Sientra, Inc.
Form 10-Q
August 09, 2016
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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 June 30, 2016

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 93117
(Address of Principal Executive Offices) (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 August 4, 2016, the number of outstanding shares of the registrant's common stock, par value $0.01 per share, was 18,134,497.

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SIENTRA, INC.

FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2016

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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)

	June 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 86,159	$ 112,801
Accounts receivable, net of allowances of $4,225 and $1,116 at June 30, 2016 and December 31, 2015, respectively	2,403	4,249
Inventories, net	18,906	20,602
Prepaid expenses and other current assets	1,958	1,473
Total current assets	109,426	139,125
Property and equipment, net	1,995	1,404
Goodwill	3,273	—
Other intangible assets, net	3,796	53
Other assets	219	223
Total assets	$ 118,709	$ 140,805
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,412	$ 4,069
Accrued and other current liabilities	7,416	6,959
Customer deposits	6,958	9,488
Total current liabilities	17,786	20,516
Warranty reserve and other long-term liabilities	2,031	1,418
Total liabilities	19,817	21,934
Commitments and contingencies (Note 10)		
Stockholders' equity:		
	—	—

Preferred stock, $0.01 par value – Authorized 10,000,000 shares; none issued or outstanding		
Common stock, $0.01 par value — Authorized 200,000,000 shares; issued 18,151,148 and 18,066,143 and outstanding 18,078,421 and 17,993,416 shares at June 30, 2016 and December 31, 2015 respectively	181	180
Additional paid-in capital	296,377	294,227
Treasury stock, at cost (72,727 shares at June 30, 2016 and December 31, 2015)	(260)	(260)
Accumulated deficit	(197,406)	(175,276)
Total stockholders' equity	98,892	118,871
Total liabilities and stockholders' equity	$ 118,709	$ 140,805

See accompanying notes to condensed financial statements.

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SIENTRA, INC.

Condensed Statements of Operations

(In thousands, except per share and share amounts)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net sales	$ 6,244	$ 14,206	$ 7,715	$ 26,640
Cost of goods sold	1,745	3,937	2,506	7,174
Gross profit	4,499	10,269	5,209	19,466
Operating expenses:				
Sales and marketing	6,287	6,951	11,396	13,805
Research and development	3,062	1,497	5,317	2,753
General and administrative	5,357	3,943	10,642	7,664
Total operating expenses	14,706	12,391	27,355	24,222
Loss from operations	(10,207)	(2,122)	(22,146)	(4,756)
Other income (expense), net:				
Interest income	16	7	31	7
Interest expense	(12)	(671)	(13)	(1,339)
Other income (expense), net	10	(206)	(2)	(288)
Total other income (expense), net	14	(870)	16	(1,620)
Loss before income taxes	(10,193)	(2,992)	(22,130)	(6,376)
Income taxes	—	—	—	—
Net loss	$ (10,193)	$ (2,992)	$ (22,130)	$ (6,376)
Basic and diluted net loss per share attributable to common stockholders	$ (0.56)	$ (0.20)	$ (1.23)	$ (0.43)
Weighted average outstanding common shares used for net loss per share attributable to common stockholders:				
Basic and diluted	18,075,010	14,931,931	18,062,803	14,927,558

See accompanying notes to condensed financial statements.

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SIENTRA, INC.

Condensed Statements of Cash Flows

(In thousands)

(Unaudited)

	June 30, 2016	2015
Cash flows from operating activities:		
Net loss	$ (22,130)	$ (6,376)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	425	153
Provision for doubtful accounts	331	4
Provision for warranties	74	286
Provision for inventory	391	55
Change in fair value of warrants	6	288
Non-cash interest expense	12	288
Stock-based compensation expense	1,664	1,082
Loss on disposal of property and equipment	122	—
Changes in assets and liabilities:		
Accounts receivable	1,514	(1,742)
Prepaid expenses, other current assets and other assets	(574)	(657)
Inventories	1,406	305
Accounts payable	(635)	(520)
Accrued and other liabilities	428	670
Customer deposits	(2,530)	(416)
Net cash used in operating activities	(19,496)	(6,580)
Cash flows from investing activities:		
Purchase of property and equipment	(874)	(511)
Business acquisition	(6,759)	—
Net cash used in investing activities	(7,633)	(511)
Cash flows from financing activities:		
Proceeds from exercise of stock options	57	92
Proceeds from issuance of common stock under ESPP	430	—
Deferred equity issuance costs, IPO	—	(71)
Net cash provided by financing activities	487	21
Net decrease in cash and cash equivalents	(26,642)	(7,070)
Cash and cash equivalents at:		
Beginning of period	112,801	96,729
End of period	$ 86,159	$ 89,659
Supplemental disclosure of cash flow information:		
Interest paid	$ —	$ 1,051
Supplemental disclosure of non-cash investing and financing activities:		

Property and equipment in accounts payable	—	85
Acquisition of business, deferred and contingent consideration obligations at fair value	550	—

See accompanying notes to condensed financial statements.

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SIENTRA, INC.

Notes to the Condensed Financial Statements

(In thousands, except per share and share amounts)

(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., on April 4, 2007. The purpose of the acquisition was to acquire the rights to the silicone breast implant clinical trials, related product specifications and premarket approval, or PMA, assets. 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, scar management, tissue expanders, and body contouring products.

b. Follow-On Offering

On September 23, 2015, the Company closed a follow-on public offering, whereby it sold 3,000,000 shares of its common stock, at a price to the public of $22.00 per share. The Company received net proceeds from the follow-on offering of approximately $61,397 after deducting underwriting discounts and commissions of $3,960 and offering expenses of approximately $643.

c. Regulatory Inquiries Regarding Products Manufactured by Silimed

There have been recent regulatory inquiries related to medical devices manufactured by Silimed Industria de Implantes Ltda. (formerly, Silimed-Silicone e Instrumental Medico-Cirugio e Hospitalar Ltda.), or Silimed, the Company’s sole source contract manufacturer for its silicone gel breast implants, tissue expanders and certain other

products.

On September 23, 2015, the Medicines and Healthcare Products Regulatory Agency, or MHRA, an executive agency of the United Kingdom, or U.K., issued a press release announcing the suspension of sales and implanting in the U.K. of all medical devices manufactured by Silimed following the suspension of the CE certificate of these products issued by TUV SUD, Silimed's notified body under European Union, or EU, regulation. The suspension of Silimed's CE certificate by TUV SUD followed TUV SUD's inspection at Silimed's manufacturing facilities in Brazil, relating to surface particles on Silimed breast products. Breast implants have stringent standards for manufacturing and robust quality systems, but there is no specific or defined standard for surface particles on breast implants. MHRA noted that no risks to patient health have been identified in connection with implanting Silimed products, and, accordingly, there is no need to adopt any procedure or action for those patients who have received them.

On October 2, 2015, the Brazilian regulatory agency ANVISA and the Department of the Secretary of State of the State of Rio de Janeiro announced that as a precautionary measure, they temporarily suspended the manufacturing and shipment of all medical devices made by Silimed, including products manufactured for Sientra, while they continue to review the technical compliance related to Good Manufacturing Practices, or GMP, of Silimed's manufacturing facility. ANVISA reiterated that no risks to patient health have been identified in connection with implanting Silimed products, and, accordingly, there is no need to adopt any procedure or action for those patients who have received them. Furthermore, ANVISA also indicated that, based on its contact to date with foreign regulatory authorities, there have been no reports of adverse events related to the use of Silimed products.

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On October 9, 2015, the Company voluntarily placed a hold on the sale of all Sientra devices manufactured by Silimed and recommended that plastic surgeons discontinue implanting the devices until further notice. The Company had ongoing discussions with the FDA regarding European and Brazilian regulatory inquiries into Silimed products, and the Company conducted its own review of the matter with the assistance of independent experts in quality management systems, GMP and data-based risk assessment. The FDA also reiterated that no reports of adverse events and no risks to patient health had been identified in connection with implanting Silimed products.

On January 27, 2016, after completing an analysis and risk assessment, ANVISA announced its authorization of Silimed to resume the commercialization and use of its previously manufactured products. ANVISA concluded there was no evidence to prove that the presence of surface particles on the silicone implants represented risks which are additional to the ones inherent in the product. However, Silimed would continue to be suspended from manufacturing and commercializing new batches of implants until an inspection was performed to reassess the fulfillment of its GMP compliance.

On March 1, 2016, after the completion of independent, third-party testing and analyses of its devices manufactured by Silimed, the Company lifted the temporary hold on the sale of such devices. The Company also sent a letter to plastic surgeons informing them of the Company's controlled market re-entry plans designed to optimize the Company's inventory supply. The results of the Company's testing indicate no anticipated significant safety concerns with the use of its products, including its breast implants, consistent with their approval status since 2012.

On July 11, 2016, after completing an inspection of Silimed's facility, ANVISA announced the reinstatement of Silimed's GMP certificate and their ability to manufacture commercial products. The GMP certificate is effective as of July 8, 2016 and is valid for two years. The Silimed facility that has been approved for manufacturing is an alternate facility to where Sientra products were previously manufactured, which was damaged by a fire on October 22, 2015. However, the products to be manufactured in the alternate facility for Sientra cannot be sold in the U.S. until Silimed submits a PMA supplement for that facility, their operations have been fully validated to U.S. FDA standards and they have successfully passed an FDA inspection, the timing of which is uncertain. Additionally, the suspension of Silimed's CE certificate by TUV SUD remains in place and continues to limit Silimed's ability to sell to countries requiring a CE mark.

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 Annual Report on Form 10-K for the year ended December 31, 2015 filed with the SEC on March 10, 2016, or the Annual Report. The results for the three and six months ended June 30, 2016 are not necessarily indicative of results to be expected for the year ending December 31, 2016, any other interim periods, or any future year or period.

b.Going Concern

The accompanying financial statements have been prepared on a going concern basis, which implies the Company will continue to realize its assets and discharge its liabilities in the normal course of business. Silimed is the Company’s sole source manufacturer of silicone gel breast implants, tissue expanders and certain other products. The continuation of the Company as a going concern is dependent upon many factors including the satisfactory resolution of the regulatory inquiries of Silimed’s medical devices, Silimed’s ability to resume the manufacturing of the Company’s medical devices, the availability of alternative manufacturing sources, and the resumption of the sale of the Company’s products. Since inception, the Company has incurred net losses. At June 30, 2016, the Company had cash and cash equivalents of $86,159.

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The Company's ability to continue to meet its obligations and to achieve its business objectives is dependent upon, amongst other things, generating sufficient revenues. The Company believes that it has the ability to continue as a going concern for at least 12 months. These financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

c.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.

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d.Significant Accounting Policies

There have been no significant changes to the accounting policies during the three and six months ended June 30, 2016, as compared to the significant accounting policies described in the "Notes to Financial Statements" in the Annual Report.

e.Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued accounting standard update, or ASU, 2014-09, Revenue from Contracts with Customers. The standard was issued to provide a single framework that replaces existing industry and transaction specific GAAP with a five step analysis of transactions to determine when and how revenue is recognized. The accounting standard update will replace most existing revenue recognition guidance in GAAP when it becomes effective. In August 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, to defer the effective date of ASU 2014-09 by one year. Therefore, ASU 2014-09 will become effective for the Company beginning in fiscal year 2018. Early adoption would be permitted for the Company beginning in fiscal year 2017. The standard permits the use of either the retrospective or cumulative transition method. The Company is currently evaluating the accounting, transition and disclosure requirements of the standard and cannot currently estimate the financial statement impact of adoption.

In February 2016, the FASB issued accounting standard update 2016-02, Leases (Topic 842) which supersedes FASB Accounting Standard Codification Leases (Topic 840). The standard is intended to increase the transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing

key information about leasing arrangements. This accounting standard update will be effective for the Company beginning in fiscal year 2019. The Company is currently evaluating the impact that adoption of the standard will have on the financial statements and related disclosures.

In March 2016, the FASB issued accounting standard update 2016-09, Compensation – Stock Compensation (Topic 718). The standard identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. This accounting standard update will be effective for the Company beginning in fiscal year 2017. The Company is currently evaluating the impact that adoption of the standard will have on the financial statements and related disclosures.

f.Reclassifications

Certain reclassifications have been made to prior year amounts to conform to the current year presentation.

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3.Acquisition of bioCorneum®

On March 9, 2016, the Company entered into an assets purchase agreement with Enaltus LLC, or Enaltus, to acquire exclusive U.S. rights to bioCorneum®, an advanced silicone scar treatment marketed exclusively to physicians. The acquisition of bioCorneum® aligns with the Company's business development objective and adds a complementary product that serves the needs of its customers. In connection with the acquisition, the Company recorded $13 of professional fees for the three months ended June 30, 2016 and $154 for the six months ended June 30, 2016, which are included in general and administrative expense. The aggregate preliminary acquisition date fair value of the consideration transferred was estimated at $7,409, which consisted of the following:

	Fair Value
Cash	$ 6,859
Deferred consideration	434
Contingent consideration	116
	$ 7,409

The deferred consideration and contingent consideration consist of future royalty payments to be paid on a quarterly basis to Enaltus on future bioCorneum® sales for the 4.5 years beginning January 1, 2024. The Company has determined the fair value of the deferred consideration and contingent consideration at the acquisition date using a Monte Carlo simulation model. The fair value of the deferred consideration is based on the future minimum royalty payments using the risk-free U.S Treasury yield curve discount rate. The estimated future payments due under the deferred consideration are $546. The fair value of the contingent consideration is based on projected future bioCorneum® sales and a risk adjusted discount rate. The terms of the agreement do not provide for a limitation on the maximum potential future payments. The inputs are significant inputs not observable in the market, which are referred to as Level 3 inputs and are further discussed in Note 5. The deferred consideration and contingent consideration components are classified as an other long-term liability and are subject to the recognition of subsequent changes in fair value through the results of operations.

The Company allocated the total consideration transferred to the tangible and identifiable intangible assets acquired based on their respective fair values on the acquisition date, with the remaining unallocated amount recorded as goodwill. The goodwill arising from the transaction is primarily attributable to expected operational synergies, and all of goodwill will be deductible for income tax purposes. The condensed financial statements for the three and six months ended June 30, 2016 include the results of operations of bioCorneum® from the date of acquisition.

The following table summarizes the allocation of the fair value of the consideration transferred by major class for the business combination completed on March 9, 2016:

	March 9, 2016
Inventory	$ 100
Prepaid expenses	36
Goodwill	3,273
Intangible assets	4,000
	$ 7,409

A summary of the intangible assets acquired, estimated useful lives and amortization method is as follows:

	Amount	Estimated useful life (in years)	Amortization method
Customer relationships	$ 3,200	10	Accelerated
Trade name	800	12	Straight-line
	$ 4,000		

The Company retained an independent third-party appraiser to assist management in its valuation; however, the purchase price allocation has not been finalized. This could result in adjustments to the carrying value of the assets acquired and

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liabilities assumed, the useful lives of intangible assets and residual amount allocated to goodwill. The preliminary allocation of the purchase price is based on the best estimates of management and is subject to revision based on the final valuations and estimates of useful lives.

Pro forma results of operations have not been presented because the effect of the acquisition was not material to the Company's condensed results of operations.

4.Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, and customer deposits are reasonable estimates of their fair value because of the short maturity of these items. The fair value of the common stock warrant liability, deferred consideration and contingent consideration is discussed in Note 5. As of June 30, 2016, the Company had no outstanding long-term debt.

5.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 warrants are valued using the fair value of common stock as of the measurement date. 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 Company assessed the fair value of the deferred consideration and contingent consideration for future royalty payments related to the acquisition of bioCorneum® using the Monte Carlo simulation model. Significant assumptions used in the measurement include future net sales for a defined term and the risk adjusted discount rate associated with the business. As the inputs are not observable, the overall, fair value measurement of the deferred consideration and contingent consideration is classified as Level 3.

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The following tables present information about the Company's liabilities that are measured at fair value on a recurring basis as of June 30, 2016 and December 31, 2015 and indicate the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of June 30, 2016 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Liability for common stock warrants	$ —	—	66	66
Liability for deferred consideration	—	—	437	437
Liability for contingent consideration	—	—	124	124
	$ —	—	627	627

	Fair Value Measurements as of December 31, 2015 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Liability for common stock warrants	$ —	—	60	60
	$ —	—	60	60

The liability for common stock warrants is included in "accrued and other current liabilities" and the liability for the deferred consideration and contingent consideration is included in the "warranty reserve and other long-term liabilities" in the balance sheet. The following table provides a rollforward of the aggregate fair values of the Company's common stock warrants, deferred and contingent consideration for which fair value is determined by Level 3 inputs:

Warrant Liability	
Balance, December 31, 2015	$ 60
Increase in fair value through June 30, 2016	6
Balance, June 30, 2016	$ 66
Deferred Consideration Liability	
Balance, December 31, 2015	$ —
Initial fair value of acquisition-related deferred consideration	434
Deferred consideration accretion expense	3
Balance, June 30, 2016	$ 437
Contingent Consideration Liability	
Balance, December 31, 2015	$ —
Initial fair value of acquisition-related contingent consideration	116
Contingent consideration accretion expense	8

Balance, June 30, 2016	$ 124

The Company recognizes changes in the fair value of the warrants, deferred consideration and contingent consideration in “other income (expense), net” in the statement of operations.

6.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, 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 if a patient experiences 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

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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 following table provides a rollforward of the accrued warranties:

	June 30,	
	2016	2015
Beginning balance	$ 1,332	$ 961
Payments made during the period	(9)	(11)
Changes in accrual related to warranties issued during the period	76	287
Changes in accrual related to pre-existing warranties	(2)	(1)
Ending balance	$ 1,397	$ 1,236

7.Net Loss Per Share

Basic net 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 net 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). Dilutive net loss per share is the same as basic net loss per share for all periods presented because the effects of potentially dilutive items were anti-dilutive.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net loss	$ (10,193)	$ (2,992)	$ (22,130)	$ (6,376)
Weighted average common shares outstanding, basic and diluted	18,075,010	14,931,931	18,062,803	14,927,558
Net loss per share attributable to common stockholders	$ (0.56)	$ (0.20)	$ (1.23)	$ (0.43)

The Company excluded the following potentially dilutive securities, outstanding as of June 30, 2016 and 2015, from the computation of diluted net loss per share attributable to common stockholders for the three and six months ended

June 30, 2016 and 2015 because they had an anti-dilutive impact due to the net loss attributable to common stockholders incurred for the periods.

	June 30,	
	2016	2015
Stock options to purchase common stock	2,190,866	2,231,748
Warrants for the purchase of common stock	47,710	47,710
	2,238,576	2,279,458

8.Balance Sheet Components

a.Allowance for Sales Returns and Doubtful Accounts

The Company has established an allowance for sales returns of $3,745 and $660 as of June 30, 2016 and December 31, 2015, respectively, recorded net against accounts receivable in the balance sheet.

The Company has established an allowance for doubtful accounts of $480 and $456 as of June 30, 2016 and December 31, 2015, respectively, recorded net against accounts receivable in the balance sheet.

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b.Property and Equipment

Property and equipment, net consist of the following:

	June 30, 2016	December 31, 2015
Leasehold improvements	$ 86	$ 86
Laboratory equipment and toolings	1,218	366
Computer equipment	281	277
Software	529	655
Office equipment	137	137
Furniture and fixtures	725	724
	2,976	2,245
Less accumulated depreciation	(981)	(841)
	$ 1,995	$ 1,404

Depreciation expense for the three months ended June 30, 2016 and 2015 was $69 and $54, respectively. Depreciation expense for the six months ended June 30, 2016 and 2015 was $139 and $122, respectively.

c.Goodwill and Other Intangible Assets, net

Goodwill represents the excess of the purchase price over the fair value of net assets of purchased businesses. Goodwill is not amortized, but instead subject to impairment tests on at least an annual basis and whenever circumstances suggest that goodwill may be impaired. The Company's annual test for impairment is performed as of October 1 of each fiscal year. The Company makes a qualitative assessment of whether it is more likely than not that a reporting unit's fair value is less than its carrying amount before applying the two-step goodwill impairment test. If the Company concludes that it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, it is not required to perform the two-step impairment test for that reporting unit.

Under the first step of the test, the Company is required to compare the fair value of a reporting unit with its carrying amount, including goodwill. If the fair value of a reporting unit exceeds its carrying amount, goodwill of the reporting unit is not considered impaired and the second step of the test is not performed. If the results of the first step of the impairment test indicate that the fair value of a reporting unit does not exceed its carrying amount, then the second step of the test is required. The second step of the test compares the implied fair value of the reporting unit goodwill with the carrying amount of that goodwill. The impairment loss is measured by the excess of the carrying amount of

the reporting unit goodwill over the implied fair value of that goodwill.

The changes in the carrying amount of goodwill during the six months ended June 30, 2016 were as follows:

Balances as of December 31, 2015	
Goodwill	$ 14,278
Accumulated impairment losses	(14,278)
	—
Goodwill acquired (Note 3)	3,273
Balances as of June 30, 2016	
Goodwill	17,551
Accumulated impairment losses	(14,278)
	$ 3,273

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The components of the Company’s other intangible assets consist of the following:

	June 30, 2016	December 31, 2015
Acquired FDA non-gel product approval	$ 1,713	$ 1,713
Customer relationships	3,200	—
Trade name	800	—
Non-compete agreement	30	—
Less accumulated amortization	(1,947)	(1,660)
	$ 3,796	$ 53

Amortization expense for the three months ended June 30, 2016 and 2015 was $212 and $16, respectively. Amortization expense for the six months ended June 30, 2016 and 2015 was $286 and $31, respectively. The following table summarizes the estimated amortization expense relating to the Company's intangible assets as of June 30, 2016:

Period	Amortization Expense
Remainder of 2016	$ 420
2017	813
2018	612
2019	464
2020	353
	$ 2,662

d.Accrued and Other Current Liabilities

Accrued and other current liabilities consist of the following:

	June 30, 2016	December 31, 2015
Accrued clinical trial and research and development expenses	$ 108	$ 215
Audit, consulting and legal fees	2,151	1,208
Payroll and related expenses	2,153	2,494
Accrued commission	2,143	1,960
Warrant liability	66	60

Other	795	1,022
	$ 7,416	$ 6,959

9.Stockholders' Equity

a.Authorized Stock

The Company's Amended and Restated Certificate of Incorporation authorizes the Company to issue 210,000,000 shares of common and preferred stock, consisting of 200,000,000 shares of common stock with $0.01 par value and 10,000,000 shares of preferred stock with $0.01 par value. As of June 30, 2016 and December 31, 2015, the Company had no preferred stock issued or outstanding.

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b.Stock Warrants

On January 17, 2013, the Company entered into a Loan and Security Agreement, or the Original Term Loan Agreement, with Oxford Finance, LLC, or Oxford. On June 30, 2014, the Company entered into the Amended and Restated Loan and Security Agreement, or the Amended Term Loan Agreement, with Oxford. 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 of $14.671. As of June 30, 2016, the Company had warrants to purchase an aggregate of 47,710 shares of common stock outstanding.

c.Stock Option Plans

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 under the 2007 Plan.

The Company's board of directors adopted the 2014 Equity Incentive Plan, or 2014 Plan, in July 2014, and the stockholders approved the 2014 Plan in October 2014. The 2014 Plan became effective upon completion of the IPO on November 3, 2014, at which time the Company ceased granting awards under the 2007 Plan. Under the 2014 Plan, the Company may issue ISOs, 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 the Company and their 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. As of June 30, 2016, a total of 2,045,495 shares of the Company's common stock were reserved for issuance under the 2014 Plan.

In March 2016, the Company's board of directors adopted the Inducement Plan. Under the Inducement Plan, the Company may issue NSOs and restricted stock unit awards, or collectively, stock awards, all of which may only be granted to new employees of the Company and their affiliates. A total of 180,000 shares of the Company's common stock were initially reserved for issuance under the Inducement Plan.

Options under the 2007 Plan and the 2014 Plan may be granted for periods of up to ten years as determined by the Company's 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. NSOs under the Inducement Plan may be granted for periods of up to ten years as determined by the board of directors, provided, the exercise price will be not less than 100% of the estimated fair value of the shares on the date of grant. Options generally vest with 25% of the grant vesting on the first anniversary and the balance vesting monthly on a straight-lined basis over the requisite service period of three additional years for the award. Additionally, options have been granted to certain key executives which vest upon achievement of performance conditions based on performance targets as defined by the board of directors, which have included net sales targets and defined corporate objectives over the performance period with possible payout ranging from 0% to 100% of the target award. Compensation expense is recognized on a straight-lined basis over the vesting term of one year based upon the probable performance target that will be met. The vesting provisions of individual options may vary but provide for vesting of at least 25% per year.

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The following summarizes all option activity under the 2007 Plan, 2014 Plan and Inducement Plan:

	Option Shares	Weighted average exercise price	Weighted average remaining contractual term (year)
Balances at December 31, 2015	2,785,672	$ 6.66	6.60
Granted	271,753	6.14	
Exercised	(14,529)	3.94	
Forfeited	(41,926)	15.25	
Balances at June 30, 2016	3,000,970	$ 6.51	6.38

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 $474 and $444 for the three months ended June 30, 2016 and 2015, respectively. Stock-based compensation expense was $848 and $889 for the six months ended June 30, 2016 and 2015, respectively. As of June 30, 2016, there was $3,837 of unrecognized compensation costs related to stock options. The expense is recorded within the operating expense components in the statement of operations based on the employees receiving the awards. These costs are expected to be recognized over weighted average period of 2.79 years.

d.Restricted Stock Units

The Company has issued restricted stock unit awards, or RSUs, under the 2014 Plan. The RSUs issued vest on a straight-line basis, either quarterly over a 4-year requisite service period or annually over a 3-year requisite service period.

Activity related to RSUs is set forth below:

	Number of shares	Weighted average grant date fair value
Balances at December 31, 2015	17,993	$ 3.88
Granted	557,240	8.21

Vested	(2,250)	3.88
Balances at June 30, 2016	572,983	$ 8.09

Stock-based compensation expense for RSUs for the three months ended months ended June 30, 2016 and 2015 was $377 and $0, respectively. Stock-based compensation expense for RSUs for the six months ended June 30, 2016 and 2015 was $641 and $0, respectively. As of June 30, 2016, there was $3,998 of total unrecognized compensation cost related to non-vested RSU awards. The cost is expected to be recognized over a weighted average period of 2.33 years.

e.Employee Stock Purchase Plan

The Company's board of directors adopted the 2014 Employee Stock Purchase Plan, or ESPP, in July 2014, and the stockholders approved the ESPP in October 2014. The ESPP allows eligible employees to purchase shares of the Company's common stock at a discount through payroll deductions of up to 15% of their eligible compensation, subject to any plan limitations. The ESPP provides offering periods not to exceed 27 months, and each offering period will include purchase periods, which will be the approximately six-month period commencing with one exercise date and ending with the next exercise date, except that the first offering period commenced on the first trading day following the effective date of the Company's registration statement. Employees are able to purchase shares at 85% of the lower of the fair market value of the Company's common stock on the first trading day of the offering period or on the exercise date. A total of 255,500 shares of common stock were initially reserved for issuance under the ESPP, subject to certain annual increases.

As of June 30, 2016, the number of shares of common stock reserved for issuance under the ESPP was 584,563. During the six months ended June 30, 2016, employees purchased 68,226 shares of common stock at a weighted average price of $6.30 per share. As of June 30, 2016, the number of shares of common stock available for future issuance was 472,087.

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The Company estimated the fair value of employee stock purchase rights using the Black-Scholes model. Stock-based compensation expense related to the ESPP was $74 and $95 for the three months ended June 30, 2016 and 2015, respectively. Stock-based compensation expense related to the ESPP was $175 and $193 for the six months ended June 30, 2016 and 2015, respectively.

10.Commitments and Contingencies

a.Operating Leases

The Company's lease for its general office facility in Santa Barbara, California expires in February 2020. The Company also leases additional industrial space for warehouse, research and development and additional general office use. Rent expense was $128 and $141 for the three months ended June 30, 2016 and 2015, respectively. Rent expense was $254 and $264 for the six months ended June 30, 2016 and 2015, 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 June 30, 2016.

On September 25, 2015, a lawsuit styled as a class action of the Company's stockholders was filed in the United States District Court for the Central District of California. The lawsuit names the Company and certain of its officers as defendants, or Sientra Defendants, and alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, in connection with allegedly false and misleading statements concerning the Company's business, operations, and prospects. The plaintiff seeks damages and an award of reasonable costs and expenses, including attorneys' fees. On November 24, 2015, three stockholders (or groups of stockholders) filed motions to appoint lead plaintiff(s) and to approve their selection on lead counsel. On December 10, 2015, the court entered an order appointing lead plaintiffs and approving their selection of lead counsel. On February 19, 2016, lead plaintiffs filed their consolidated amended complaint, which added a claim under Section 11 of the Securities Act and named as defendants the underwriters associated with the Company's follow-on public offering that closed on September 23, 2015, or the Underwriter Defendants. On March 21, 2016, the Sientra Defendants and the Underwriter Defendants each filed a motion to dismiss, or the Motions to Dismiss, the consolidated amended complaints. On April 20, 2016, lead plaintiffs filed their opposition to the Motions to Dismiss, and the Sientra Defendants and Underwriter Defendants filed separate replies on May 5, 2016. On June 9, 2016, the court granted in part and denied in part the Motions to Dismiss. On July 14, 2016, the Sientra Defendants moved the court to reconsider its June 9, 2016 order and grant the Motions to Dismiss in full. On August 4, 2016, lead plaintiffs filed an opposition to the motion for

reconsideration.

On October 28, November 5, and November 19, 2015, three lawsuits styled as class actions of the Company's stockholders were filed in the Superior Court of California for the County of San Mateo. The lawsuits name the Company, certain of its officers and directors, and the underwriters associated with the Company's follow-on public offering that closed on September 23, 2015 as defendants. The lawsuits allege violations of Sections 11, 12(a)(2), and 15 of the Securities Act in connection with allegedly false and misleading statements in the Company's offering documents associated with the follow-on offering concerning its business, operations, and prospects. The plaintiffs seek damages and an award of reasonable costs and expenses, including attorneys' fees. On December 4, 2015, defendants removed all three lawsuits to the United States District Court for the Northern District of California. On December 15 and December 16, 2015, plaintiffs filed motions to remand the lawsuits back to San Mateo Superior Court, or the Motions to Remand. On January 19, 2016, defendants filed their opposition to the Motions to Remand, and plaintiffs filed their reply in support of the Motions to Remand on January 26, 2016.

On May 20, 2016, the United States District Court for the Northern District of California granted plaintiffs' Motions to Remand, and the San Mateo Superior Court received the remanded cases on May 27, 2016. On July 19, 2016, the San Mateo Superior Court consolidated the three lawsuits. On August 2, 2016, plaintiffs filed their consolidated complaint.

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On August 5, 2016, defendants filed a motion to stay all proceedings in favor of the class action filed in the United States District Court for the Central District of California.

It is possible that additional suits will be filed, or allegations made by stockholders, with respect to these same or other matters and also naming the Company and/or its officers and directors as defendants. The Company believes it has meritorious defenses and intends to defend these lawsuits vigorously. Due to the early stage of these proceedings, the Company is not able to predict or reasonably estimate the ultimate outcome or possible losses relating to these claims.

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, 2015 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission on March 10, 2016. 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 and Section 21E of 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," "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 choices to board certified plastic surgeons and patients in need of medical aesthetics products. We have developed a broad portfolio of products with technologically differentiated characteristics, supported by independent laboratory testing and strong clinical trial outcomes. We sell our breast implants and breast tissue expanders, or Breast Products, exclusively to board certified and board admissible plastic surgeons and tailor our customer service offerings to their specific needs, which we believe helps secure their loyalty and confidence. We began selling bioCorneum®, an advanced silicone scar treatment, or Scar Management Products, directly to physicians after we acquired bioCorneum® from Enaltus on March 9, 2016.

Our primary products are silicone gel breast implants for use in breast augmentation and breast reconstruction procedures, which we offer in over 195 variations of shapes, sizes, fill volumes and textures. Our breast implants are primarily used in elective procedures which are generally performed on a cash pay basis. Many of our breast implants incorporate one or more differentiated technologies, including a proprietary high strength, cohesive silicone gel and proprietary texturing branded TRUE Texture®. Our breast implants offer a desired balance between strength, shape retention and softness due to the high strength, cohesive silicone gel used in our manufacturing process. TRUE Texture® provides texturing on the implant shell that is designed to reduce the incidence of malposition, rotation and capsular contracture. We also offer breast

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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, or the Study, of our breast implants in 1,788 women across 36 investigational sites in the United States, which included 3,506 implants (approximately 53% of which were smooth and 47% of which were textured). Our clinical trial is the largest prospective, long term safety and effectiveness pivotal study of breast implants in the United States and included the largest magnetic resonance imaging, or MRI, cohort with 571 patients. The MRI cohort is a subset of study patients that underwent regular MRI screenings in addition to the other aspects of the clinical trial protocol prior to FDA approval. Post-approval, all patients in the Study are subject to serial MRI screening as part of the clinical protocol. The clinical data we collected over a nine year follow up period demonstrated rupture rates, capsular contracture rates and reoperation rates that were comparable to or better than those of our competitors, at similar time points. In addition to our pivotal study, our clinical data is supported by our Continued Access Study of 2,497 women in the United States. We have also commissioned a number of bench trials run by independent laboratories that we believe further demonstrate the advantages of our breast implants over those of our competitors.

We sell our Breast Products exclusively to board certified and board admissible plastic surgeons, as determined by the American Board of Plastic Surgery, who we refer to as Plastic Surgeons. These surgeons have completed the extensive multi year plastic surgery residency training required by the American Board of Plastic Surgery. While aesthetic procedures are performed by a wide range of medical professionals, including dermatologists, otolaryngologists, obstetricians, gynecologists, dentists and other specialists, the majority of aesthetic surgical procedures are performed by Plastic Surgeons. Plastic Surgeons are thought leaders in the medical aesthetics industry. According to the American Board of Plastic Surgery, there are approximately 6,500 board certified plastic surgeons in the United States. We seek to provide Plastic Surgeons with differentiated services, including enhanced customer service offerings, a ten year limited warranty that we believe is the best in the industry based on: providing patients with the largest cash reimbursement for certain out of pocket costs related to revision surgeries in a covered event; a lifetime no charge implant replacement program for covered ruptures; and our industry first CapCon Care Program, or C3 Program, through which we offer no charge replacement implants to breast augmentation patients who experience capsular contracture within the first five years after implantation with our smooth or textured breast implants.

Between October 9, 2015 and March 1, 2016, we voluntarily suspended the sale of all Sientra devices manufactured by our sole manufacturer and supplier Silimed due to the suspension of Silimed's CE certificate by TUV SUD, Silimed's notified body under EU regulations, followed by Brazilian regulatory inquiries and a temporary suspension by the Brazilian regulatory agency ANVISA and the Department of the Secretary of State of Rio de Janeiro of the manufacturing and shipment of all medical devices made by Silimed, and recommended that plastic surgeons discontinue implanting the devices until further notice. See Note 1c to our Condensed Financial Statements for more information on the history of these developments with Silimed.

After ongoing discussions with the FDA and our own review of the matter with the assistance of independent experts in quality management systems, Good Manufacturing Practices, or GMP, and data-based risk assessment, on March 1, 2016, we lifted the temporary hold on sale and also sent a letter to our Plastic Surgeons informing them of our market re-entry plans. We have limited inventory of our Breast Products due to (i) the fire on October 22, 2015 at the manufacturing building where Silimed primarily manufactured our breast implants, and (ii) Silimed's ability to manufacture products (only recently reinstated by ANVISA on July 11, 2016) for commercial sale in the U.S. at their alternate facility, which will require Silimed to submit a PMA supplement for the alternate facility and require the manufacturing operations to receive a validation of U.S. FDA standards and a successful FDA inspection, the timing of which is uncertain. Accordingly, we developed and communicated to our Plastic Surgeons a controlled market

re-entry plan designed to optimize our inventory supply.

We are working with Silimed to seek clarity as to the near and long-term capabilities of Silimed's manufacturing operations. There are several uncertainties regarding the recent events involving Silimed that may have a material unfavorable impact on our net sales of Breast Products, including the impact on inventory levels and inventory adjustments we may need to make in order to address uncertainty regarding Silimed's ability to manufacture our Breast Products, the feasibility and timing of production capacity at Silimed's alternate facility, the uncertainty and timing regarding regulatory

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requirements Silimed must satisfy in order to be able manufacture our Breast Products for commercial sale in the U.S., and uncertainty of our customers' responsiveness to our market re-entry plans after we had imposed our voluntary hold on the sale and implanting of all Sientra devices manufactured by Silimed between October 9, 2015 and March 1, 2016. See "Risk Factors — Risks Relating to Our Business and Our Industry" for further detail.

We sell our products in the United States through a direct sales organization consisting of 45 employees, including 38 sales representatives and 7 sales managers, as of June 30, 2016.

Recent Developments

The following is a summary of significant developments affecting our business that have occurred since the filing of our Quarterly Report on Form 10-Q for the period ended March 31, 2016. For additional developments see our Annual Report on Form 10-K for the year ended December 31, 2015 and our Quarterly Report on Form 10-Q for the period ended March 31, 2016.

On August 9, 2016, we announced our collaboration with Vesta Intermediate Funding, Inc., or Vesta, pursuant to which we are working with Vesta towards establishing a dedicated contract manufacturing facility for Sientra's breast implant products. Vesta is a Lubrizol LifeSciences Company and leading medical device contract manufacturer of silicone products and other medical devices headquartered in Wisconsin.

Components of Operating Results

Net Sales

We recognize revenue, net of sales discounts and estimated returns, as the customer has a standard six-month window to return purchased Breast Products. We commenced sales of our Breast Products in the United States in the second quarter of 2012 and our Breast Products have historically accounted for substantially all of our net sales. However, sales of our Breast Products accounted for 79% of our net sales for the three and six months ended June 30, 2016, as compared to 98% of our net sales for the three and six months ended June 30, 2015. The percentage decrease in sales of Breast Products for the 2016 periods reflects the combined effect of the temporary hold on sales and implanting of Breast Products until March 1, 2016 and the commercial introduction of our Scar Management Products as a result of the acquisition of bioCorneum® on March 9, 2016. Sales of Scar Management Products are included the results of operations from the date of acquisition and accounted for 18% of our net sales for the three and six months ended June 30, 2016.

We expect that, in the future, assuming a favorable outcome of the aforementioned recent events, that 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 manufacturers, reserve for product warranties and warehouse and other related costs.

Our Breast Products, tissue expanders and certain other products are manufactured in Brazil under an exclusive contract with Silimed. Under our contract with Silimed, each particular style of implant has a fixed unit cost. Our bioCorneum® Scar Management Products are manufactured in the U.S. under an exclusive contract with Formulated Solutions, LLC, or Formulated Solutions. Under our contract with Formulated Solutions, each particular product has a fixed unit cost.

In addition to product costs, we provide a commercial warranty on our silicone gel-filled breast implants. The warranty covers device ruptures in certain circumstances. Estimated warranty costs are recorded at the time of sale. Our warehouse and other related costs include labor, rent, product shipments from our third-party manufacturer and other related costs.

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We expect our overall gross margin, which is calculated as net sales less cost of goods sold for a given period divided by net sales, to fluctuate in future periods primarily as a result of quantity of units sold, manufacturing price increases, the changing mix of products sold with different gross margins, overhead costs 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 no-charge product evaluation units, as well as educational, promotional and marketing activities, including direct and online marketing. We expect our sales and marketing expenses to fluctuate in future periods as a result of headcount and timing of our marketing programs. However, we generally expect these costs will increase in absolute dollars.

Research and Development Expenses

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

We expect our R&D expenses to vary as different development projects are initiated, including improvements to our existing products, expansions of our existing product lines, new product acquisitions and our FDA required PMA 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, corporate insurance, employee benefits, facilities and information technologies expenses. In 2015, G&A expenses also include the federal excise tax on the sale of our medical devices in the United States.

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 continue to incur G&A expenses in connection with operating as a public company, which may increase further when we are no longer able to rely on the “emerging growth company” exemption we are afforded under the Jumpstart Our Business Startups Act, or the JOBS Act, as well as legal counsel and litigation expenses in connection with the lawsuits styled as class actions of the Company’s stockholders filed in the fourth quarter of 2015.

Other Income (Expense), net

Other income (expense), net primarily consists of interest income and changes in the fair value of common stock warrants.

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 2 of the “Notes to Financial Statements” in our audited financial statements included in

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our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission on March 10, 2016. There have been no material changes to our critical accounting policies and estimates from those disclosed in our Annual Report on Form 10-K.

Recent Accounting Pronouncements

Please refer to Note 2 - Summary of Significant Accounting Policies in the notes to the unaudited condensed financial statements included in this Form 10-Q for information on recent accounting pronouncements and the expected impact on our financial statements.

Results of Operations

Comparison of the Three Months Ended June 30, 2016 and 2015

The following table sets forth our results of operations for the three months ended June 30, 2016 and 2015:

	Three Months Ended June 30,	
	2016	2015
	(unaudited, in thousands)	
Statement of operations data		
Net sales	$ 6,244	$ 14,206
Cost of goods sold	1,745	3,937
Gross profit	4,499	10,269
Operating Expenses		
Sales and marketing	6,287	6,951
Research and development	3,062	1,497
General and administrative	5,357	3,943
Total operating expenses	14,706	12,391
Loss from operations	(10,207)	(2,122)
Other income (expense), net		
Interest income	16	7
Interest expense	(12)	(671)
Other income (expense), net	10	(206)

Total other income (expense), net	14	(870)
Net loss	$ (10,193)	$ (2,992)

Net Sales

Net sales decreased $8.0 million, or 56.0%, to $6.2 million for the three months ended June 30, 2016, as compared to $14.2 million for the three months ended June 30, 2015. Net sales of our Breast Products decreased $8.9 million for the three months ended June 30, 2016, as compared to the three months ended June 30, 2015, as a result of our controlled re-entry to market designed to optimize our supply of Breast Product inventory. The decrease in Breast Product net sales was offset by $1.0 million of Scar Management Product net sales, for the three months ended June 30, 2016, following the acquisition of bioCorneum® on March 9, 2016.

As of June 30, 2016, our sales organization included 38 sales representatives as compared to 46 sales representatives as of June 30, 2015.

Cost of Goods Sold and Gross Margin

Cost of goods sold decreased $2.2 million, or 55.7%, to $1.7 million for the three months ended June 30, 2016, as compared to $3.9 million for the three months ended June 30, 2015. This decrease was primarily due to a decrease in sales volume driven by our controlled re-entry into the marketplace.

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The gross margins for the three months ended June 30, 2016 and 2015 were 72.1% and 72.3%, respectively. The decrease was primarily due to an incremental $0.1 million reserve for inventory obsolescence recorded for product that we estimate to expire prior to being sold and greater fixed overhead as a percentage of net sales.

Sales and Marketing Expenses

Sales and marketing decreased $0.7 million, or 9.6%, to $6.3 million for the three months ended June 30, 2016, as compared to $7.0 million for the three months ended June 30, 2015. This decrease consisted of a $0.7 million decrease in marketing costs due to lower no charge customer shipping costs and less direct and online marketing activities in the period.

Research and Development Expenses

R&D expenses increased $1.6 million, or 104.5%, to $3.1 million for the three months ended June 30, 2016, as compared to $1.5 million for the three months ended June 30, 2015. This increase was primarily due to a $1.5 million increase in product development costs and consulting fees.

General and Administrative Expenses

G&A expenses increased $1.4 million, or 35.9%, to $5.4 million for the three months ended June 30, 2016, as compared to $3.9 million for the three months ended June 30, 2015. This increase consisted primary of a $1.5 million increase in outside legal counsel and litigation expenses, along with an increase in acquisition-related costs, a $0.3 million increase in stock compensation expense, offset by a $0.2 million decrease in medical device excise tax costs as a result of the suspension of the tax during calendar years 2016 and 2017.

Other Income (Expense), net

Other income (expense), net for the three months ended June 30, 2016 was primarily associated with interest income on cash held in a money market account and income recognized for the change in fair value of warrants. Other income (expense), net for the three months ended June 30, 2015 was primarily associated with interest expense on our Oxford term loans, which were repaid in full in the fourth quarter of 2015.

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Comparison of the Six Months Ended June 30, 2016 and 2015

The following table sets forth our results of operations for the six months ended June 30, 2016 and 2015:

	Six Months Ended June 30,	
	2016	2015
	(unaudited, in thousands)	
Statement of operations data		
Net sales	$ 7,715	$ 26,640
Cost of goods sold	2,506	7,174
Gross profit	5,209	19,466
Operating Expenses		
Sales and marketing	11,396	13,805
Research and development	5,317	2,753
General and administrative	10,642	7,664
Total operating expenses	27,355	24,222
Loss from operations	(22,146)	(4,756)
Other income (expense), net:		
Interest income	31	7
Interest expense	(13)	(1,339)
Other income (expense), net	(2)	(288)
Total other income (expense), net	16	(1,620)
Net loss	$ (22,130)	$ (6,376)

Net Sales

Net sales decreased $18.9 million, or 71.0%, to $7.7 million for the six months ended June 30, 2016, as compared to $26.6 million for the six months ended June 30, 2015. Net sales of our Breast Products decreased $20.0 million for the six months ended June 30, 2016, as compared to the six months ended June 30, 2015, as a result of both our voluntary hold on the sale and implanting of all Sientra devices manufactured by Silimed between October 9, 2015 and March 1, 2016 and our controlled re-entry to market designed to optimize our supply of Breast Products inventory. The decrease in Breast Product net sales were offset by $1.1 million of Scar Management Product net sales for the six months ended June 30, 2016, following the acquisition of bioCorneum® on March 9, 2016.

Cost of Goods Sold and Gross Margin

Cost of goods sold decreased $4.7 million, or 65.1%, to $2.5 million for the six months ended June 30, 2016, as compared to $7.2 million for the six months ended June 30, 2015. This decrease was due to a decrease in sales volume driven by both our voluntary hold on sales from October 9, 2015 to March 1, 2016 and our controlled re-entry into the marketplace, offset by an incremental $0.4 million reserve for inventory obsolescence recorded for product that we estimate to expire prior to being sold.

The gross margins for the six months ended June 30, 2016 and 2015 were 67.5% and 73.1%, respectively. This decrease was primarily due to an incremental $0.4 million reserve for inventory obsolescence recorded for product that we estimate to expire prior to being sold and greater fixed overhead as a percentage of net sales.

Sales and Marketing Expenses

Sales and marketing decreased $2.4 million, or 17.5%, to $11.4 million for the six months ended June 30, 2016, as compared to $13.8 million for the six months ended June 30, 2015. This decrease consisted primarily of a $1.7 million decrease in marketing costs due to lower no charge customer shipping costs and less direct and online marketing activities in the period and as well as a $0.8 million decrease in employee-related costs for the sales department.

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Research and Development Expenses

R&D expenses increased $2.6 million, or 93.1%, to $5.3 million for the six months ended June 30, 2016, as compared to $2.8 million for the six months ended June 30, 2015. This increase was primarily due to a $1.7 million increase in product development costs and consulting fees.

General and Administrative Expenses

G&A expenses increased $3.0 million, or 38.9%, to $10.6 million for the six months ended June 30, 2016, as compared to $7.7 million for the six months ended June 30, 2015. This increase consisted primary of a $2.4 million increase in outside legal counsel and litigation expenses, along with an increase in acquisition-related costs, a $0.4 million increase in stock compensation expense, a $0.3 million increase in amortization expense related to the bioCorneum® acquisition, and a $0.3 million increase in bad debt expense, offset by a $0.5 million decrease in medical device excise tax costs as a result of the suspension of the tax during calendar years 2016 and 2017.

Other Income (Expense), net

Other income (expense), net for the six months ended June 30, 2016 was primarily associated with interest income on cash held in a money market account offset by expense recognized for the change in fair value of warrants. Other income (expense), net for the six months ended June 30, 2015 was primarily associated with interest expense on our Oxford term loans, which were repaid in full in the fourth quarter of 2015.

Liquidity and Capital Resources

Since our inception, we have incurred significant net operating losses and anticipate that our losses will continue in the near term. We expect our operating expenses will continue to grow as we expand our operations. We will need to generate significant net sales to achieve profitability. To date, we have funded our operations primarily with proceeds from the sales of preferred stock, borrowings under our term loans, sales of our products since 2012, and the proceeds from the sale of our common stock in public offerings. As of June 30, 2016, we had no long-term debt.

In November 2014, we completed our IPO of common stock in which we sold 5,750,000 shares at a price of $15.00 per share, raising approximately $77.0 million in net proceeds after deducting underwriting discounts and commissions of approximately $6.0 million and offering expenses of approximately $3.2 million.

On September 23, 2015, we completed a follow-on public offering of common stock in which we sold 3,000,000 shares at a price of $22.00 per share, raising approximately $61.4 million in net proceeds after deducting underwriting discounts and commissions of approximately $4.0 million and offering expenses of approximately $0.6 million.

As of June 30, 2016, we had $86.2 million in cash and cash equivalents. Our historical cash outflows have primarily been associated with research and development activities, especially 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 as well as the expansion of our sales force and marketing programs. We believe that our available cash on hand will be sufficient to satisfy our liquidity requirements for at least the next 12 months. However, we expect that the recent events involving Silimed, including our voluntary hold on the sale and implanting of all Sientra devices manufactured by Silimed between October 9, 2015 and March 1, 2016, our uncertainty regarding the amount of additional expenses we may incur in connection with regulatory inquiries, as well as expenses we may incur in connection with reestablishing our inventory supply as a result of the fire in Silimed's manufacturing facility, as well as expenses we may incur defending against litigation claims, including the lawsuits styled as class actions filed in the fourth quarter of 2015, may have a material effect on our future cash outflows and our liquidity. 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.

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Cash Flows

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

	Six Months Ended June 30,	
	2016	2015
	(unaudited, in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (19,496)	$ (6,580)
Investing activities	(7,633)	(511)
Financing activities	487	21
Net change in cash and cash equivalents	$ (26,642)	$ (7,070)

Cash used in operating activities

Net cash used in operating activities was $19.5 million during the six months ended June 30, 2016, as compared to $6.6 million during the six months ended June 30, 2015. The increase in cash used in operating activities between the six months ended June 30, 2016 and 2015 was primarily associated with the increase in net loss of $15.8 million and a decrease in customer deposits, offset by a decrease in inventory.

Cash used in investing activities

Net cash used in investing activities was $7.6 million during the six months ended June 30, 2016 as compared to $0.5 million during the six months ended June 30, 2015. The increase in cash used in investing activities between the six months ended June 30, 2016 and 2015 was primarily due to a $0.3 million increase in property and equipment purchases and a $6.8 million cash outflow for the acquisition of bioCorneum®.

Cash used in financing activities

Net cash provided by financing activities was $0.5 million during the six months ended June 30, 2016 as compared to $21 thousand during the six months ended June 30, 2015. The increase in cash provided by financing activities was primarily the result of $0.4 million in contributions from common stock issued under the employee stock purchase plan.

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:

- our continued ability to rely on Silimed to manufacture and supply our silicone gel breast implants, tissue expanders and certain other products or the timing and availability of alternative manufacturing sources;
- net sales generated by our Breast Products, Scar Management Products, and any other future products that we may develop and commercialize;
- costs associated with expanding our sales force and marketing programs;
- cost associated with developing and commercializing our proposed products or technologies;
- expenses we incur in connection with potential litigation or governmental investigations;
- cost of obtaining and maintaining regulatory clearance or approval for our current or future products;
- cost of ongoing compliance with regulatory requirements;
- anticipated or unanticipated capital expenditures; and

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· unanticipated G&A expenses.

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

· cost of ongoing compliance with recent regulatory inquiries involving Silimed;

· costs associated with our own review and testing at Silimed's manufacturing facilities and of our own inventory;

expenses we incur in connection with defending against the lawsuits filed against us alleging violations of the Exchange Act and the Securities Act in connection with allegedly false and misleading statements concerning Sientra's business, operations, and prospects;

· support of our sales and marketing efforts related to our current and future products;
· new product acquisition and development efforts;
· facilities expansion needs; and
· investment in inventory required to meet customer demands.

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

Contractual Obligations and Commitments

As of June 30, 2016, 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 Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission on March 10, 2016.

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

As of June 30, 2016, we had $86.2 million in cash and cash equivalents. We generally hold our cash in checking accounts and interest-bearing money market accounts. Our exposure to market risk related to interest rate sensitivity is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents.

ITEM 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 maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current

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reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. 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.

As of June 30, 2016, we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of June 30, 2016.

An evaluation was also performed under the supervision and with the participation of our management, including our chief executive officer and our principal financial officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On September 25, 2015, a lawsuit styled as a class action of the Company's stockholders was filed in the United States District Court for the Central District of California. The lawsuit names the Company and certain of our officers as defendants, or the Sientra Defendants, and alleges violations of Sections 10(b) and 20(a) of the Exchange Act of 1934, as amended, or the Exchange Act, in connection with allegedly false and misleading statements concerning the Company's business, operations, and prospects. The plaintiff seeks damages and an award of reasonable costs and expenses, including attorneys' fees. On November 24, 2015, three stockholders (or groups of stockholders) filed motions to appoint lead plaintiff(s) and to approve their selection on lead counsel. On December 10, 2015, the court entered an order appointing lead plaintiffs and approving their selection of lead counsel. On February 19, 2016, lead plaintiffs filed their consolidated amended complaint, which added a claim under Section 11 of the Securities Act and named as defendants the underwriters associated with the Company's follow-on public offering that closed on September 23, 2015, or the Underwriter Defendants. On March 21, 2016, the Sientra Defendants and the Underwriter Defendants each filed a motion to dismiss, or the Motions to Dismiss, the consolidated amended complaints. On April 20, 2016, lead plaintiffs filed their opposition to the Motions to Dismiss, and the Sientra Defendants and Underwriter Defendants filed separate replies on May 5, 2016. On June 9, 2016, the court granted in part and denied in part the Motions to Dismiss. On July 14, 2016, the Sientra Defendants moved the court to reconsider its June 9, 2016 order

and grant the Motions to Dismiss in full. On August 4, 2016, lead plaintiffs filed an opposition to the motion for reconsideration.

On October 28, November 5, and November 19, 2015, three lawsuits styled as class actions of the Company's stockholders were filed in the Superior Court of California for the County of San Mateo. The lawsuits name the Company, certain of our officers and directors, and the underwriters associated with our follow-on public offering that closed on September 23, 2015 as defendants. The lawsuits allege violations of Sections 11, 12(a)(2), and 15 of the Securities Act in connection with allegedly false and misleading statements in our offering documents associated with the follow-on offering concerning our business, operations, and prospects. The plaintiffs seek damages and an award of reasonable costs and expenses, including attorneys' fees. On December 4, 2015, defendants removed all three lawsuits to the United States District Court for the Northern District of California. On December 15 and December 16, 2015, plaintiffs filed motions to remand the lawsuits back to San Mateo Superior Court, or Motions to Remand. On January 19, 2016, defendants filed their opposition to the Motions to Remand, and plaintiffs filed their reply in support of the Motions to Remand on January 26, 2016.

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On May 20, 2016, the United States District Court for the Northern District of California granted plaintiffs' Motions to Remand, and the San Mateo Superior Court received the remanded cases on May 27, 2016. On July 19, 2016, the San Mateo Superior Court consolidated the three lawsuits. On August 2, 2016, plaintiffs filed their consolidated complaint. On August 5, 2016, defendants filed a motion to stay all proceedings in favor of the class action filed in the United States District Court for the Central District of California.

It is possible that additional suits will be filed, or allegations made by stockholders, with respect to these same or other matters and also naming us and/or our officers and directors as defendants. We believe we have meritorious defenses and intend to defend these lawsuits vigorously. Due to the early stage of these proceedings, we are not able to predict or reasonably estimate the ultimate outcome or possible losses relating to these claims.

Item 1A. RISK FACTORS

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 Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission on March 10, 2016.

Risks Relating to Our Business and Our Industry

There have been several foreign regulatory inquiries which have affected our ability to rely on Silimed, our sole source, third-party manufacturer and supplier of our silicone gel breast implants, tissue expanders and certain other products.*

We currently rely on Silimed, our sole source, third-party manufacturer located in Brazil, to manufacture and supply our silicone gel breast implants, tissue expanders and certain other products. Several recent events have occurred which have affected our ability to rely on Silimed as our source for these products in the short and long term.

On September 23, 2015, the Medicines and Healthcare Products Regulatory Agency, or the MHRA, an executive agency of the U.K., issued a press release announcing the suspension of sales and implanting in U.K. of all medical devices manufactured by Silimed following the suspension of the CE certificate of these products issued by TUV SUD, Silimed's notified body under EU regulation. The suspension of Silimed's CE certificate by TUV SUD followed TUV SUD's inspection at Silimed's manufacturing facilities in Brazil, relating to particles on Silimed breast products.

On October 2, 2015, the Brazilian regulatory agency ANVISA and the Department of the Secretary of State of the State of Rio de Janeiro announced that while they would continue to review the technical compliance related to GMP of Silimed's manufacturing facility, as a precautionary measure, they temporarily suspended the manufacturing and

shipment of all medical devices made by Silimed, including products manufactured for Sientra.

On January 27, 2016, after completing an analysis and risk assessment, ANVISA announced their authorization of Silimed to resume the commercialization and use of its previously manufactured products. ANVISA concluded there was no evidence that the presence of surface particles on the silicone implants represented risks which are additional to the ones inherent in the product. However, Silimed would continue to be suspended from manufacturing and commercializing new batches of implants until an inspection is performed to reassess the fulfillment of its GMP compliance. On July 11, 2016, after completing an inspection of Silimed's facility, ANVISA announced the reinstatement of Silimed's GMP certificate and their ability to manufacture commercial products. The GMP certificate is effective as of July 8, 2016 and is valid for two years. The Silimed facility that has been approved for manufacturing is an alternate facility to where Sientra products were previously manufactured. However, the products manufactured in the alternate facility cannot be sold in the U.S. until Silimed submits a PMA supplement for the facility, their operations have been fully validated to U.S. FDA standards and they have successfully passed an FDA inspection.

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Additionally, the suspension of Silimed's CE certificate by TUV SUD, and the suspension on the commercialization of Silimed's previously manufactured products in Europe by the MHRA remains in place and the determination of Silimed's manufacturing facilities is still under evaluation, and we cannot predict the outcome of these matters. The FDA and other U.S. and foreign regulatory agencies have substantial discretion to require additional testing, to impose restrictions on marketed products or on us, including the withdrawal or recall of such products from the market.

The suspension of the sale and manufacturing of Silimed's products by foreign regulatory agencies, our uncertainty regarding the resolution of the regulatory inquiries and our uncertainty as to when Silimed may be able to resume manufacturing our products may result in a delay or inability for us to meet our demand to supply our products in a timely manner and as a result, our ability to generate net sales may be impaired, market acceptance of our products could be adversely affected and customers may instead purchase or use our competitors' products, any of which could materially adversely and severely affect our business, financial condition and results of operations.

We depend on a positive reaction from our Plastic Surgeons and their patients to successfully re-enter the market after our voluntary suspension of the sale of Sientra devices manufactured by Silimed.*

As a result of the regulatory inquiries into Silimed products, between October 9, 2015 and March 1, 2016, we voluntarily placed a temporary hold on the sale of all Sientra devices manufactured by Silimed and recommended that plastic surgeons discontinue implanting the devices until further notice. We have been in ongoing discussions with the FDA regarding European and Brazilian regulatory inquiries into Silimed products, and conducted our own review of the matter with the assistance of independent experts in quality management systems, GMP and data-based risk assessment. Breast implants have stringent standards for manufacturing and robust quality systems, but there is no specific or defined standard for particles on breast implants. Each of the FDA, ANVISA and MHRA noted that no risks to patient health have been identified in connection with implanting Silimed products, and, accordingly, there is no need to adopt any procedure or action for those patients who have received them. Additionally, the FDA and ANVISA indicated that there have been no reports of adverse events related to this issue. After extensive independent, third-party testing and analyses of our finished goods inventory indicated no anticipated significant safety concerns with the use of our products, including our breast implants, consistent with their FDA approval status in 2012, as of March 1, 2016, we lifted the temporary hold on the sale of our devices manufactured by Silimed and also sent a letter to our Plastic Surgeons informing them of our market re-entry plans. Although our market re-entry decision was based on extensive testing and detailed independent third party reviews, we depend on a positive reception from our Plastic Surgeon customers and their patients to be able to reestablish the market position we had prior to the voluntary suspension. Our re-entry into the market requires us to effectively and responsibly educate accounts on the results of our testing and reconfirm our strong clinical data, while providing the same high levels of customer service to which our Plastic Surgeons are accustomed. Our plastic surgery consultants are working diligently to solidify the trust and support of all our Plastic Surgeons during this important phase of our market re-entry, however, if we are not successful in re-establishing these relationships, adapting our business systems, or competing effectively in this market, our sales revenues, market share and financial performance will be affected negatively.

The fire at one of Silimed's manufacturing buildings has affected our ability to rely on Silimed as our source for our silicone gel breast implants, tissue expanders and certain other products.*

On October 22, 2015, there was a fire at one of Silimed's two manufacturing buildings in Rio de Janeiro, Brazil. The fire occurred in the building where Sientra's breast implants are primarily manufactured, or building F2. Silimed has indicated to us that a smaller production facility in Silimed's second building, or building F1, which was not impacted by the fire, has the potential to be modified for breast implant manufacturing. In order to commence the manufacturing of breast implants, certain areas in building F1 would need to be reconfigured and receive certification

and approval by appropriate regulatory bodies. We are working with Silimed to seek clarity as to the near and long-term capabilities of Silimed's manufacturing operations, including the status of equipment that is used to manufacture breast implants and the potential feasibility, production capacity and timing related to Silimed's ability to manufacture our breast implants. The delay in the manufacturing of our breast implants caused by the fire, our uncertainty regarding when Silimed's facility will be operational and able to manufacture our breast implants, and the extent of the damage caused by the fire may have a severe impact on our ability to meet our demand to supply our products in a timely manner and as a result, our financial condition and results of operations may be adversely affected.

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We may not be able to find an alternate manufacturer if Silimed is unable to resume manufacturing.*

If Silimed is unable to resume manufacturing of our silicone gel breast implants, tissue expanders and certain other products, or if Silimed becomes unwilling to manufacture and supply our products once it is able to resume manufacturing, we may not be able to replace Silimed quickly. Although we are collaborating with Vesta towards establishing a dedicated contract manufacturing facility for Sientra's breast implant products, we have not entered into a definitive manufacturing agreement with Vesta, nor has Vesta been qualified as a manufacturer to source our implants. Indeed, we must submit a PMA Supplement to the FDA before Vesta can commence manufacturing of our products, and the timing of when we submit such PMA Supplement, or when we obtain FDA approval, if any, could be subject to delays, some of which are beyond our control. Moreover, we need to negotiate the terms of a definitive manufacturing agreement with Vesta or any other alternate manufacturer and they would have to be qualified with the FDA, which is an expensive and time-consuming process. A decision to not execute a manufacturing agreement with Vesta, or any delays or our inability to qualify Vesta or another alternate manufacturer could result in a supply interruption, which could materially adversely affect our business, financial condition and results of operations.

Our existing contract with Silimed contains prohibitive terms and limitations.*

Our existing contract with Silimed has prohibitive terms and limitations including that it expires in April 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 or they may impose increased pricing terms if the contract is renegotiated or renewed. Additionally, our agreement with Silimed contains exclusive terms and does not permit us to sell the products we obtain from Silimed in any country other than the United States and Canada. If Silimed is unable to resume manufacturing and supplying our products, we may need to terminate our existing contract with Silimed to secure an alternate supplier, and Silimed may be unwilling to comply with the termination of our agreement. If Silimed is unwilling to comply or cooperate with the termination of our agreement if they are unable to resume manufacturing our products, or if they increase our pricing terms or refuse to continue to manufacture and supply our products, we could be materially adversely affected and our business, financial condition and results of operations could suffer.

Contracting with any third-party manufacturer and supplier involves inherent risks and various factors outside our direct control may adversely affect the manufacturing and supply of our breast implants, tissue expanders and other products.*

Our reliance on any third-party manufacturer, including Silimed, involves a number of risks. 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 and quality as well as 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:

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

- our products may be mishandled while in production or in preparation for transit;

- we are subject to transportation and import and export risk, particularly given the global nature of our supply chain;

- the third-party manufacturer may discontinue manufacturing and supplying products to us for risk management reasons;

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- the third-party manufacturer may lose access to critical services and components, resulting in an interruption in the manufacturing or shipment of our products;

- the third-party manufacturer may encounter financial or other hardships unrelated to us and our demand for products, which could inhibit our ability to fulfill our orders;

- there may be delays in analytical results or failure of analytical techniques that we depend on for quality control and release of products;

- natural disasters, labor disputes, financial distress, lack of raw material supply, issues with facilities and equipment or other forms of disruption to business operations affecting our manufacturer or its suppliers may occur; and

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

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

We have incurred significant net operating losses since inception and cannot assure you that we will achieve profitability.*

Since our inception, we have incurred significant net operating losses. As of June 30, 2016, we had an accumulated deficit of $197.4 million. To date, we have financed our operations primarily through sales of preferred stock, borrowings under our term loans, sales of our products since 2012, our initial public offering and our follow-on public offering of our common stock. We have devoted substantially all of our resources to the acquisition and clinical development of our products, the commercial launch of our products, the development of a sales and marketing team and the assembly of a management team to manage our business.

We commenced sales of our breast implants in the second quarter of 2012. For the six months ended June 30, 2016, our net loss was $22.1 million. The extent of our future operating losses and the timing of profitability are uncertain, especially in light of our inventory supply issues related to Silimed's manufacturing capacity and ongoing regulatory and qualification concerns. 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.*

Our Breast Products have historically accounted for substantially all of our net sales and we expect our net sales to continue to be based primarily on sales of our Breast Products. Our ability to manage our inventory supply issues related to Silimed's ongoing manufacturing capacity and regulatory and qualification concerns, the potential loss of market acceptance of our Breast Products, and any adverse rulings by regulatory authorities, any adverse publicity or other adverse events relating to us or our Breast Products, or the introduction of competitive products by our competitors and other third parties, would adversely affect our business, financial condition and results of operations.

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, including the suspension of Silimed's CE certificate by TUV SUD, and the subsequent suspension by ANVISA on the manufacturing and shipment of all medical devices made

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by Silimed, including products manufactured for Sientra, could result in negative publicity and could materially reduce market acceptance of our products. These responses or any investigations and potential resulting negative publicity may have a material adverse effect on our business and reputation and negatively impact our financial condition, results of operations or the market price of our common stock. In addition, significant negative publicity could result in an increased number of product liability claims against us.

We may not realize the benefits of our acquisition of bioCorneum® which may be subject to additional risks and uncertainties.*

We recently acquired bioCorneum®, an advanced silicone gel scar management product from Enaltus, LLC for $7.4 million in an effort to add a differentiated and complementary product that serves the needs of board-certified plastic surgeons while diversifying our business mix. Our acquisition of bioCorneum® involves risks and uncertainties including that we have limited experience in the scar management industry, our management's attention may be diverted from our existing business as we attempt to integrate bioCorneum® and the integration may not be successful. Additionally, bioCorneum+® is an over the counter product registered with the FDA, and there may be risks associated with the use of bioCorneum® including skin irritation, rash, itching or accidental application into the eye or ingestion. We also rely on Formulated Solutions, LLC as our sole source, third-party manufacturer of bioCorneum® and if Formulated Solutions, LLC becomes unable or unwilling to supply bioCorneum®, we may not be able to find an alternate supplier in a timely manner. We do not know if we will be able to successfully integrate bioCorneum® into our existing business, or whether unforeseen risks associated with the use of bioCorneum® will materialize and our potential inability to integrate bioCorneum® effectively or realize anticipated synergies may adversely affect our business, financial condition and results of operations.

Silimed relies on a sole source, third-party supplier of the medical-grade silicone used in its silicone gel breast implants, tissue expanders and certain other products.*

Silimed, our sole source, third-party manufacturer and supplier of our silicone gel breast implants, tissue expanders and certain other products relies on Applied Silicone Corporation, or ASC, an affiliate of Nusil Technology LLC, or Nusil, as its sole source, third-party supplier of medical-grade silicone based in Santa Paula, California, for the silicone gel used in its breast implants, tissue expanders and certain other products. Other than ASC and Nusil, there are few suppliers of medical-grade silicone available. If ASC becomes unable or unwilling to supply medical-grade silicone to Silimed, Silimed may not be able to find an alternate supplier in a timely manner, since the availability of suppliers of medical-grade silicone is limited. In addition, ASC may discontinue manufacturing and supplying products to Silimed for risk management reasons, lose access to critical services and components, resulting in an interruption in the manufacturing or shipment of our products, or encounter financial or other hardships unrelated to Silimed and our demand for products, which could inhibit its ability to fulfill Silimed's orders. If Silimed is able to resume manufacturing our products, and any of these risks related to Silimed's reliance on ASC materialize, our business, financial condition and results of operations could be adversely affected.

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

Silimed's 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.

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

In addition to our recent acquisition of bioCorneum®, 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

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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 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.

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

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

- implement and execute our business strategy;
- expand and improve the productivity of our sales force and marketing programs to grow sales of our existing and proposed products;
- increase awareness of our brand and build loyalty among Plastic Surgeons;
- manage expanding operations;
- respond effectively to competitive pressures and developments;
- enhance our existing products and develop new products;
- obtain regulatory clearance or approval to enhance our existing products and commercialize new products;
- perform clinical trials with respect to our existing products and any new products; and
- attract, retain and motivate qualified personnel in various areas of our business.

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

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risks, we may not be able to execute key components of our business strategy, and our business, financial condition and operating results may suffer.

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

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

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

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

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

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complications, we could be subject to mandatory product recalls, suspension or withdrawal of clearance or approval by the FDA or other applicable regulatory bodies and significant legal liability.

Among the long-term health risks of breast implants which are being studied is the possible association between breast implants and a rare form of cancer called anaplastic large-cell lymphoma.*

In January 2011, the FDA indicated that there was a possible association between saline and silicone gel-filled breast implants and anaplastic large-cell lymphoma, or ALCL. Since our FDA approval in 2012, Sientra's breast-implant product label, which is approved by the FDA, has been required to contain a description of ALCL as a possible, though rare, outcome. Since its report in January 2011, the FDA continued to gather information about ALCL in women with breast implants through the review of medical device reports, review of medical literature, and collaboration with international regulators, scientific experts, the American Society of Plastic Surgeons, or ASPS, and other organizations. In January 2016, the FDA reiterated, after a review of information since 2011, that ALCL is a very rare condition and the FDA recommended the same measures as it had before for health care providers and patients. Further studies or clinical experience may indicate that breast implants, including our products, expose individuals to a more substantial risk of developing ALCL or other unexpected complications. As a result, we may be exposed to increased regulatory scrutiny, negative publicity and lawsuits from any individual who may develop ALCL after using our products, any of which could have a significant negative impact on our results of operations or financial condition. Moreover, if long-term results and clinical experience indicate that our products cause unexpected or serious complications, we could be subject to mandatory product recalls, suspension or withdrawal of regulatory clearances and approvals and significant legal liability.

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.

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.

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

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

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

We need to maintain substantial levels of inventory to protect ourselves from supply interruptions, provide our customers with a wide range of shapes and sizes of our breast implants, and account for the high return rates we experience as Plastic Surgeons typically order our products in multiple sizes for a single surgery and then return what they do not use. As a result of our substantial inventory levels, we are subject to the risk that a substantial portion of our inventory becomes obsolete. The materialization of any of these risks may have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory. Additionally, the suspension of Silimed's manufacturing by ANVISA, the fire at Silimed's facility that manufactures our breast implants and the potential feasibility, production capacity and timing related to Silimed's ability to manufacture breast implants in other facilities, or our ability to find an alternate supplier in a timely manner, may affect our ability to maintain the level of inventory supply we require to protect ourselves from supply interruptions which could have an unfavorable impact on our net sales.

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

Our principal offices are located in Santa Barbara, California. Substantially all of our operations are conducted at this location, including customer service, development and management and administrative functions. Substantially all of our inventory of 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.

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

Our corporate headquarters and certain other facilities are located in Santa Barbara, California, which in the past has experienced both severe earthquakes and wildfires. 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. If we lose additional key employees, if we are unable to attract or retain other qualified personnel, or if our management team is not able to effectively manage us through these events, our business, financial condition, and results of operations may be adversely affected.

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

As of June 30, 2016, we had approximately 86 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.

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Risks Related to Our Financial Results

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

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

- the length of time that Silimed is unable to manufacture our Breast Products as a result of manufacturing capacity and ongoing regulatory and qualification concerns at Silimed's facility;
- the timing and availability of alternative manufacturing sources to supply our silicone gel breast implants, tissue expanders and certain other products;
- our ability to integrate and achieve the anticipated benefits of our recent acquisition of bioCorneum®;
- 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;
- the impact of the recent regulatory inquiries of Silimed's medical devices on our brand and reputation;
- timing of our research and development activities and initiatives;
- the mix of our products sold due to different profit margins among our products;
- timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;
- the ability of our suppliers to timely provide us with an adequate supply of products;
- the evolving product offerings of our competitors;
- regulatory approvals and legislative changes affecting the products we may offer or those of our competitors;
- increased labor and related costs;
- interruption in the manufacturing or distribution of our products;
- the effect of competing technological, industry and market developments;
- changes in our ability to obtain regulatory clearance or approval for our products; and
- our ability to expand the geographic reach of our sales and marketing efforts.

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

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

As of June 30, 2016, we had $86.2 million in cash and cash equivalents. We believe that our available cash on hand will be sufficient to satisfy our liquidity requirements for at least the next 12 months. However, the continued growth of our business, including the expansion of our sales force and marketing programs, and research and development activities, and potential partnerships or strategic acquisitions could significantly increase our expenses. In addition, we expect that the recent events involving Silimed, including our voluntary hold on the sale and implanting of all Sientra devices manufactured by Silimed between October 9, 2015 and March 1, 2016, our uncertainty regarding the amount of additional expenses we may incur in connection with regulatory inquiries, as well as expenses we may incur in connection with reestablishing our inventory supply and expenses we may incur defending against litigation claims, may have a material effect our future cash outflows and our financial condition.

Our future capital requirements will depend on many factors, including:

- our continued ability to rely on Silimed to manufacture and supply our silicone gel breast implants, tissue expanders and certain other products or the timing and availability of alternative manufacturing sources;
- net sales generated by our silicone gel breast implants and tissue expanders and any other future products that we may develop and commercialize;
- expenses we incur in connection with potential litigation or governmental investigations;
- costs associated with our own review and testing at Silimed’s manufacturing facilities and of our own inventory;
- 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 defending against the lawsuit filed against us and certain of our officers alleging violations of Sections 10(b) and 20(a) of the Exchange Act and Section 11, 12(A)(2) and 15 of the Securities Act in connection with allegedly false and misleading statements concerning Sientra’s business, operations, and prospects;
- anticipated or unanticipated capital expenditures; and
- unanticipated general and administrative expenses.

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

As of December 31, 2015, we had federal net operating loss carryforwards, or NOLs, of approximately $137.8 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 future transactions in our stock, our ability to utilize NOLs could be further limited by Section 382 of the Code. As a result of these limitations, we may not be able to utilize a material portion of the NOLs reflected on our balance sheet and for this reason, we have fully reserved against the value of our NOLs on our balance sheet. We have not completed a Section 382 analysis to determine if an ownership change has occurred. Until such analysis is completed, we cannot be sure that the full amount of the existing federal NOLs will be available to us, even if we do generate taxable income before their expiration.

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

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

Risks Related to Our Intellectual Property and Potential Litigation

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

Our success depends in part on our ability to protect our intellectual property rights. Our intellectual property portfolio consists of no patents or patent applications, and we do not currently plan to file for patent protection in the future, in the United States or elsewhere. We instead rely on trade secrets, proprietary know-how and regulatory barriers to protect our products and technologies and seek protection of our rights, in part, through confidentiality and proprietary information agreements. However, these agreements may not provide sufficient protection or adequate

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

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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.

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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, such as our Breast Products. 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, employment practices, 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.

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Risks Related to Our Legal and Regulatory Environment

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

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

- the federal Anti-Kickback Statute, which applies to our business activities, including our marketing practices, educational programs, pricing policies and relationships with healthcare providers, by prohibiting, among other things, knowingly and willfully soliciting, receiving, offering or providing any remuneration (including any bribe, kickback or rebate) directly or indirectly, overtly or covertly, in cash or in kind, intended to induce or in return for the purchase or recommendation of any good, facility, item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare or Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to commit a violation. In addition, following passage of the PPACA violations of the federal Anti-Kickback Statute became per se violations of the False Claims Act;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal civil 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 government 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 additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- and, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, also imposes certain regulatory and contractual requirements on certain types of people and entities regarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, enacted under the PPACA, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to make annual reports to the Centers for Medicare & Medicaid Services, or CMS, regarding any "transfers of value" provided to physicians and teaching hospitals. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1 million per year for "knowing failures," for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission. We are required to report detailed payment data and submit legal attestation to the accuracy of such data by March 31st of each calendar year; 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

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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, diminished profits and future earnings, 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.

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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. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products.

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

In addition, even after we have obtained the proper regulatory clearance or approval to market a product, the FDA has the power to require us to conduct post marketing studies. For example, we are required to continue to study and report clinical results to the FDA on our silicone gel breast implants. Failure to conduct this or other required studies in a timely manner

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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 manufacturers 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 manufacturers fail to adhere to QSR requirements, have significant non-compliance issues or fail to timely and adequately respond to any adverse inspectional observations or product safety issues, or if any corrective action plan that we or our manufacturers propose in response to observed deficiencies is not sufficient, the FDA could take enforcement action against us, which could delay production of our products and may include:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;

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

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

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

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

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

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

In the United States, our silicone gel breast implants are marketed pursuant to a PMA order issued by the FDA in March 2012, and our tissue expanders are marketed pursuant to pre-market clearance under Section 510(k) of the FDCA. Any modifications to a PMA-approved or 510(k)-cleared device that could significantly affect its safety or effectiveness, including significant design and manufacturing changes, or that would constitute a major change in its intended use, manufacture, design, components, or technology requires a new 510(k) clearance or, possibly, approval of a new PMA application or PMA supplement. However, certain changes to a PMA-approved device do not require submission and approval of a new PMA or PMA supplement and may only require notice to FDA in a PMA 30-Day Notice, Special PMA Supplement – Changes Being Effected or PMA Annual Report. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have modified some of our 510(k) cleared products, and have determined based on our review of the applicable FDA guidance that in certain instances the changes did not require new 510(k) clearances or PMA approvals. If the FDA disagrees with our determination and requires us to seek new 510(k) clearances or PMA approvals for modifications to our previously cleared or approved products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. Furthermore, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. Delays in receipt or failure to receive approvals, the loss of previously received approvals, or the failure to comply with any other existing or future regulatory requirements, could reduce our sales, profitability and future growth prospects.

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

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses

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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. 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 preclinical development activities. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third

parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory clearance or approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

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

Furthermore, the healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with service providers. Therefore, we cannot be certain that the breast reconstruction

procedures using our products will be reimbursed at a cost-effective level. Nor can we be certain that third-party payors using a methodology that sets amounts based on the type of procedure performed, such as those utilized by government programs and in many privately managed care systems, will view the cost of our products to be justified so as to incorporate such costs into the overall cost of the procedure. Moreover, we are unable to predict what changes will be made to the reimbursement methodologies used by third-party payors in the future.

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

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

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

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations 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. For example, in March 2010, the PPACA was signed into law. While one 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 ways in which the PPACA significantly impacts our industry, 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;
- expands eligibility criteria for Medicaid programs;
- 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.

The medical device excise tax has been suspended by the CAA, with respect to medical device sales during calendar years 2016 and 2017. Absent further Congressional action, this excise tax will be reinstated for medical device sales beginning January 1, 2018. The CAA also temporarily delays implementation of other taxes intended to help fund PPACA programs. We are unsure of the full impact that the PPACA will have on our business. There have been judicial and Congressional challenges to certain aspects of the PPACA, and we expect there will be additional challenges and amendments in the future.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, 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

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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, following passage of the Bipartisan Budget Act of 2015, and will stay in effect through 2025 unless additional Congressional action is taken. Additionally, on January 2, 2013, President Obama signed into law 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 reduced.

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 are currently not able to obtain Health Canada's approval to market our breast implant products in Canada due to the suspension of Silimed's ISO 13485 certificate. Even if Silimed's ISO certification is reinstated, the time required to obtain regulatory approval in Canada may be longer than the time required to obtain FDA pre-market approval and Health Canada may want additional information prior to approval as well. The Canadian regulatory approval process includes many of the risks associated with obtaining FDA approval and we may not obtain Canadian regulatory approval on a timely basis, if at all. FDA approval does not ensure approval by regulatory authorities in other countries, including Canada, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. However, the failure to obtain clearance or approval in one jurisdiction may have a negative impact on our ability to obtain clearance or approval elsewhere. If we do not obtain or maintain necessary approvals to commercialize our products in Canada, it would negatively affect our overall market penetration.

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

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

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

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

We are unable to predict what changes to the HIPAA Privacy Standards and Security Standards might be made in the future or how those changes could affect our business. Any new legislation or regulation in the area of privacy and security of personal information, including personal health information, could also adversely affect our business operations. If we do not comply with existing or new applicable federal or state laws and regulations related to patient health information, we could be subject to criminal or civil sanctions and any resulting liability could adversely affect our financial condition.

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

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

Risks Related to Our Common Stock

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

The market price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. For example, our common stock price declined from $20.58 to $2.78 from September 23, 2015 to November 17, 2015 as a result of the recent events concerning Silimed. These factors include those discussed in this “Risk Factors” section of this Form 10-Q and others such as:

- a determination that our Silimed-manufactured products are not in compliance with regulatory requirements, or its facilities are not maintained in compliance with regulatory requirements;
- a slowdown in the medical device industry, the aesthetics industry or the general economy;
- actual or anticipated quarterly or annual variations in our results of operations or those of our competitors;
- changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;
- actual or anticipated changes in our growth rate relative to our competitors;
- changes in earnings estimates or recommendations by securities analysts;

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- fluctuations in the values of companies perceived by investors to be comparable to us;
- announcements by us or our competitors of new products or services, significant contracts, commercial relationships, capital commitments or acquisitions;
- competition from existing technologies and products or new technologies and products that may emerge;
- the entry into, modification or termination of agreements with our sales representatives or distributors;
- developments with respect to intellectual property rights;
- sales, or the anticipation of sales, of our common stock by us, our insiders or our other stockholders, including upon the expiration of contractual lock-up agreements;
- our ability to develop and market new and enhanced products on a timely basis;
- our ability to integrate and achieve the anticipated benefits of our recent acquisition of bioCorneum®;
- 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 and certain of our executive officers and directors have been named as defendants in recently initiated securities class action lawsuit that could result in substantial costs and divert management's attention.*

On September 25, 2015, a lawsuit styled as a class action of our stockholders was filed in the United States District Court for the Central District of California. The lawsuit names us and certain of our officers as defendants and alleges violations of Sections 10(b) and 20(a) of the Exchange Act and Securities 11, 12(A), and 15 of the Securities Act in connection with allegedly false and misleading statements concerning our business, operations, and prospects. On October 28, November 5, and November 19, 2015, three lawsuits styled as class actions of our stockholders were filed in the Superior Court of California for the County of San Mateo. The lawsuits name us, certain of our officers and directors, and the underwriters associated with our follow-on public offering that closed on September 23, 2015 as defendants and alleges violations of Sections 11, 12(a)(2), and 15 of the Securities Act in connection with allegedly false and misleading statements in our offering documents associated with the follow-on offering concerning our business, operations, and prospects. We intend to engage in a vigorous defense of such litigation. If we are not successful in our defense of such litigation, we could be forced to make significant payments to or other settlements with our stockholders and their lawyers, and such payments or settlement arrangements could have a material adverse effect on our business, operating results or financial condition. Even if these claims are not successful, the litigation could result in substantial costs and significant adverse impact on our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results or financial condition.

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. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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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 August 4, 2016, our executive officers, directors and principal stockholders beneficially owned approximately 47.0% of our outstanding voting stock. As a result, these stockholders have the ability to influence us through their ownership position and may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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

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

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

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

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

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

As a public company, and increasingly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and NASDAQ impose numerous requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Also, the Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel 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.

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Overall, our incremental costs resulting from operating as a public company, including compliance with these rules and regulations, was approximately $3.2 million for the year ended December 31, 2015. 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.

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

As a public company, we are required to comply with certain of the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, regarding internal control over financial reporting. However, for as long as we remain an “emerging growth company” as defined in the JOBS Act, we intend to utilize the provision exempting us from the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting

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

The process of becoming fully compliant with Section 404 may divert internal resources and will take a significant amount of time and effort to complete, and may result in additional deficiencies and material weaknesses being identified by us or our independent registered public accounting firm. We may experience higher than anticipated operating expenses, as well as increased independent registered public accounting firm fees during the implementation of any required changes and thereafter. Completing documentation of our internal control system and financial processes, remediation of control deficiencies and management testing of internal controls will require substantial effort by us. If our internal control over financial reporting or our related disclosure controls and procedures are not effective, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that our officers, directors or the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. As of August 4, 2016, we had approximately 18,134,497 shares of common stock outstanding. Of these shares, all of the shares of our common stock sold in our initial public offering, which was completed on November 3, 2014, and all of the shares sold in our follow-on public offering, which was completed on September 23, 2015 are freely tradable, without restriction, in the public market.

Based on shares outstanding as of August 4, 2016, and information contained in Form 4s and Schedule 13Gs filed with the SEC, up to an additional 4,948,780 shares of common stock became eligible for sale in the public market, approximately 19,003 of which are held by our executive officers and directors and approximately 4,929,777 of which are held by our affiliates (including stockholders affiliated with our directors) and subject to volume limitations under Rule 144 under the Securities Act.

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Holders of an aggregate of approximately 6,287,277 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.

On March 7, 2016 we adopted an Inducement Plan pursuant to which our board of directors may grant stock options or restricted stock units which may be exercised or settled, as applicable, for up to an initial aggregate of 180,000 shares of our common stock, to new employees as inducement material to such new employees entering into employment with us which we have registered on a Registration Statement on Form S-8. These shares can be freely sold in the public market once vested in accordance with Rule 144, including volume restrictions applicable to "control securities" held by our officers and directors.

As of August 4, 2016, options to purchase an aggregate of 2,995,223 shares of our common stock were outstanding under our 2007 Plan, our 2014 Plan and our Inducement Plan, which have been registered on a Registration Statement on Form S-8, and an additional, 173,591 shares of common stock are reserved for issuance under our 2014 Plan and our Inducement Plan are registered on the Registration Statement on Form S-8. These shares can be freely sold in the public market upon issuance and once vested in accordance with Rule 144, including volume restrictions applicable to "control securities" held by our officers and directors.

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

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

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

Pursuant to the 2014 Plan, our management is authorized to grant stock options to our employees, directors and consultants, and pursuant to the Inducement Plan, our board of directors is authorized to grant stock options to our new employees.

As of June 30, 2016, the number of shares of common stock reserved for issuance under our 2014 plan was 2,045,495. The number of shares of our common stock reserved for issuance under the 2014 Plan automatically increases 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. Pursuant to the foregoing provision, effective January 1, 2016, our board of directors increased the number of shares of common stock reserved for issuance under the 2014 Plan by 4% of the number of shares of

our capital stock outstanding on December 31, 2015, or 719,736 shares.

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. As of June 30, 2016, the number of shares of common stock reserved for issuance under our ESPP was 584,563. The number of shares of our common stock reserved for issuance under the ESPP automatically

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increases on January 1 of each year, beginning on January 1, 2015 and continuing through and including January 1, 2024, by 1% 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. Pursuant to the foregoing provision, effective January 1, 2016, our board of directors increased the number of shares of common stock reserved for issuance under the ESPP by 1% of the number of shares of our capital stock outstanding on December 31, 2015, or 179,934 shares.

Pursuant to our Inducement Plan, our board of directors is authorized to grant stock options or restricted stock units which may be exercised or settled, as applicable, for up to an aggregate of 180,000 shares of our common stock to new employees as inducements material to such new employees entering into employment with us. The number of shares which may be granted under the Inducement Plan may be increased in the future by our board of directors.

Our management team may invest or spend the proceeds from our IPO and our follow-on public offering 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 public offerings, and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. For example, we used a portion of the net proceeds from our public offerings to repay our long-term debt.

Because of the number and variability of factors that will determine our use of the net proceeds from our public offerings, 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 that we will use the net proceeds from our public offerings for the following purposes: (i) we may acquire or invest in complementary products, technologies, businesses or international expansion opportunities; however, we currently have no agreements or commitments to complete any such transaction, and (ii) for working capital and other 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 public offerings in high-quality, short-term interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from our public offerings 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;

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- 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, including the recent suspension of our rating by certain analysts as a result of recent events involving Silimed, 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

Recent Sales of Unregistered Securities

None.

Purchase of Equity Securities

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

Use of Proceeds from Registered Securities

On October 28, 2014, our registration statement on Form S-1 (File No. 333-198837) was declared effective by the Securities and Exchange Commission pursuant to which we sold 5,750,000 shares of our common stock at a public offering price of $15.00 per share for an aggregate gross offering price of $86.2 million. The net offering proceeds to us, after deducting underwriting discounts and commissions and offering costs, were approximately $77.0 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.

On September 17, 2015 our registration statement on Form S-1 (File No. 333-206755) was declared effective for our follow-on public offering pursuant to which we sold 3,000,000 shares of common stock at a price of $22.00 per share for an aggregate gross offering price of $66.0 million. The net offering proceeds to us, after deducting underwriting discounts and commissions and offering costs, were approximately $61.4 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 in either of our IPO or follow-on public offering. 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 our IPO and our follow-on public offering.

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Upon receipt, the net proceeds from our IPO and our follow-on public offering were held in cash and cash equivalents, primarily bank money market accounts. 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, or from our follow-on public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act on September 23, 2015. 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 has broad discretion in the application of the net proceeds. As of June 30, 2016, we have used approximately $24.5 million of the proceeds to repay outstanding debt and $7.0 million for the acquisition of bioCorneum® and related transaction costs.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

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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.
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.

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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.

August 9, 2016 By: /s/ Jeffrey Nugent
Jeffrey Nugent
Chief Executive Officer

August 9, 2016 By: /s/ Matthew Pigeon
Matthew Pigeon
Chief Financial Officer and Treasurer