30, 2014 and 2013 was $47 and $38, respectively. Depreciation expense for the nine month ended September 30, 2014 and 2013 was $126 and $110, respectively.

c. Goodwill and Other Intangible Assets, net

The goodwill on the condensed balance sheets was $14,278 for all periods presented.

The components of the Company’s intangible assets are as follows:

	September 30, 2014	December 31, 2013
Acquired FDA non-gel product approval	$ 1,713	1,713
Less accumulated amortization	(1,575)	(1,506)
	$ 138	207

Amortization expense for the three months ended September 30, 2014 and 2013 was $23 and $33, respectively. Amortization expense for the nine months ended September 30, 2014 and 2013 was $70 and $99, respectively.

d. Accrued and Other Current Liabilities

Accrued and other current liabilities consist of the following:

	September 30, 2014	December 31, 2013
Accrued clinical trial and research and development expenses	$ 180	166
Audit, consulting and legal fees	181	124
Payroll and related expenses	2,039	1,890
Accrued commission	1,081	1,563
Other	1,112	322
	$ 4,593	4,065

8. Long-term Debt

On January 17, 2013, the Company entered into a Loan and Security Agreement, or the Original Term Loan Agreement, with Oxford providing for a $15,000 term loan facility consisting of original term loans of (i) a $7,500 tranche A term loan, (ii) a $2,500 tranche B term loan and (iii) a $5,000 tranche C term loan, maturing on February 1, 2017. The term loan facility is collateralized by a first-priority security interest in substantially all of the Company's assets. Borrowings under the term loan facility bear interest at a rate equal to 8.4% per annum and the Original Term Loan Agreement provides for interest-only payments through June 30, 2015. The term loans include an additional lump sum payment of $975 due on February 1, 2017.

On June 30, 2014, the Company entered into the Amended and Restated Loan and Security Agreement, or the Amended Term Loan Agreement, with Oxford, under which the interest-only period for the original term loans was extended to August 1, 2015 and raised an additional $10,000 in a fourth tranche (tranche D) maturing on January 1, 2019. The term loans are collateralized by a first-priority security interest in substantially all of the Company's assets. The term loans bear interest at a rate equal to 8.4% per annum. The interest-only period for the tranche A, B and C term loans ends on August 1, 2015 and the interest-only period for the tranche D term loan ends on the same date, but with a possible extension of another year if the Company raises at least $50,000 in gross proceeds as part of an initial public offering before June 30, 2015 (see Note 11). The tranche D term loan includes an additional lump sum payment of $650 due on January 1, 2019.

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

The aggregate maturities of long-term debt as of September 30, 2014 are: $0 in the remaining three months of 2014, $3,757 in 2015, $11,094 in 2016, $5,558 in 2017, $4,223 in 2018 and $368 in 2019.

In connection with the Original Term Loan Agreement and the Amended Term Loan Agreement, the Company issued to Oxford (i) seven-year warrants in January 2013 to purchase shares of the Company's common stock with a value equal to 3.0% of the tranche A, B and C term loans amounts and (ii) seven-year warrants in June 2014 to purchase shares of the Company's common stock with a value equal to 2.5% of the tranche D term loan amount. The warrants have an exercise price per share equal to the lesser of (i) the Series C preferred stock conversion price of $14.671 per share or (ii) the price per share in a subsequent qualified round of financing where gross proceeds are greater than $10,000.

The fair value of the warrants at September 30, 2014 and December 31, 2013 was $335 and $90, respectively, and was recorded in accrued and other current liabilities in the balance sheet. The Company recognized changes in the fair value of these warrants amounting to $42 and $14 in other (expense) income, net in the statements of operations for the three months ended September 30, 2014 and 2013, respectively, and $135 and $34 for the nine months ended September 30, 2014 and 2013, respectively.

9. Stockholders' Deficit

a. Convertible Preferred Stock

Under the Company's certificate of incorporation, as amended, the Company's convertible preferred stock is issued in three series: A, B and C. At September 30, 2014 and December 31, 2013, the Company's convertible preferred stock consists of the following:

Series	Shares authorized	Outstanding	Proceeds net of issuance costs	Liquidation value	Issue Date
A	1,000,000	1,000,000	$ 994	1,000	October 2006
B	11,409,397	11,409,397	84,909	85,000	April 2007 and October 2008
C	12,183,690	12,183,690	64,553	65,000	March 2012
	24,593,087	24,593,087	$ 150,456	151,000	

b. Common Stock

The Company's certificate of incorporation, as amended, authorizes the Company to issue 30,200,000 shares of $0.01 par value common stock. At September 30, 2014 and December 31, 2013, the Company has reserved sufficient shares of common stock for issuance upon conversion of convertible preferred stock and exercise of stock options. Common stockholders are entitled to dividends when and if declared by the board of directors. There have been no dividends declared to date. The holder of each share of common stock is entitled to one vote.

c. Stock Option Plan

In April 2007, the Company adopted the 2007 Equity Incentive Plan, or the 2007 Plan. The 2007 Plan provides for the granting of stock options to employees, directors and consultants of the Company. Options granted under the 2007 Plan may either be incentive stock options or nonstatutory stock options. Incentive stock options, or ISOs, may be granted only to Company employees. Nonstatutory stock options, or NSOs, may be granted to all eligible recipients. A total of 1,690,448 shares of the Company's common stock were reserved for issuance for the 2007 Plan.

Options under the 2007 Plan may be granted for periods of up to ten years as determined by the board of directors, provided, however, that (i) the exercise price of an ISO shall not be less than 100% of the estimated fair value of the shares on the date of grant, and (ii) the exercise price of an ISO granted to a more than 10% shareholder shall not be less than 110% of the estimated fair value of the shares on the date of grant. An NSO has no such exercise price limitations. The options generally vest over four years. The vesting provisions of individual options may vary but provide for vesting of at least 25% per year.

The following summarizes all option activity under the 2007 Equity Incentive Plan:

		Options outstanding		
	Options available for grant	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Balances at December 31, 2013	260,980	1,422,315	$ 2.67	5.76
Additional shares authorized	—	—		
Options granted	(224,707)	224,707	11.70	
Options exercised	—	(2,193)	3.99	
Options forfeited	12,907	(12,907)	3.95	
Balances at September 30, 2014	49,180	1,631,922	$ 3.90	5.63

For stock-based awards the Company recognizes compensation expense based on the grant date fair value using the Black-Scholes option valuation model. Stock-based compensation expense was $169 and $85 for the three months ended September 30, 2014 and 2013, respectively. Stock-based compensation expense was $368 and $256 for the nine months ended September 30, 2014 and 2013, respectively. As of September 30, 2014, there was $1,784 of unrecognized compensation costs related to stock options. The expense is recorded within the operating expense captions in the statement of operations based on the employees receiving the awards. These costs are expected to be recognized over weighted average period of 2.84 years.

10. Commitments and Contingencies

a. Operating Leases

The Company's general office facility in Santa Barbara, California, lease expires in February 2020. The Company also has warehouse leases for additional general office, warehouse and research and development. Rent expense was $152 and $84 for the three months ended September 30, 2014 and 2013, respectively, and $332 and $256 for the nine months ended September 30, 2014 and 2013, respectively. The Company recognizes rent expense on a straight-line basis over the lease term.

b. Contingencies

The Company is subject to claims and assessment from time to time in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. There were no contingent liabilities requiring accrual at September 30, 2014.

On March 27, 2012, Mentor Worldwide LLC, or Mentor, a wholly owned subsidiary of Johnson & Johnson, filed thirteen lawsuits against fifteen employees of the Company (all former Mentor employees) and, on June 8, 2012, filed a fourteenth lawsuit against the Company and an additional employee. In general, these fourteen lawsuits alleged that the former employees of Mentor breached their confidentiality and non-compete agreements when they resigned in favor of employment with the Company; misappropriated confidential Mentor information and trade secrets; and breached their respective duties of loyalty. Although not a party to thirteen employee lawsuits, the Company provided for the defense of its employees in the lawsuits. In the employee lawsuits, all of Mentor's claims for Preliminary Injunctive Relief were denied. Following that, some of the employee lawsuits were dismissed with prejudice and others dismissed without prejudice. On October 3, 2013, the last of the thirteen employee lawsuits was dismissed.

In the sole lawsuit against the Company, the Company and its employee prevailed at trial with verdicts of "no liability" rendered by the jury and judge. Final judgment in this case was entered on October 3, 2013 with the plaintiff ordered to reimburse defendants for certain court costs, and in 2014, Mentor waived its right to appeal.

In 2012, the Company filed a claim with the Hartford Insurance Company, or Hartford, for reimbursement of legal costs incurred in connection with litigation with Mentor. The Company held a D&O insurance policy with Hartford, and the Company and Hartford settled the matter in May of 2014. The Company received settlement payments from Hartford and recovery of costs associated with the Mentor litigation of $0 and $0 for the three months ended September 30, 2014 and 2013, respectively, and $2,358 and $0 for the nine months ended September 2014 and 2013, respectively.

11. Subsequent Events

a. Reverse Stock Split

On October 10, 2014, the board of directors and stockholders approved an amendment to the Company's fourth amended and restated certificate of incorporation, which was filed on October 17, 2014, which effected a 1 for 2.75 reverse stock split of the Company's issued and outstanding shares of common stock. The par value of the common stock was not adjusted as a result of the reverse stock split. All issued and outstanding shares of common stock, stock options and warrants and the related per share amounts contained in the Company's condensed financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented. Also, as a result of the reverse stock split of the common stock, the conversion ratios for all of the Company's convertible preferred stock have been adjusted such that the preferred stock are now convertible into shares of common stock at a conversion rate of 2.75-to-1 instead of 1-to-1. The number of issued and outstanding shares of preferred stock and their related per share amounts have not been affected by the reverse stock split and therefore have not been adjusted in the Company's condensed financial statements. However, to the extent that the convertible preferred stock are presented on an as converted to common stock basis, such share and per share amounts contained in the Company's financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented.

b. Initial Public Offering

On November 3, 2014, the Company completed the IPO whereby it sold a total of 5,750,000 shares of common stock at $15.00 per share including 750,000 shares sold to underwriters for the exercise of their option to purchase additional shares. The Company received net proceeds from the IPO of approximately $77,213, after deducting underwriting discounts and commissions and offering expenses of approximately $9,038. These expenses will be recorded against the proceeds received from the IPO.

The interest-only period for the tranche D term loan was extended from August 1, 2015 to August 1, 2016 as a result of having raised at least $50,000 in gross proceeds in the IPO and the completion of the IPO before June 30, 2015.

The outstanding shares of convertible preferred stock were converted on a 2.75-to-1 basis into shares of common stock concurrent with the closing of the IPO. All of the outstanding shares of Series A, Series B and Series C preferred stock converted into 8,942,925 shares of common stock. Following the closing of the IPO, there were no shares of preferred stock outstanding.

The accompanying unaudited pro forma balance sheet data as of September 30, 2014 has been prepared to give effect to the automatic conversion of all outstanding shares of convertible preferred stock into 8,942,925 shares of common stock and the issuance of 5,750,000 shares of common stock at a price of $15.00 per share, net of deducting underwriting discounts and estimated offering costs in connection with the closing of this IPO.

	As of September 30, 2014 (Unaudited) (In thousands)	
Balance sheet data (at end of period):	**Actual**	**Pro Forma As Adjusted**
Cash and cash equivalents	$ 19,816	97,029
Total assets	62,275	139,488
Long-term debt	25,304	25,304
Convertible preferred stock	150,456	—
Total stockholders' (deficit) equity	(128,910)	98,759

c. 2014 Equity Incentive Plan

Our board of directors adopted our 2014 Equity Incentive Plan, or 2014 Plan, in July 2014, and our stockholders approved the 2014 Plan in October 2014. The 2014 Plan became effective upon completion of the IPO, at which time the Company ceased making awards under the 2007 Plan. Under the 2014 Plan, the Company may issue ISO, NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards and other forms of stock awards, or collectively, stock awards, all of which may be granted to employees, including officers, non-employee directors and consultants of us and our affiliates. ISOs may be granted only to employees. A total of 1,027,500 shares of common stock were initially reserved for issuance under the 2014 Plan, subject to certain annual increases.

d. 2014 Employee Stock Purchase Plan

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

ITEM 2 . MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2013 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our final prospectus filed with the Securities and Exchange Commission, or SEC, on October 29, 2014 relating to our Registration Statement on Form S-1, as amended (File No. 333-198837) for our initial public offering, or IPO. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "Sientra," "the Company," "we," "us" and "our" refer to Sientra, Inc.

Forward-Looking Statements

The information in this discussion contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in Part II, Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q and in our other filings with the SEC. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements.

Overview

We are a medical aesthetics company committed to making a difference in patients' lives by enhancing their body image, growing their self-esteem and restoring their confidence. We were founded to provide greater choice to board-certified plastic surgeons and patients in need of medical aesthetics products. We have developed a broad portfolio of products with technologically differentiated characteristics, supported by independent laboratory testing and strong clinical trial outcomes.

Our primary products are silicone gel breast implants for use in breast augmentation and breast reconstruction procedures, which we offer in over 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. 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.

We commenced sales of our breast implants in the United States in the second quarter of 2012. We sell our breast implants and breast tissue expanders, or Breast Products, exclusively to board-certified and board-admissible plastic surgeons, who we refer to as Plastic Surgeons, and tailor our customer service offerings to their specific needs, which we believe helps secure their loyalty and confidence. We currently sell our products in the United States where we sell our products through a direct sales organization consisting of 42 employees, including sales representatives and sales management, as of September 30, 2014.

Recent Developments

- On October 10, 2014, the board of directors and stockholders approved an amendment to the Company's fourth amended and restated certificate of incorporation, which was filed on October 17, 2014, which effected a 1 for 2.75 reverse stock split of the Company's issued and outstanding shares of common stock. As a result of the reverse stock split of the common stock, the conversion ratios for all of the Company's convertible preferred stock have been adjusted such that the preferred stock are now convertible into shares of common stock at a conversion rate of 2.75-to-1 instead of 1-to-1.

- On November 3, 2014, we completed our IPO, whereby we sold a total of 5,750,000 shares of common stock at $15.00 per share including 750,000 shares sold to underwriters for the exercise of their option to purchase additional shares. We received net proceeds from our IPO of approximately $77.2 million after deducting underwriting discounts, commissions and offering expenses of approximately $9 million. These expenses will be recorded against the proceeds received from the IPO.

- The interest-only period for the tranche D term loan with Oxford was extended from August 1, 2015 to August 1, 2016 as a result of having raised at least $50.0 million in gross proceeds in the IPO and the completion of the IPO before June 30, 2015.

- Upon the completion of our IPO, all outstanding shares of our convertible preferred stock were converted into 8,942,925 shares of our common stock.

- Our board of directors adopted our 2014 Plan in July 2014 and our stockholders approved the 2014 Plan in October 2014. The 2014 Plan became effective upon completion of the IPO, at which time the Company ceased making awards under the 2007 Plan. Under the 2014 Plan, the Company may issue ISO, NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards and other forms of stock awards, or collectively, stock awards, all of which may be granted to employees, including officers, non-employee directors and consultants of us and our affiliates. ISOs may be granted only to employees. A total of 1,027,500 shares of common stock were initially reserved for issuance under the 2014 Plan, subject to certain annual increases.

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

2007 Acquisition of Grader Street

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

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

Components of Operating Results

Net Sales

We commenced sales of our breast implants in the United States in the second quarter of 2012 and our Breast Products have historically accounted for substantially all of our net sales. Sales of our Breast Products accounted for 97% and 98% of our net sales for the three months ended September 30, 2014 and 2013, respectively, and 97% and 97% of our net sales for the nine months ended September 30, 2014 and 2013, respectively.

We recognize revenue, net of sales discounts and returns, as the customer has a standard six-month window to return purchased products. We anticipate our net sales will increase as we expand our sales force and marketing programs, increase awareness of our products and increase the comfort of Plastic Surgeons using anatomically-shaped breast implants. We also expect that, in the future, our net sales will fluctuate on a quarterly basis due to a variety of factors, including seasonality of breast augmentation procedures. We believe that breast implant sales are subject to seasonal fluctuation due to breast augmentation patients' planning their surgery leading up to the summer season and in the period around the winter holiday season.

Cost of Goods Sold and Gross Margin

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

Our silicone gel breast implants, tissue expanders and other products are manufactured under an exclusive contract with Silimed. Under our contract with Silimed, each particular style of implant has a fixed unit cost. In addition to product costs, we provide a commercial warranty on our silicone gel filled breast implants. The warranty covers device ruptures in certain circumstances. Estimated warranty costs are recorded at the time of sale. Our warehouse and other related costs include labor, rent, product shipments from our third party manufacturer and other related costs.

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

Sales and Marketing Expenses

Our sales and marketing expenses primarily consist of salaries, bonuses, benefits, incentive compensation and travel for our sales, marketing and customer support personnel. Our sales and marketing expenses also include expenses for trade shows, our no-charge customer shipping program and product evaluation, as well as educational, promotional and marketing activities, including direct and online marketing. We expect our sales and marketing expenses to increase in absolute dollars as we increase our headcount and expand our marketing programs.

Research and Development Expenses

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

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

General and Administrative Expenses

Our general and administrative, or G&A, expenses primarily consist of salaries, bonuses, benefits and stock-based compensation for our executive, financial, legal, business development and administrative functions. Other G&A expenses include outside legal counsel and litigation expenses, independent auditors and other outside consultants, insurance, benefits, facilities and information technologies expenses. Beginning in 2013, G&A expenses also include the federal excise tax on the sale of medical devices in the United States.

In 2012, Mentor filed one lawsuit against us and one of our employees, in addition to thirteen lawsuits against fifteen of our employees who were all former Mentor employees, which we refer to as the Mentor litigation. In general, these lawsuits alleged that the former employees of Mentor breached their confidentiality and non-compete agreements when they resigned in favor of employment with us, misappropriated confidential Mentor information and trade secrets, and breached their respective duties of loyalty. Although not a party to thirteen of the lawsuits, we provided for the defense of our employees. In those lawsuits, all of Mentor's claims for preliminary injunctive relief were denied and, following that, each of those lawsuits was dismissed. In the sole lawsuit against us and our employee, we prevailed at trial with verdicts of "no liability" rendered by the jury and judge on all claims. Final judgment in this case was entered on October 3, 2013 with Mentor ordered to reimburse us for certain court costs, and in 2014, Mentor waived its right to appeal. For the three months ended September 30, 2014 and 2013, and for the nine months ended September 30, 2014 and 2013, we incurred $0.0 million, $4.7 million, $0.0 million and $10.2 million, respectively, of G&A expenses related to the Mentor litigation, net of Mentor's reimbursement for certain court costs and preliminary insurance recoveries.

In addition, for the three months ended September 30, 2014 and 2013, and for the nine months ended September 30, 2014 and 2013, we incurred $0.0 million, $0.0 million, $0.0 million and $1.1 million, respectively, of G&A expenses related to the Grader Street arbitration.

Excluding the historic litigation and arbitration expenses described above, we expect future G&A expenses to increase as we build our finance, legal, information technology, human resources and other general administration resources to continue to advance the commercialization of our products. In addition, we expect to incur increased G&A expenses in connection with becoming a public company, which may increase further when we are no longer able to rely on the "emerging growth company" exemption we are afforded under the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012.

Other (Expense) Income, net

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

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of our unaudited condensed financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities, and the revenues and expenses incurred during the reported periods. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We discussed accounting policies and assumptions that involve a higher degree of judgment and complexity in Note 3 to our financial statements in our Registration Statement on Form S-1, as amended (File No. 333-196081). There have been no material changes to our critical accounting policies and estimates of those disclosed in our Registration Statement on Form S-1.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued accounting standard update 2014-09, *Revenue from Contracts with Customers* . The standard was issued to provide a single framework that replaces existing industry and transaction specific US GAAP with a five step analysis of transactions to determine when and how revenue is recognized. This accounting standard updated will be effective for the Company beginning in fiscal year 2018. The Company is currently assessing the impact that the standard will have on the financial statements upon adoption of the guidance.

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

Results of Operations

Comparison of the Three Months Ended September 30, 2014 and 2013

The following table sets forth our results of operations for the three months ended September 30, 2014 and 2013.

	Three Months Ended September 30	
	2014	2013
	(unaudited, in thousands)	
Statement of operations data		
Net sales	10,670	7,981
Cost of goods sold	2,832	1,968
Gross profit	7,838	6,013
Operating Expenses		
Sales and marketing	4,711	4,704
Research and development	1,246	1,234
General and administrative	2,634	6,304
Total operating expenses	8,591	12,242
Loss from operations	(753)	(6,229)
Other (expense) income, net:		
Interest expense	(665)	(232)
Other (expense) income, net	(34)	(14)
Total other (expense) income, net	(699)	(246)
Net loss	(1,452)	(6,475)

Net Sales

Net sales increased $2.7 million, or 33.7%, to $10.7 million for the three months ended September 30, 2014, as compared to $8.0 million for the three months ended September 30, 2013. This increase was 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

Cost of Goods Sold and Gross Margin

Cost of goods sold increased $0.9 million, or 43.9%, to $2.8 million for the three months ended September 30, 2014, as compared to $2.0 million for the three months ended September 30, 2013. This increase was primarily due to an increase in sales volume.

The gross margins for the three months ended September 30, 2014 and 2013 were 73.5% and 75.3%, respectively. This decrease was primarily due to manufacturing price increases, incremental warehouse costs, and targeted pricing programs.

Sales and Marketing Expenses

Sales and marketing expenses remained constant at $4.7 million for the three months ended September 30, 2014 and 2013. This was primarily due to a $0.5 million increase in employee related expense for the sales department and a $0.5 million decrease in marketing costs.

Research and Development Expenses

R&D expenses remained constant at $1.2 million for the three months ended September 30, 2014 and 2013.

General and Administrative Expenses

G&A expenses decreased $3.7 million, or 58.2%, to $2.6 million for the three months ended September 30, 2014, as compared to $6.3 million for the three months ended September 30, 2013. This decrease was primarily due to the $4.7 million decrease in litigation expenses related to the Mentor litigation partially offset by an increase in expenses related to the federal excise tax and accounting costs.

Other (Expense) Income, net

Other (expense) income, net for the three months ended September 30, 2014 and 2013 was primarily associated with interest expense on our term loans of $0.7 million and $0.2 million, respectively.

Comparison of the Nine Months Ended September 30, 2014 and 2013

The following table sets forth our results of operations for the nine months ended September 30, 2014 and 2013.

	Nine Months Ended September 30	
	2014	2013
	(unaudited, in thousands)	
Statement of operations data		
Net sales	32,617	25,921
Cost of goods sold	8,287	6,352
Gross profit	24,330	19,569
Operating Expenses		
Sales and marketing	16,574	15,501
Research and development	3,551	3,400
General and administrative	7,542	16,072
Total operating expenses	27,667	34,973
Loss from operations	(3,337)	(15,404)
Other (expense) income, net:		
Interest expense	(1,507)	(612)
Other income (expense), net	2,230	(34)
Total other income (expense), net	723	(646)
Net loss	(2,614)	(16,050)

Net Sales

Net sales increased $6.7 million, or 25.8%, to $32.6 million for the nine months ended September 30, 2014, as compared to $25.9 million for the nine months ended September 30, 2013. This increase was 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.

Cost of Goods Sold and Gross Margin

Cost of goods sold increased $1.9 million, or 30.5%, to $8.3 million for the nine months ended September 30, 2014, as compared to $6.4 million for the nine months ended September 30, 2013. This increase was primarily due to an increase in sales volume.

The gross margins for the nine months ended September 30, 2014 and 2013 were 74.6% and 75.5%, respectively. This decrease was primarily due to manufacturing price increases and targeted pricing programs.

Sales and Marketing Expenses

Sales and marketing expenses increased $1.1 million, or 6.9%, to $16.6 million for the nine months ended September 30, 2014, as compared to $15.5 million for the nine months ended September 30, 2013. This increase was primarily due to a $0.9 million increase in employee related expense for the sales department and a $0.1 million increase in marketing costs.

Research and Development Expenses

R&D expenses increased $0.2 million, or 4.4%, to $3.6 million for the nine months ended September 30, 2014, as compared to $3.4 million for the nine months ended September 30, 2013. This increase was primarily due to an increase in employee-related expenses and costs associated with our post-approval study.

General and Administrative Expenses

G&A expenses decreased $8.5 million, or 53.1%, to $7.5 million for the nine months ended September 30, 2014, as compared to $16.1 million for the nine months ended September 30, 2013. This decrease was primarily due to the $10.2 million decrease in litigation expenses related to the Mentor litigation and $1.1 million decrease in arbitration expenses related to the Grader Street arbitration, partially offset by an increase in expenses related to the federal excise tax and accounting costs.

Other (Expense) Income, net

Other (expense) income, net for the nine months ended September 30, 2014 was primarily associated with interest expense on our term loans of $1.5 million and income from recovery of costs associated with the Mentor litigation of $2.4 million. Other (expense) income, net for the nine months ended September 30, 2013 was primarily associated with interest expense on our term loans of $0.6 million.

Liquidity and Capital Resources

Since our inception, we have incurred significant net operating losses and anticipate that our losses will continue in the near term. We expect our operating expenses will continue to grow as we expand our operations. We will need to generate significant net sales to achieve profitability. To date, we have funded our operations primarily with proceeds from the sales of preferred stock, borrowings under our term loans and, since 2012, sales of our Breast Products. To date, we have received gross proceeds from the sales of preferred stock totaling $151.0 million. We issued and sold preferred stock for aggregate gross proceeds of $65.0 million in March 2012, which was our most recent issuance and sale of preferred stock. As of September 30, 2014, we had $25.3 million outstanding on our term loans.

On November 3, 2014, we completed our IPO of common stock pursuant to a Registration Statement that was declared effective on October 28, 2014. We sold 5,000,000 shares of our common stock at a price of $15.00 per share. Additionally, the underwriters exercised their option to purchase an additional 750,000 shares at $15.00 per share. As a result of our IPO, we raised a total of approximately $77.2 million in net proceeds after deducting underwriting discounts and commissions of approximately $6.0 million and offering expenses of approximately $3.0 million. Costs directly associated with our IPO were capitalized and recorded as deferred IPO costs prior to the completion of our IPO. These costs are capitalized in other current assets on the condensed balance sheet at September 30, 2014 and will be recorded as a reduction of the proceeds received in arriving at the amount to be recorded in additional paid-in capital during the fourth quarter. Upon completion of our IPO, all outstanding shares of our convertible preferred stock were converted into 8,942,925 shares of common stock.

As of September 30, 2014, we had $19.8 million in cash and cash equivalents. We believe that our available cash on hand and proceeds from our IPO will be sufficient to satisfy our liquidity requirements for at least the next 18 months. However, the continued growth of our business, including the expansion of our sales force and marketing programs, and research and development activities, will significantly increase our expenses. In addition, the amount of our future product sales is difficult to predict, especially in light of the recent commercialization of our silicone gel breast implants, and actual sales may be not be in line with our forecasts. As a result, we may be required to seek additional funds in the future from public or private offerings of our capital stock, borrowings under term loans or other sources, subject to the restrictions under our Amended Term Loan Agreement.

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

Cash Flows

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

	Nine Months Ended September 30	
	2014	2013
	(unaudited, in thousands)	
Net cash provided by (used in):		
Operating activities	1,546	(18,358)
Investing activities	(320)	(18,060)
Financing activities	8,868	9,642
Net change in cash and cash equivalents	10,094	(26,776)

Cash provided by (used in) operating activities

Net cash provided by operating activities was $1.5 million during the nine months ended September 30, 2014 as compared to cash used in operating activities of $18.4 million during the nine months ended September 30, 2013. The decrease in cash used in operating activities between the nine months ended September 30, 2014 and 2013 was primarily associated with the decrease in net loss of $13.4 million and a decrease in cash outflows from operating assets and liabilities resulting from a decrease in inventory purchases, an increase in customer deposits and improved collections of accounts receivable, offset by a reduction in accounts payable.

Cash used in investing activities

Net cash used in investing activities was $0.3 during the nine months ended September 30, 2014 as compared to $18.0 million during the nine months ended September 30, 2013. The decrease in cash used in investing activities of $17.7 million between the nine months ended September 30, 2014 and 2013 was primarily due to a nonrecurring $18.0 million payment made to Grader Street in May 2013 in connection with the obligations relating to our 2007 acquisition of Grader Street.

Cash provided by financing activities

Net cash provided by financing activities was $8.9 million during the nine months ended September 30, 2014 as compared to $9.6 million during the nine months ended September 30, 2013. The decrease in cash provided by financing activities of $0.8 million between the nine months ended September 30, 2014 and 2013 was primarily the result of the payment of deferred equity transaction costs of $1.0 million during the nine month ended September 30, 2014 offset by the payment of $0.3 million for the repurchase of common stock during the nine months ended September 30, 2013. Our liquidity position and capital requirements are subject to a number of factors. For example, our cash inflow and outflow may be impacted by the following:

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

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

- support of our commercialization efforts related to our current and future products;
- new product acquisition and development efforts;
- payment of monthly interest due under our term loans; and
- facilities expansion needs.

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

Indebtedness

Term Loan Agreement

On January 17, 2013, we entered into a Loan and Security Agreement with Oxford, which was amended and restated on June 30, 2014, or the Amended Term Loan Agreement. Under the Amended Term Loan Agreement, we have (i) a $7.5 million tranche A term loan, (ii) a $2.5 million tranche B term loan, (iii) a $5.0 million tranche C term loan and (iv) a $10.0 million tranche D term loan. The tranche A, B and C term loans mature on February 1, 2017 and the tranche D term loan matures on January 1, 2019. The term loans are collateralized by a first-priority security interest in substantially all of our assets. The term loans bear interest at a rate equal to 8.4% per annum. The interest-only period for the tranche A, B and C term loans ends on August 1, 2015 and the interest-only period for the tranche D term loan was extended from August 1, 2015 to August 1, 2016 as a result of having raised at least $50.0 million in gross proceeds in the IPO and the completion of the IPO before June 30, 2015.

We may voluntarily repay amounts outstanding under the term loan at any time, subject to paying the final payment. Upon making the final payment of each term loan, whether on prepayment or at maturity, we are required to pay a 6.5% fee on the aggregate principal amount of the term loan being paid. In connection with the Amended Term Loan Agreement, we issued to Oxford (i) seven-year warrants in January 2013 to purchase shares of our common stock with a value equal to 3.0% of the tranche A, B and C term loans amounts and (ii) seven-year warrants in June 2014 to purchase shares of our common stock with a value equal to 2.5% of the tranche D term loan amount. The warrants have an exercise price per share equal to the lesser of (i) the Series C preferred stock conversion price of $14.671 per share or (ii) the price per share in a subsequent qualified round of financing where gross proceeds are greater than $10.0 million.

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

Contractual Obligations and Commitments

There have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations" in our final prospectus dated October 29, 2014 filed pursuant to Rule 424(b) of the Securities Act with the SEC on October 29, 2014.

Off-Balance Sheet Arrangements

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

ITEM 3: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4: CONTROLS AND PROCEDURES

Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. GAAP. We have not performed an evaluation of our internal control over financial reporting, such as required by Section 404 of the Sarbanes-Oxley Act, nor have we engaged an independent registered public accounting firm to perform an audit of our internal control over financial reporting as of any balance sheet date or for any period reported in our financial statements. Presently, we are not an accelerated filer, as such term is defined by Rule 12b-2 of the Exchange Act, and therefore, our management is not presently required to perform an annual assessment of the effectiveness of our internal control over financial reporting. This requirement will first apply to our Annual Report on Form 10-K for the year ended December 31, 2014. Our independent registered public accounting firm will first be required to attest to the effectiveness of our internal control over financial reporting for our Annual Report on Form 10-K for the first year we are no longer an "emerging growth company" under the JOBS Act. However, in connection with our audit as of and for the year ended December 31, 2013, our independent registered public accounting firm identified two material weaknesses in our internal control over financial reporting. See "Risk Factors — Risks Related to This Offering and Ownership of Our Common Stock — 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," for a discussion of these matters.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

Item 1A. RISK FACTORS.

An investment in our common stock involves risks. You should carefully consider the following risk factors, as well as the other information in this report, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business. We have marked with an asterisk (*) those risk factors that reflect changes from the risk factors included in our final prospectus filed with the Securities and Exchange Commission, or SEC, on October 29, 2014 related to our Registration Statement on Form S-1, as amended (File No. 333-198837) for our initial public offering, or IPO.

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 September 30, 2014, we had an accumulated deficit of $128.9 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 nine months ended September 30, 2014, our gross profit was $24.3 million. However, although we have achieved a positive gross profit, we still operate at a 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 97% and 97% of our net sales for the nine months ended September 30, 2014 and 2013, 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 or Silimed quickly, and we have not qualified another silicone supplier nor another manufacturer to source our implants in that event. Even if we were able to identify a replacement manufacturer or silicone supplier, either would have to be qualified with the FDA, which is an expensive and time-consuming process during which we may experience a supply interruption. As a result, our financial position and results of operations may be adversely affected. There can also be no guarantee that ASC or Silimed will be able to meet our demand to produce sufficient quantities of medical-grade silicone or our products in a timely manner. Furthermore, our current contract with Silimed expires in 2017, and there can be no assurance that Silimed will agree to continue to manufacture and supply our products after the expiration of our contract, which would have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

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

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

- failure of our manufacturer to follow Good Manufacturing Practices, or cGMP, requirements or mishandling of our products while in production or in preparation for transit;
- transportation and import and export risk, particularly given the global nature of our supply chain;

- delays in analytical results or failure of analytical techniques that we depend on for quality control and release of products;
- natural disasters, labor disputes, financial distress, lack of raw material supply, issues with facilities and equipment or other forms of disruption to business operations affecting our manufacturer or its suppliers; and
- latent defects that may become apparent after products have been released and which may result in a recall of such products.

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

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

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

- implement and execute our business strategy;
- expand and improve the productivity of our sales force and marketing programs to grow sales of our existing and proposed products;
- increase awareness of our brand and build loyalty among Plastic Surgeons;
- manage expanding operations;
- respond effectively to competitive pressures and developments;
- 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.

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 compared our five-year data to our competitors' six-year data in some cases in our final prospectus filed with the SEC on October 29, 2014, 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 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 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.

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 September 30, 2014, we had approximately 93 full-time employees. Our management and personnel, and the systems and facilities we currently have in place, may not be adequate to support future growth. Effectively executing our growth strategy requires that we increase net sales through sales and marketing activities, recruit and retain additional employees and continue to improve our operational, financial and management controls, reporting systems and procedures. If we are not able to effectively expand our organization in these ways, we may not be able to successfully execute our growth strategy, and our business, financial condition and results of operations may suffer.

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

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

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

We currently have no commitments with respect to any partnership or acquisition. We do not know if we will be able to identify partnerships or acquisitions we deem suitable, whether we will be able to successfully complete any such partnerships or acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any partnered or acquired products or technologies. Our potential inability to integrate any partnered or acquired products or technologies effectively or realize anticipated synergies may adversely affect our business, financial condition and results of operations.

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.

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 September 30, 2014, we had $19.8 million in cash and cash equivalents. We believe that our available cash on hand and the proceeds from our IPO will be sufficient to satisfy our liquidity requirements for at least the next 18 months. However, the continued growth of our business, including the expansion of our sales force and marketing programs, and research and development activities, will significantly increase our expenses. In addition, the amount of our future product sales is difficult to predict, especially in light of the recent commercialization of our silicone gel breast implants, and actual sales may not be in line with our forecasts. As a result, we may be required to seek additional funds in the future. Our future capital requirements will depend on many factors, including:

- net sales generated by our silicone gel breast implants and tissue expanders and any other future products that we may develop and commercialize;
- costs associated with expanding our sales force and marketing programs;

- cost associated with developing and commercializing our proposed products or technologies;
- cost of obtaining and maintaining regulatory clearance or approval for our current or future products;
- cost of ongoing compliance with regulatory requirements;
- expenses we incur in connection with potential litigation or governmental investigations;
- anticipated or unanticipated capital expenditures; and
- unanticipated general and administrative expenses.

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

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

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

Our Amended Term Loan Agreement with Oxford contains certain restrictive covenants that limit our ability to transfer or dispose of certain assets, engage in new lines of business, change the composition of our management, merge with or acquire other companies, incur additional debt, create new liens and encumbrances, pay dividends or subordinated debt and enter into material transactions with affiliates, among others. We therefore may not be able to engage in any of the foregoing transactions unless we obtain the consent of the lender or terminate the Amended Term Loan Agreement. The Amended Term Loan Agreement also contains financial reporting requirements. There is no guarantee that we will be able to pay the principal and interest under the Amended Term Loan Agreement or that future working capital, borrowings or equity financing will be available to repay or refinance the amounts outstanding under the Amended Term Loan Agreement. In addition, we may enter into debt agreements in the future that may contain similar or more burdensome terms and covenants, including financial covenants.

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

As of December 31, 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.

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;
- 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.

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 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 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 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.

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;
- 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.

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.

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.

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

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

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

Risks Related to Our Common Stock

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

The market price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in this "Risk Factors" section of this Form 10-Q and others such as:

- a slowdown in the medical device industry, the aesthetics industry or the general economy;
- actual or anticipated quarterly or annual variations in our results of operations or those of our competitors;
- changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;
- actual or anticipated changes in our growth rate relative to our competitors;
- changes in earnings estimates or recommendations by securities analysts;
- fluctuations in the values of companies perceived by investors to be comparable to us;
- announcements by us or our competitors of new products or services, significant contracts, commercial relationships, capital commitments or acquisitions;
- competition from existing technologies and products or new technologies and products that may emerge;
- the entry into, modification or termination of agreements with our sales representatives or distributors;
- developments with respect to intellectual property rights;
- sales, or the anticipation of sales, of our common stock by us, our insiders or our other stockholders, including upon the expiration of contractual lock-up agreements;
- our ability to develop and market new and enhanced products on a timely basis;
- our commencement of, or involvement in, litigation;
- additions or departures of key management or technical personnel; and
- changes in laws or governmental regulations applicable to us.

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

We could be subject to securities class action litigation.

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

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

We do not anticipate declaring any cash dividends to holders of our common stock in the foreseeable future. In addition, our ability to pay cash dividends is currently prohibited by the terms of our Amended Term Loan Agreement and may be prohibited by future loan agreements. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

As of November 3, 2014, our executive officers, directors and principal stockholders beneficially owned approximately 74.9% of our outstanding voting stock. As a result, these stockholders have the ability to influence us through their ownership position and may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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

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

- we were 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 our final prospectus filed with the SEC on October 29, 2014;

- 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 were permitted to provide less extensive disclosure about our executive compensation arrangements in our final prospectus filed with the SEC on October 29, 2014, and are permitted to also provide reduced disclosure about our executive compensation arrangements in our periodic reports, proxy statements and registration statements; and

- we are not required to give our stockholders non-binding advisory votes on executive compensation or golden parachute arrangements.

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

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

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

As a public company, and increasingly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and NASDAQ impose numerous requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Also, the 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.

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 no longer an "emerging growth company" as defined in the JOBS Act. However, in connection with our audit as of and for the year ended December 31, 2013, our independent registered public accounting firm identified two material weaknesses in our internal control over financial reporting.

One material weakness related to our not having properly designed controls in place to account for complex debt and equity transactions, including preferred stock and warrants associated with debt issuances. We plan to increase the size and expertise of our internal accounting team to assist in remediating this weakness. The second material weakness related to our not having properly designed controls in place to record the bonus accrual and related expense in the appropriate period, which we believe we will have remediated as of December 31, 2014.

We cannot assure you that our plans will sufficiently address the identified weaknesses, nor can we assure you that there will not be material weaknesses or significant deficiencies in our internal controls in the future. Additionally, in the event that our internal control over financial reporting is perceived as inadequate, or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the trading price of our common stock could decline.

Future sales of shares of our common stock by existing stockholders could cause our stock price to decline.*

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that our officers, directors or the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. As of November 3, 2014, we had approximately 14,912,613 shares of common stock outstanding. Of these shares, only the 5,750,000 shares of common stock sold in our IPO and 37,871 shares of common stock held by existing stockholders are freely tradable, without restriction, in the public market, unless purchased by our affiliates or our existing stockholders subject to lock-up agreements. Each of our directors and officers, and certain of our stockholders, have entered into lock-up agreements with the underwriters that restrict their ability to sell or transfer their shares (including any shares purchased through the directed share program). The lock-up agreements pertaining to our IPO will expire on April 27, 2015. Piper Jaffray & Co. and Stifel, Nicolaus & Company, Incorporated, however, may, in their sole discretion, permit our officers, directors and other existing stockholders who are subject to the contractual lock-up to sell shares prior to the expiration of the lock-up agreements. After the lock-up agreements expire, based on shares outstanding as of November 3, 2014, up to an additional 9,124,742 shares of common stock will be eligible for sale in the public market, approximately 90,909 of which are held by our directors and executive officers, and will be subject to volume limitations under Rule 144 under the Securities Act. In addition, 1,621,578 shares of our common stock that are subject to outstanding options as of November 3, 2014 will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements, the lock-up agreements and Rules 144 and 701 under the Securities Act.

Holders of an aggregate of approximately 8,942,925 shares of our common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

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

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

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our 2014 Plan, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.*

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

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

Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2014 Plan is 1,027,500 shares. Additionally, the number of shares of our common stock reserved for issuance under the 2014 Plan will automatically increase on January 1 of each year, beginning on January 1, 2015 and continuing through and including January 1, 2024, by 4% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

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

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

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

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

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

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

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

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

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

During the nine months ended September 30, 2014, we granted options under our 2007 Plan in unregistered transactions to purchase an aggregate of 224,707 shares of common stock to our employees, directors and consultants at a weighted average exercise price of $11.70 per share. During such period, options were exercised in unregistered transactions to purchase 2,193 shares for cash consideration in the aggregate amount of $9 thousand.

The sales and issuances of securities in the transactions described above were deemed to be exempt from registration under the Securities Act of 1933, as amended, or the Securities Act, in reliance upon Rule 701 promulgated under Section 3(b) of the Securities Act as transactions pursuant to compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of such securities were employees, directors or bona fide consultants of ours and received the securities under our 2007 Plan. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us. Shares of common stock to be issued pursuant to awards (including options) under our 2007 Plan and our 2014 Plan, which was adopted concurrently with the completion of our IPO, were registered on a Registration Statement on Form S-8, filed with the SEC on October 29, 2014.

Purchase of Equity Securities

We did not purchase any of our registered securities during the period covered by this Quarterly Report on Form 10-Q.

Use of Proceeds from Registered Securities

We commenced our IPO pursuant to a registration statement on Form S-1 (File No. 333-198837) that was declared effective by the Securities and Exchange Commission on October 28, 2014 and registered an aggregate of 5,000,000 shares of our common stock for sale at a public offering price of $15.00 per share and an aggregate offering price of $75.0 million. On October 29, 2014, we sold 5,000,000 shares of our common stock at a public offering price of $15.00 per share for an aggregate gross offering price of $75.0 million. In addition, 750,000 shares were sold pursuant to the underwriters' option to purchase additional shares with a public offering price of $15.00 per share for additional gross proceeds of approximately $11.2 million. On November 3, 2014, we completed our IPO. Piper Jaffray & Co. and Stifel, Nicolaus & Company, Incorporated acted as joint book-running managers and Leerink Partners, LLC and William Blair & Company, L.L.C. acted as co-managers in the IPO.

The underwriting discounts and commissions for the offering totaled approximately $6.0 million. We incurred additional costs of approximately $3.0 million in offering expenses, which when added to the underwriting discounts and commissions paid by us, amounts to total fees and costs of approximately $9.0 million. Thus, net offering proceeds to us, after deducting underwriting discounts and commissions and offering costs, were approximately $77.2 million. No offering costs were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

Upon receipt, the net proceeds from our IPO were held in cash and cash equivalents, primarily bank money market accounts. Through November 3, 2014, we have not used any of the net proceeds from our IPO. There has been no material change in our planned use of the net proceeds from the offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act on October 29, 2014. The amount and timing of our actual expenditures depend on numerous factors, including the ongoing status of and results from clinical trials, as well as any unforeseen cash needs. Accordingly, our management will have broad discretion in the application of the net proceeds.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The following exhibits are filed or furnished as part of this report:

Number	Description
3.1(1)	Amended and Restated Certificate of Incorporation of the Registrant.
3.2(1)	Amended and Restated Bylaws of the Registrant.
4.1(1)	Form of Common Stock Certificate of the Registrant.
4.2(1)	Conversion and Amendment Agreement by and among the Registrant and certain of its stockholders, dated October 10, 2014.
10.1(1)+	Form of Indemnity Agreement by and between Sientra, Inc. and its directors and officers.
10.2(1)+	2014 Equity Incentive Plan and forms of awards agreements thereunder.
10.3(1)+	2014 Non-Employee Director Compensation Policy.
10.4(1)+	2014 Employee Stock Purchase Plan.
10.5(1)+	Offer Letter to R. Scott Greer, dated July 9, 2014.
10.6(1)+	Offer Letter to Kevin O'Boyle, dated July 9, 2014.
10.7(1)+	Offer Letter to Jeffrey Nugent, dated July 9, 2014.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

(1) Incorporated by reference to Sientra, Inc.'s Registration Statement on Form S-1 (No. 333-198837), as amended.
+ Indicates a management contract or compensatory plan or arrangement.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SIENTRA, INC.

November 21, 2014 By: /s/ Hani Zeini
Hani Zeini
President and Chief Executive Officer

November 21, 2014 By: /s/ Matthew Pigeon
Matthew Pigeon
Chief Financial Officer and Treasurer

Exhibit 31.1

Certification of President and Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Hani Zeini, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Sientra, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 21, 2014

/s/ Hani Zeini
Hani Zeini
President and Chief Executive Officer

Exhibit 31.2

Certification of Chief Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Matthew Pigeon, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Sientra, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 21, 2014

/s/ Matthew Pigeon
Matthew Pigeon
Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Sientra, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Hani Zeini, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Hani Zeini
Name: Hani Zeini
Title: President and Chief Executive Officer

Date: November 21, 2014

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Sientra, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Matthew Pigeon, Chief Financial Officer and Treasurer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Matthew Pigeon
Name: Matthew Pigeon
Title: Chief Financial Officer and Treasurer

Date: November 21, 2014

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.