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

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**FORM 10-Q**

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(Mark One)

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

For the quarterly period ended **September 30, 2017**

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**

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**SIENTRA, INC.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**

(State or Other Jurisdiction of  
Incorporation or Organization)

**420 South Fairview Avenue, Suite 200**

**Santa Barbara, California**

(Address of Principal Executive Offices)

**20-5551000**

(I.R.S. Employer  
Identification No.)

**93117**

(Zip Code)

**(805) 562-3500**

(Registrant's Telephone Number, Including Area Code)

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

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

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

Large accelerated filer

Non-accelerated filer

(Do not check if a smaller reporting company)

Accelerated filer

Smaller reporting company

Emerging growth company

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

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

As of November 3, 2017, the number of outstanding shares of the registrant's common stock, par value \$0.01 per share, was 19,395,285.

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SIENTRA, INC.

FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2017

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PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	<u>September 30,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 37,641	\$ 67,212
Accounts receivable, net of allowances of \$4,657 and \$4,329 at September 30, 2017 and December 31, 2016, respectively	4,678	3,082
Inventories, net	23,069	18,484
Insurance recovery receivable	75	9,375
Prepaid expenses and other current assets	4,074	1,852
Total current assets	69,537	100,005
Property and equipment, net	4,360	2,986
Goodwill	12,507	4,878
Other intangible assets, net	19,504	6,186
Other assets	736	228
Total assets	<u>\$ 106,644</u>	<u>\$ 114,283</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 3,990	\$ 3,555
Accrued and other current liabilities	13,669	6,507
Legal settlement payable	1,000	10,900
Customer deposits	5,572	6,559
Total current liabilities	24,231	27,521
Long-term debt	24,747	—
Deferred and contingent consideration	12,341	1,637
Warranty reserve and other long-term liabilities	1,718	1,508
Total liabilities	63,037	30,666
Commitments and contingencies (Note 13)		
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 19,437,978 and 18,671,409 and outstanding 19,365,251 and 18,598,682 shares at September 30, 2017 and December 31, 2016 respectively	193	186
Additional paid-in capital	305,308	299,133
Treasury stock, at cost (72,727 shares at September 30, 2017 and December 31, 2016)	(260)	(260)
Accumulated deficit	(261,634)	(215,442)
Total stockholders' equity	43,607	83,617
Total liabilities and stockholders' equity	<u>\$ 106,644</u>	<u>\$ 114,283</u>

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net sales	\$ 9,819	\$ 6,531	\$ 25,477	\$ 14,246
Cost of goods sold	3,484	1,814	8,427	4,319
Gross profit	<u>6,335</u>	<u>4,717</u>	<u>17,050</u>	<u>9,927</u>
Operating expenses:				
Sales and marketing	7,981	5,137	21,100	16,533
Research and development	2,911	2,052	7,677	7,370
General and administrative	9,298	5,684	23,753	16,327
Legal settlement	—	1,618	10,000	1,618
Total operating expenses	<u>20,190</u>	<u>14,491</u>	<u>62,530</u>	<u>41,848</u>
Loss from operations	(13,855)	(9,774)	(45,480)	(31,921)
Other income (expense), net:				
Interest income	54	16	112	47
Interest expense	(409)	(105)	(603)	(118)
Other income (expense), net	(155)	(52)	(151)	(54)
Total other income (expense), net	<u>(510)</u>	<u>(141)</u>	<u>(642)</u>	<u>(125)</u>
Loss before income taxes	(14,365)	(9,915)	(46,122)	(32,046)
Income taxes	16	48	70	48
Net loss	<u>\$ (14,381)</u>	<u>\$ (9,963)</u>	<u>\$ (46,192)</u>	<u>\$ (32,094)</u>
Basic and diluted net loss per share attributable to common stockholders	<u>\$ (0.74)</u>	<u>\$ (0.55)</u>	<u>\$ (2.42)</u>	<u>\$ (1.77)</u>
Weighted average outstanding common shares used for net loss per share attributable to common stockholders:				
Basic and diluted	<u>19,328,244</u>	<u>18,208,112</u>	<u>19,079,788</u>	<u>18,111,593</u>

See accompanying notes to condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	\$ (46,192)	\$ (32,094)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,037	734
Provision for doubtful accounts	84	384
Provision for warranties	133	133
Provision for inventory	468	519
Amortization of acquired inventory step-up	802	—
Change in fair value of warrants	151	57
Change in fair value of deferred and contingent consideration	758	—
Non-cash portion of debt extinguishment loss	16	—
Amortization of debt discount and issuance costs	97	—
Non-cash interest expense	1	23
Stock-based compensation expense	4,777	2,630
Loss on disposal of property and equipment	12	124
Deferred income taxes	70	48
Changes in assets and liabilities, net of effects from acquisitions:		
Accounts receivable	411	1,053
Inventories	1,208	1,136
Insurance recovery receivable	9,300	(9,282)
Prepaid expenses, other current assets and other assets	(2,083)	(58)
Accounts payable	(478)	(986)
Accrued and other liabilities	3,613	460
Legal settlement payable	(9,900)	10,900
Customer deposits	(987)	(3,288)
Net cash used in operating activities	<u>(35,702)</u>	<u>(27,507)</u>
Cash flows from investing activities:		
Purchase of property and equipment	(1,173)	(916)
Business acquisitions, net of cash acquired	<u>(18,455)</u>	<u>(6,759)</u>
Net cash used in investing activities	<u>(19,628)</u>	<u>(7,675)</u>
Cash flows from financing activities:		
Proceeds from exercise of stock options	1,327	910
Proceeds from issuance of common stock under ESPP	647	753
Tax payments related to shares withheld for vested restricted stock units (RSUs)	(569)	—
Gross borrowings under the Term Loan	25,000	—
Gross borrowings under the Revolving Line of Credit	5,000	—
Payment on the Revolving Line of Credit	(5,000)	—
Deferred financing costs	(646)	—
Net cash provided by financing activities	<u>25,759</u>	<u>1,663</u>
Net decrease in cash and cash equivalents	<u>(29,571)</u>	<u>(33,519)</u>
Cash and cash equivalents at:		
Beginning of period	67,212	112,801
End of period	<u>\$ 37,641</u>	<u>\$ 79,282</u>
Supplemental disclosure of cash flow information:		
Interest paid	\$ 305	\$ 96
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment in accounts payable and accrued liabilities	700	140
Acquisition of business, deferred and contingent consideration obligations at fair value	10,912	550
Forgiveness of SVB Loan commitment fee	750	—

See accompanying notes to condensed consolidated financial statements.

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

**1. Formation and Business of the Company**

**a. Formation**

Sientra, Inc., or the Company, was incorporated in the State of Delaware on August 29, 2003 under the name Juliet Medical, Inc. and subsequently changed its name to Sientra, Inc. in April 2007. The Company acquired substantially all the assets of Silimed, Inc. 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.

In November 2014, the Company completed an initial public offering, or IPO, and its common stock is listed on the Nasdaq Stock Exchange under the symbol "SIEN."

**b. Acquisition of Miramar Labs, Inc.**

On June 11, 2017, Sientra entered into an Agreement and Plan of Merger, or the Merger Agreement, with Miramar Labs, Inc., or Miramar, pursuant to which Sientra commenced a tender offer to purchase all of the outstanding shares of Miramar's common stock for (i) \$0.3149 per share, plus (ii) the contractual right to receive one or more contingent payments upon the achievement of certain future sales milestones. The total merger consideration was \$18.7 million in upfront cash and the contractual rights represent potential contingent payments of up to \$14 million. The transaction, which closed on July 25, 2017, added the miraDry® System to Sientra's aesthetics portfolio.

**c. Regulatory Inquiries Regarding Products Manufactured by Silimed**

There have been regulatory inquiries related to medical devices manufactured by Silimed Indústria de Implantes Ltda. (formerly, Silimed-Silicone e Instrumental Medico-Cirurgio e Hospitalar Ltda.), or Silimed, the Company's former sole source contract manufacturer for its silicone gel breast implants.

On October 9, 2015, following the suspension of sales in the United Kingdom and the suspension of the manufacturing and shipment of all medical devices made by Silimed in Brazil, 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.

On March 1, 2016, after the completion of extensive independent, third-party testing and analyses of its devices manufactured by Silimed, the Company lifted the temporary hold on the sale of such devices and informed plastic surgeons of the Company's controlled market re-entry plan designed to optimize the Company's inventory supply. The results of the Company's testing indicated no significant safety concerns with the use of its products, including its breast implants, consistent with their approval status since 2012. Additionally, the FDA reiterated prior statements of Medicines and Healthcare Products Regulatory Agency, or MHRA, an executive agency of the United Kingdom, and by the Brazilian regulatory agency ANVISA that no reports of adverse events and no risks to patient health had been identified in connection with implanting Silimed-manufactured products. The Company's existing manufacturing contract with Silimed expired on its terms in April 2017 and the Company did not renew the contract. The Company has engaged Vesta Intermediate Funding, Inc., or Vesta, a Lubrizol Lifesciences company, for the manufacture and supply of the Company's breast implants. On March 14, 2017, the Company announced it had

submitted a PMA supplement to the FDA for the manufacturing of the Company's PMA-approved breast implants by Vesta.

## **2. Summary of Significant Accounting Policies**

### ***a. Basis of Presentation***

The accompanying unaudited condensed consolidated 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 consolidated financial statements should be read in conjunction with the Company's audited condensed consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2016 filed with the SEC on March 14, 2017, or the Annual Report. The results for the three and nine months ended September 30, 2017 are not necessarily indicative of results to be expected for the year ending December 31, 2017, any other interim periods, or any future year or period.

### ***b. Going Concern***

The accompanying condensed consolidated 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. The Company's manufacturing contract with Silimed expired on its terms on April 1, 2017, and the Company did not renew that contract. Accordingly, the Company continues to evaluate the availability of alternative manufacturing sources, including with Vesta, which is establishing manufacturing capacity for the Company and with which the Company executed a definitive manufacturing agreement for the long-term supply of the Company's PMA-approved silicone gel breast implants. The continuation of the Company as a going concern is dependent upon many factors including the availability of alternative manufacturing sources and continued sale of the Company's products. Since inception, the Company has incurred net losses. As of September 30, 2017, the Company had cash and cash equivalents of \$37.6 million. On July 25, 2017, the Company acquired Miramar and also entered into certain credit agreements with MidCap Financial Trust, or MidCap, which are further discussed in Note 9.

The Company believes that it has the ability to continue as a going concern for at least 12 months from the date the Company's condensed consolidated financial statements are issued. These condensed consolidated 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 consolidated 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 condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates.

### ***d. Significant Accounting Policies***

There have been no significant changes to the accounting policies during the three and nine months ended September 30, 2017, as compared to the significant accounting policies described in the "Notes to Financial Statements" in the Annual Report.

**e. Recent Accounting Pronouncements**

*Recently Adopted Accounting Standards*

In April 2015, the FASB issued accounting standard update 2015-03, *Interest — Imputation of Interest*. The standard was issued to simplify the presentation of debt issuance costs and require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The Company adopted ASU 2015-03 in fiscal year 2016. The adoption resulted in \$0 and \$0.4 million being classified as a direct deduction to debt on the Company's condensed consolidated balance sheet as of December 31, 2016 and September 30, 2017, respectively.

In July 2015, the FASB issued accounting standard update, or ASU, 2015-11, *Inventory - Simplifying the Measurement of Inventory*. The standard simplifies the subsequent measurement of inventory by requiring inventory to be measured at the lower of cost and net realizable value, thereby simplifying the previous guidance under which an entity must measure inventory at the lower of cost or market. The accounting standards update will not apply to inventories that are measured by using either the last-in, first-out method or the retail inventory method. The Company adopted ASU 2015-11 in the first quarter of 2017 on a prospective basis. The adoption of this ASU did not have a material impact on the Company's consolidated financial statements.

In March 2016, the FASB issued ASU 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 consolidated statement of cash flows. The Company adopted ASU 2016-09 in the first quarter of 2017 on a prospective basis. The Company has made an accounting policy election to account for forfeitures when they occur. The adoption of this ASU did not have a material impact on the Company's consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, *Intangibles - Goodwill and Other (Topic 350) - Simplifying the Test for Goodwill Impairment*. The standard update eliminates Step 2 from the goodwill impairment test. The guidance requires an entity to perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value. In addition, the guidance eliminates the requirements for any reporting unit with a zero or negative carrying amount to perform a qualitative assessment. The Company adopted ASU 2017-04 in the first quarter of 2017 on a prospective basis. The adoption of this ASU did not have a material impact on the Company's consolidated financial statements.

*Recently Issued Accounting Standards*

In May 2014, the FASB issued 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. In December 2016, the FASB issued ASU 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers*. ASU 2016-20 is intended to clarify and suggest improvements to the application of current standards under Topic 606 and other Topics amended by ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The effective date of ASU 2016-20 is the same as the effective date for ASU 2014-09. In preparation for the adoption of the new standard for fiscal year ending December 31, 2018, the Company is reviewing contracts and other forms of agreements with customers and evaluating the provisions contained therein in light of the five-step model specified by the new guidance. That five-step model includes: (1) determination of whether a contract—an agreement between two or more parties that creates legally enforceable rights and obligations—exists; (2) identification of the performance obligations in the contract; (3) determination of the transaction price; (4) allocation of the transaction

price to the performance obligations in the contract; and (5) recognition of revenue when (or as) the performance obligation is satisfied. The Company is also evaluating the impact of the new standard on certain common practices currently employed by the Company and by other medical device companies, such as allowance for sales returns, rebates, warranty and other pricing programs. The Company has not yet determined the impact of the new standard on the Company's consolidated financial statements or whether the Company will adopt on a full retrospective or modified retrospective basis in the first quarter of the Company's fiscal year ending December 31, 2018.

In January 2017, the FASB issued ASU 2017-01, *Business Combinations (Topic 805) - Clarifying the Definition of a Business*. The standard adds guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses by providing a more specific definition of a business. The updated accounting standard will be effective for the Company beginning in fiscal year 2018. The Company will evaluate the impact of this ASU on future acquisitions.

In May 2017, the FASB issued ASU 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting*. The standard provides clarification on when modification accounting should be used for changes to the terms or conditions of a share-based payment award to which an entity would be required to apply modification accounting under ASC 718. The ASU is effective for the Company beginning in fiscal year 2018. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements and related disclosures.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815)*. The standard is broken in to two parts. Part I addresses the complexity of accounting for certain financial instruments with down round features. Part II addresses the difficulty of navigating Topic 480 because of the existence of extensive pending content in the *FASB Accounting Standards Codification*. The ASU is effective for the Company beginning in fiscal year 2019. The Company has not yet determined the impact of the new standard on the Company's consolidated financial statements.

*f. Reclassifications*

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

**3. Acquisitions**

*a. Acquisition of Miramar Labs, Inc.*

On June 11, 2017, Sientra entered into the Merger Agreement with Miramar, pursuant to which Sientra commenced a tender offer to purchase all of the outstanding shares of Miramar's common stock for (i) \$0.3149 per share, plus (ii) the contractual right to receive one or more contingent payments upon the achievement of certain future sales milestones. The total merger consideration was \$18.7 million in upfront cash and the contractual rights represent potential contingent payments of up to \$14 million. The transaction, which closed on July 25, 2017, or the Acquisition Date, added the miraDry® System, the only FDA cleared device to reduce underarm sweat, odor and permanently reduce hair of all colors, to Sientra's aesthetics portfolio. In connection with the acquisition, the Company recorded \$2.6 million and \$3.0 million of professional fees for the three and nine months ended September 30, 2017, respectively, which are included in general and administrative expense. The aggregate preliminary acquisition date fair value of the consideration transferred was approximately \$29.6 million, consisting of the following (in thousands):

	<u>Fair Value</u>
Cash consideration at Acquisition Date (other than debt payoff)	\$ 6,193
Cash consideration at Acquisition Date (debt payoff)	12,467
Deferred consideration	966
Contingent consideration	9,946
Total purchase consideration	<u>\$ 29,572</u>

The Company funded the cash consideration, including the debt payoff amount with cash on hand. The cash consideration included the payoff of Miramar's existing term loan, or the Note Purchase Agreement dated January 27, 2017 and bridge loan, or the January 2017 Bridge Loan, including interest. The deferred consideration relates to cash held back to be used for either potential litigation-related expenses or for payments to certain former investors of Miramar, as defined in the Note Purchase Agreement dated January 27, 2017, one year following the Acquisition Date. Contingent consideration of future cash payments of a maximum of \$14.0 million represents the contractual right of certain former Miramar shareholders to receive one or more contingent payments upon achievement of certain future sales milestones and includes certain amounts due to investors related to the remaining balances on the January 2017 Bridge Note and accrued royalty obligations, with certain amounts held back for potential litigation-related expenses. The fair value of the contingent consideration at the acquisition date was determined using a Monte-Carlo simulation model. The inputs include the estimated amount and timing of future net sales, and a risk-adjusted discount rate. 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 contingent consideration component is subject to the recognition of subsequent changes in fair value through general and administrative expense in the condensed consolidated statement of operations.

In accordance with ASC 805, the Company has recorded the acquired assets (including identifiable intangible assets) and liabilities assumed at their respective fair value. The preliminary allocation of the total purchase price is as follows (in thousands):

	July 25, 2017
Cash	\$ 205
Accounts receivable, net	2,091
Inventories, net	7,064
Other current assets	170
Property and equipment, net	528
Goodwill	7,629
Intangible assets	14,800
Restricted cash	305
Other assets	12
Liabilities assumed:	
Accounts payable	(908)
Accrued and other current liabilities	(2,294)
Other current liabilities	(30)
Net assets acquired	<u>\$ 29,572</u>

Goodwill has been allocated to the miraDry® reportable segment. The goodwill recognized is attributable primarily to the assembled workforce and additional market opportunities. Goodwill is not expected to be deductible for tax purposes.

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

	Amount	Estimated useful life	Amortization method
Developed technology	\$ 3,000	15 years	Accelerated
Customer relationships	6,300	14 years	Accelerated
Distributor relationships	500	9 years	Accelerated
Trade name	5,000	15 years	Accelerated
	<u>\$ 14,800</u>		

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 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.

### Unaudited Pro Forma Information

The following unaudited pro forma financial information presents combined results of operations for each of the periods presented, as if Miramar had been acquired as of the beginning of fiscal year 2016. The pro forma information includes adjustments to amortization for intangible assets acquired, the purchase accounting effect on inventory acquired, interest expense for the additional indebtedness incurred to complete the acquisition, restructuring charges in connection with the acquisition and acquisition costs. The pro forma data are for informational purposes only and are not necessarily indicative of the consolidated results of operations of the combined business had the merger actually occurred at the beginning of fiscal year 2016 or of the results of future operations of the combined business. Consequently, actual results will differ from the unaudited pro forma information presented below (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	Pro Forma		Pro Forma	
Net sales	\$ 10,668	\$ 10,834	\$ 35,681	\$ 30,280
Net loss	(12,131)	(14,975)	(51,844)	(56,732)
Pro forma loss per share attributable to ordinary shares - basic and diluted	\$ (0.63)	\$ (0.82)	\$ (2.72)	\$ (3.13)

#### b. 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 objectives and adds a complementary product that serves the needs of its customers. In connection with the acquisition, the Company recorded \$2,000 and \$0.2 million of professional fees for the three and nine months ended September 30, 2016, respectively, which are included in general and administrative expense. The company did not record any professional fees related to the acquisition for the three and nine months ended September 30, 2017. The aggregate acquisition date fair value of the consideration transferred was estimated at \$7.4 million, which consisted of the following (in thousands):

	Fair Value
Cash	\$ 6,859
Deferred consideration	434
Contingent consideration	116
	<u>\$ 7,409</u>

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 minimum estimated future payments due under the deferred consideration are \$0.5 million. 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 subject to the recognition of subsequent changes in fair value through general and administrative expense in the condensed consolidated statement 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 consolidated financial statements for the three and nine months ended September 30, 2017 and 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 (in thousands):

	<b>March 9, 2016</b>
Inventory	\$ 100
Prepaid expenses	36
Goodwill	3,273
Intangible assets	4,000
	<u>\$ 7,409</u>

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

	<b>Amount</b>	<b>Estimated useful life</b>	<b>Amortization method</b>
Customer relationships	\$ 3,200	10 years	Accelerated
Trade name	800	12 years	Straight-line
	<u>\$ 4,000</u>		

The Company retained an independent third-party appraiser to assist management in its valuation and the purchase price has been finalized. Pro forma results of operations have not been presented because the effect of the acquisition was not material to the Company's results of operations.

*c. Acquisition of Tissue Expander Portfolio from Specialty Surgical Products, Inc.*

On November 2, 2016, the Company entered into an asset purchase agreement with Specialty Surgical Products, Inc., or SSP, to acquire certain assets, consisting of the Dermaspan™, Softspan™, and AlloX2® tissue expanders, from SSP. The acquisition adds a complete portfolio of premium, differentiated tissue expanders and aligns with the Company's business development plans for growth in the breast reconstruction market. The Company did not record any professional fees for the three and nine months ended September 30, 2017 and 2016 in connection with the acquisition. The aggregate preliminary acquisition date fair value of the consideration transferred was estimated at \$6.0 million, which consisted of the following (in thousands):

	<b>Fair Value</b>
Cash	\$ 4,950
Contingent consideration	1,050
	<u>\$ 6,000</u>

The contingent consideration consists of future cash payments of a maximum of \$2.0 million to be paid to SSP based upon the achievement of certain milestones of future net sales. The Company has determined the fair value of the contingent consideration at the acquisition date using a Monte-Carlo simulation model. The inputs include the estimated amount and timing of future net sales, and a risk-adjusted discount rate. 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 contingent consideration components are subject to the recognition of subsequent changes in fair value through general and administrative expense in the condensed consolidated statement of operations.

The Company allocated the total consideration transferred to the tangible and identifiable intangible assets acquired and liabilities assumed 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 consolidated financial statements for the three and nine months ended September 30, 2017 include the results of operations of the Dermaspan™, Softspan™, and AlloX2® tissue expanders.

The following table summarizes the allocation of the fair value of the consideration transferred by major class for the business combination completed on November 2, 2016 (in thousands):

	<b>November 2, 2016</b>
Accounts receivable, net	\$ 196
Inventory	1,555
Equipment	34
Goodwill	1,605
Intangible assets	2,860
Liabilities assumed	(250)
	<u>\$ 6,000</u>

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

	<b>Amount</b>	<b>Estimated useful life</b>	<b>Amortization method</b>
Customer relationships	\$ 1,740	9 years	Accelerated
Regulatory approvals	670	14 months	Straight-line
Trade names	450	indefinite-lived	
	<u>\$ 2,860</u>		

The Company retained an independent third-party appraiser to assist management in its valuation and the purchase price allocation has been finalized. Pro forma results of operations have not been presented because the effect of the acquisition was not material to the Company's 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. See Note 5 for discussion of the fair value of the common stock warrant liability, deferred consideration and contingent consideration. The fair value of the long-term debt is based on the amount of future cash flows associated with the instrument discounted using the Company's market rate. As of September 30, 2017, the carrying value of the long-term debt was not materially different from the fair value.

## 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® and the contingent consideration for future milestone payments for both the acquisition of the tissue expander portfolio from SSP and the acquisition of Miramar 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.

The following tables present information about the Company's liabilities that are measured at fair value on a recurring basis as of September 30, 2017 and December 31, 2016 and indicate the level of the fair value hierarchy utilized to determine such fair value (in thousands):

	Fair Value Measurements as of			
	September 30, 2017 Using:			
	Level 1	Level 2	Level 3	Total
<b>Liabilities:</b>				
Liability for common stock warrants	\$ —	—	250	250
Liability for deferred consideration	—	—	1,351	1,351
Liability for contingent consideration	—	—	11,956	11,956
	\$ —	—	13,557	13,557

	Fair Value Measurements as of December 31, 2016 Using:			
	Level 1	Level 2	Level 3	Total
<b>Liabilities:</b>				
Liability for common stock warrants	\$ —	—	99	99
Liability for deferred consideration	—	—	395	395
Liability for contingent consideration	—	—	1,242	1,242
	<u>\$ —</u>	<u>—</u>	<u>1,736</u>	<u>1,736</u>

The liability for common stock warrants and the current portion of deferred consideration is included in “accrued and other current liabilities” and the long-term liabilities for the deferred consideration and contingent consideration are included in “deferred consideration and contingent consideration” 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 (in thousands):

<b>Warrant Liability</b>	
Balance, December 31, 2016	\$ 99
Fair value of warrants to be issued upon borrowing under the SVB Loan Agreement (Note 9)	88
Warrants extinguished upon termination of SVB Loan Agreement	(88)
Change in fair value through September 30, 2017	151
Balance, September 30, 2017	<u>\$ 250</u>
<b>Deferred Consideration Liability</b>	
Balance, December 31, 2016	\$ 395
Initial fair value of acquisition-related deferred consideration	966
Change in fair value of deferred consideration	(10)
Balance, September 30, 2017	<u>\$ 1,351</u>
<b>Contingent Consideration Liability</b>	
Balance, December 31, 2016	\$ 1,242
Initial fair value of acquisition-related contingent consideration	9,946
Change in fair value of contingent consideration	768
Balance, September 30, 2017	<u>\$ 11,956</u>

The Company recognizes changes in the fair value of the warrants in “other income (expense), net” in the condensed consolidated statement of operations and changes in deferred consideration and contingent consideration are recognized in “general and administrative” expense in the condensed consolidated 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 and a product warranty for the Company’s miraDry® Systems. Under the breast implant 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 breast implant lifetime product replacement program, the Company provides no-charge replacement breast implants if a patient experiences a covered event. Under the miraDry® warranty, the Company currently provides a standard product warranty for two years to cover the consoles, hand pieces and accessories. Additionally, the warranty covers the shelf-life of the miraDry® consumables, or bioTips™. Additionally, an extended warranty may be purchased to provide additional protection of the miraDry® System.

The following table provides a rollforward of the accrued warranties (in thousands):

	<u>Nine Months Ended September 30,</u>	
	<u>2017</u>	<u>2016</u>
Beginning balance as of January 1	\$ 1,378	\$ 1,332
Acquired warranty liability	137	—
Payments made during the period	(11)	(19)
Changes in accrual related to warranties issued during the period	125	134
Changes in accrual related to pre-existing warranties	8	(1)
Balance as of September 30	<u>\$ 1,637</u>	<u>\$ 1,446</u>

## 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.

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Net loss (in thousands)	\$ (14,381)	\$ (9,963)	\$ (46,192)	\$ (32,094)
Weighted average common shares outstanding, basic and diluted	19,328,244	18,208,112	19,079,788	18,111,593
Net loss per share attributable to common stockholders	<u>\$ (0.74)</u>	<u>\$ (0.55)</u>	<u>\$ (2.42)</u>	<u>\$ (1.77)</u>

The Company excluded the following potentially dilutive securities, outstanding as of September 30, 2017 and 2016, from the computation of diluted net loss per share attributable to common stockholders for the three and nine months ended September 30, 2017 and 2016 because they had an anti-dilutive impact due to the net loss attributable to common stockholders incurred for the periods.

	<u>September 30,</u>	
	<u>2017</u>	<u>2016</u>
Stock options to purchase common stock	1,872,999	1,760,596
Warrants for the purchase of common stock	47,710	47,710
	<u>1,920,709</u>	<u>1,808,306</u>

## 8. Balance Sheet Components

### a. Allowance for Sales Returns and Doubtful Accounts

The Company has established an allowance for sales returns of \$4.2 million and \$3.9 million as of September 30, 2017 and December 31, 2016, respectively, recorded net against accounts receivable in the balance sheet.

The Company has established an allowance for doubtful accounts of \$0.5 million and \$0.4 million as of September 30, 2017 and December 31, 2016, respectively, recorded net against accounts receivable in the balance sheet.

**b. Inventories**

Upon the acquisition of Miramar, the Company now has raw materials and work in progress, in addition to finished goods.

Inventories, net consist of the following (in thousands):

	<u>September 30,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Raw materials	\$ 1,784	\$ —
Work in progress	2,865	—
Finished goods	18,420	18,484
	<u>\$ 23,069</u>	<u>\$ 18,484</u>

**c. Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consist of the following (in thousands):

	<u>September 30,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Prepaid expenses	\$ 2,046	\$ 1,145
Other current assets	2,028	707
Total	<u>\$ 4,074</u>	<u>\$ 1,852</u>

**d. Property and Equipment**

Property and equipment, net consist of the following (in thousands):

	<u>September 30,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Leasehold improvements	\$ 940	\$ 86
Laboratory equipment and toolings	5,049	2,264
Computer equipment	594	287
Software	1,077	669
Office equipment	134	129
Furniture and fixtures	885	743
	<u>8,679</u>	<u>4,178</u>
Less accumulated depreciation	<u>(4,319)</u>	<u>(1,192)</u>
	<u>\$ 4,360</u>	<u>\$ 2,986</u>

Depreciation expense for the three months ended September 30, 2017 and 2016 was \$0.2 million and \$0.1 million, respectively. Depreciation expense for the nine months ended September 30, 2017 and 2016 was \$0.6 million and \$0.2 million, respectively.

**e. 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. 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 impairment assessment for that reporting unit.

The applicable accounting guidance requires the Company 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. The impairment loss is measured by the excess of the carrying amount of the reporting unit goodwill over the fair value of that goodwill.

The changes in the carrying amount of goodwill during the nine months ended September 30, 2017 were as follows (in thousands):

Balances as of December 31, 2016	
Goodwill	\$ 19,156
Accumulated impairment losses	(14,278)
Goodwill, net	<u>\$ 4,878</u>
Goodwill acquired (Note 3)	<u>7,629</u>
Balances as of September 30, 2017	
Goodwill	\$ 26,785
Accumulated impairment losses	(14,278)
Goodwill, net	<u>\$ 12,507</u>

The components of the Company's other intangible assets consist of the following (in thousands):

	Average Amortization Period (in years)	September 30, 2017		
		Gross Carrying Amount	Accumulated Amortization	Intangible Assets, net
<b>Intangibles with definite lives</b>				
Customer relationships	11	\$ 11,240	\$ (1,464)	\$ 9,776
Trade names - finite life	14	5,800	(146)	5,654
Developed technology	15	3,000	(40)	2,960
Distributor relationships	9	500	(17)	483
Regulatory approvals	1	670	(526)	144
Non-compete agreement	2	80	(47)	33
Acquired FDA non-gel product approval	11	1,713	(1,709)	4
Total definite-lived intangible assets		<u>\$ 23,003</u>	<u>\$ (3,949)</u>	<u>\$ 19,054</u>
<b>Intangibles with indefinite lives</b>				
Trade names - indefinite life	—	450	—	450
Total indefinite-lived intangible assets		<u>\$ 450</u>	<u>\$ —</u>	<u>\$ 450</u>

	Average Amortization Period (in years)	December 31, 2016		
		Gross Carrying Amount	Accumulated Amortization	Intangible Assets, net
<b>Intangibles with definite lives</b>				
Customer relationships	10	\$ 4,940	\$ (602)	\$ 4,338
Trade names - finite life	12	800	(56)	744
Regulatory approvals	1	670	(96)	574
Non-compete agreement	2	80	(17)	63
Acquired FDA non-gel product approval	11	1,713	(1,696)	17
Total definite-lived intangible assets		<u>\$ 8,203</u>	<u>\$ (2,467)</u>	<u>\$ 5,736</u>
<b>Intangibles with indefinite lives</b>				
Trade names - indefinite life	—	450	—	450
Total indefinite-lived intangible assets		<u>\$ 450</u>	<u>\$ —</u>	<u>\$ 450</u>

Amortization expense for the three months ended September 30, 2017 and 2016 was \$1.0 million and \$0.2 million, respectively. Amortization expense for the nine months ended September 30, 2017 and 2016 was \$1.8 million and \$0.5 million, respectively. The following table summarizes the estimated amortization expense relating to the Company's definite-lived intangible assets as of September 30, 2017 (in thousands):

Period	Amortization Expense
Remainder of 2017	\$ 705
2018	2,308
2019	2,321
2020	2,197
2021	1,996
Thereafter	9,527
	<u>\$ 19,054</u>

**f. Accrued and Other Current Liabilities**

Accrued and other current liabilities consist of the following (in thousands):

	September 30, 2017	December 31, 2016
Payroll and related expenses	\$ 4,369	\$ 2,592
Audit, consulting and legal fees	3,060	812
Accrued commissions	2,024	1,222
Deferred consideration, current portion	966	—
Accrued marketing and sales expenses	482	31
Warrant liability	250	99
Accrued clinical trial and research and development expenses	183	119
Other	2,335	1,632
	<u>\$ 13,669</u>	<u>\$ 6,507</u>

**9. Long-Term Debt and Revolving Loan**

On July 25, 2017, the Company entered into a Credit and Security Agreement, or the Term Loan Credit Agreement, and a Credit and Security Agreement, or the Revolving Credit Agreement with Midcap, and, together with the Term Loan Credit Agreement, the Credit Agreements, which replaced the Company's then-existing Silicon Valley Bank

Loan Agreement, or the SVB Loan Agreement. Upon executing the Credit Agreements, the Company repaid in full its indebtedness under the SVB Loan Agreement, which totaled approximately \$5.0 million related to a revolving line of credit, or the Revolving Line of Credit. In connection with the refinancing, the Company was forgiven a commitment fee payable of approximately \$0.8 million, which was included in long term liabilities, net of the current portion included in accrued and other current liabilities in the condensed consolidated balance sheet, and extinguishment of corresponding warrants of approximately \$0.1 million related to the SVB Loan Agreement. The Company also recorded an expense of approximately \$16,000 related to the write-off of related issuance costs, which has been included in interest expense in the condensed consolidated statements of operations. Unamortized debt issuance costs from the SVB Loan Agreement related to the modification will be amortized over the term of the new Credit Agreements.

Under the terms of the Term Loan Credit Agreement, as of July 25, 2017, Midcap funded \$25.0 million to the Company, the Closing Date Term Loan. Midcap also made available to the Company until March 31, 2018, a \$10.0 million term loan, or the March 2018 Term Loan, subject to the satisfaction of certain conditions, including FDA certifications of the manufacturing facility operated by Vesta, and an additional \$5.0 million term loan, subject to the satisfaction of certain conditions, including evidence that the Company's Net Revenue for the past 12 months was greater than or equal to \$75.0 million, as defined in the Term Loan Credit Agreement, collectively the Term Loans. Under the Revolving Credit Agreement, Midcap made available to the Company a revolving line of credit, or the Revolving Loan. The amount of loans available to be drawn is based on a borrowing base equal to 85% of the net collectible value of eligible accounts receivable plus 40% of eligible finished goods inventory, or the Borrowing Base, provided that availability from eligible finished goods inventory does not exceed 20% of the Borrowing Base. The Company used the proceeds to repay in full the Company's then-existing indebtedness under its SVB Loan Agreement and to pay fees and expenses in connection with the foregoing and the Company intends to use the proceeds for general corporate purposes.

Any indebtedness under the Term Loan Credit Agreement bears interest at a floating per annum rate equal to the LIBOR as reported by Midcap with a floor of 1.00%, which as of September 30, 2017 was 1.24%, plus 7.50%. The Term Loans have a scheduled maturity date of December 1, 2021, or the Maturity Date. The Company must make monthly payments of accrued interest under the Term Loans from the funding date of the Term Loans, until December 31, 2018, followed by monthly installments of principal and interest through the Maturity Date. The Company may prepay all of the Term Loans prior to its maturity date provided the Company pays Midcap a prepayment fee. The Company paid an origination fee of 0.50% of the Term Loans total amount of \$40.0 million on the closing date. As of September 30, 2017, there was \$25.0 million outstanding related to the Term Loans. As of September 30, 2017, the unamortized debt issuance costs on the Term Loans was approximately \$0.1 million current portion and approximately \$0.3 million long-term portion and are included as a reduction to debt on the condensed consolidated balance sheet.

Any indebtedness under the Revolving Credit Agreement bears interest at a floating per annum rate equal to the LIBOR as reported by Midcap with a floor of 1.00%, plus 4.50%. The Company may make and repay borrowings from time to time under the Revolving Credit Agreement until the maturity of the facility on December 1, 2021. The Company is required to pay an annual collateral management fee of 0.50% on the outstanding balance, and an annual unused line fee of 0.50% of the average unused portion. The Company may prepay all of the outstanding balance prior to the maturity date provided the Company pays Midcap a prepayment fee. The Company paid an origination fee of 0.50% of the Revolving Loan amount of \$10.0 million on the closing date. As of September 30, 2017, there were no borrowings outstanding related to the Revolving Loan or any material outstanding letters of credit. As of September 30, 2017, the unamortized debt issuance costs related to the Revolving Loan was approximately \$0.2 million and was included in other long-term assets on the condensed consolidated balance sheet.

The amortization of debt issuance costs for the three months ended September 30, 2017 was \$28,500, relating to the Term Loans and Revolving Loan. The amortization of debt issuance costs for the nine months ended September 30, 2017 was \$0.1 million, relating to the Revolving Line of Credit, the Term Loans, and the Revolving Loan and were included in interest expense in the condensed consolidated statements of operations.

The Credit Agreements includes customary affirmative and restrictive covenants and representations and warranties, including a financial covenant for minimum revenues, a financial covenant for minimum cash requirements, a

covenant against the occurrence of a “change in control,” financial reporting obligations, and certain limitations on indebtedness, liens, investments, distributions, collateral, mergers or acquisitions, taxes, and deposit accounts. Upon the occurrence of an event of default, a default interest rate of an additional 5.0% may be applied to any outstanding principal balances, and Midcap may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Credit Agreements. The Company’s obligations under the Credit Agreements are secured by a security interest in substantially all of The Company’s assets, other than intellectual property.

**Future Principal Payments of Debt**

The future schedule of principal payments for the outstanding Term Loan as of September 30, 2017 was as follows (in thousands):

<b>Fiscal Year</b>		
Remainder of 2017	\$	—
2018		—
2019		8,333
2020		8,333
2021		8,334
Thereafter		—
<b>Total</b>	<b>\$</b>	<b>25,000</b>

**10. 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 September 30, 2017 and December 31, 2016, the Company had no preferred stock issued or outstanding.

*b. Common 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 an 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 September 30, 2017, there were 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 initially 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 September 30, 2017, a total of 361,637 shares of the Company's common stock were available for issuance under the 2014 Plan.

Pursuant to a board-approved 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 in accordance with NASDAQ Stock Market Rule 5635(c)(4) as an inducement material to such individuals entering into employment with the Company. As of September 30, 2017, inducement grants for 330,000 shares of common stock have been awarded, and 34,000 shares of common stock were available for future 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 not be 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 that 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.

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

	<b>Option Shares</b>	<b>Weighted average exercise price</b>	<b>Weighted average remaining contractual term (year)</b>
Balances at December 31, 2016	2,786,977	\$ 7.27	6.28
Granted	180,000	9.12	
Exercised	(475,171)	2.79	
Forfeited	(286,880)	12.82	
Balances at September 30, 2017	<u>2,204,926</u>	\$ 7.66	7.51

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 \$0.5 million and \$0.4 million for the three months ended September 30, 2017 and 2016, respectively. Stock-based compensation expense was \$1.6 million and \$1.2 million for the nine months ended September 30, 2017 and 2016, respectively. As of September 30, 2017, there was \$3.2 million of unrecognized compensation costs related to stock options. The expense is recorded within the operating expense components in the condensed consolidated statement of operations based on the recipients receiving the awards. These costs are expected to be recognized over a weighted average period of 2.12 years.

**d. Restricted Stock Units**

The Company has issued restricted stock unit awards, or RSUs, under the 2014 Plan and the Inducement Plan. The RSUs issued generally 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:

	<u>Number of shares</u>		<u>Weighted average grant date fair value</u>
Balances at December 31, 2016	430,733	\$	7.99
Granted	761,345		8.61
Vested	(252,285)		7.74
Forfeited	(39,416)		8.46
Balances at September 30, 2017	<u>900,377</u>	\$	8.57

Stock-based compensation expense for RSUs for the three months ended September 30, 2017 and 2016 was \$1.0 million and \$0.5 million, respectively. Stock-based compensation expense for RSUs for the nine months ended September 30, 2017 and 2016 was \$2.8 million and \$1.1 million, respectively. As of September 30, 2017, there was \$6.0 million of total unrecognized compensation costs related to non-vested RSU awards. The cost is expected to be recognized over a weighted average period of 1.88 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 for 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. 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 September 30, 2017, the number of shares of common stock reserved for issuance under the ESPP was 770,549. During the nine months ended September 30, 2017, employees purchased 108,081 shares of common stock at a weighted average price of \$5.98 per share. As of September 30, 2017, the number of shares of common stock available for future issuance was 495,551.

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 \$0.1 million for both the three months ended September 30, 2017 and 2016. Stock-based compensation expense related to the ESPP was \$0.3 million for both the nine months ended September 30, 2017 and 2016.

**11. Income Taxes**

The Company operates in several tax jurisdictions and is subject to taxes in each jurisdiction in which it conducts business. To date, the Company has incurred cumulative net losses and maintains a full valuation allowance on its net deferred tax assets due to the uncertainty surrounding realization of such assets. However, the Company has deferred tax liabilities associated with indefinite-lived intangible assets that cannot be considered sources of income to support the realization of the deferred tax assets, and has provided for tax expense and a corresponding deferred tax liability associated with these indefinite-lived intangible assets. Tax expense was \$16,000 and \$48,000 for the three months ended September 30, 2017 and 2016, respectively. Tax expense was \$0.1 million and \$48,000 for the nine months ended September 30, 2017 and 2016, respectively.

## 12. Segment Information

### Reportable Segments

The Company has two reportable segments: Breast Product and miraDry®. The Breast Product segment focuses on sales of silicone gel breast implants, tissue expanders and scar management products under the brands Sientra®, AlloX2®, Dermaspan™, Softspan™ and BIOCORNEUM®. The miraDry® segment focuses on sales of the miraDry® System, consisting of a console and a handheld device which uses consumable single-use bioTips™. These segments align with the Company's principal target markets. On July 25, 2017, the Company acquired Miramar. See Note 3a – Acquisitions for additional details. Miramar has been included in the consolidated results of operations as of the Acquisition Date and financial performance of the acquired business is reported in the miraDry® segment. The segments represent components for which separate financial information is available that is utilized on a regular basis by the Chief Executive Officer, who has been identified as the Chief Operating Decision Maker, or CODM, as defined by authoritative guidance on segment reporting, in determining how to allocate resources and evaluate performance. The segments are determined based on several factors, including client base, homogeneity of products, technology, delivery channels and similar economic characteristics.

The Company's CODM assesses the performance of each segment and allocates resources to those segments based on net sales and operating income (loss). Operating income (loss) by segment includes items that are directly attributable to each segment, including sales and marketing functions, as well as finance, information technology, human resources, legal and related corporate infrastructure costs, along with certain benefit-related expenses. There are no unallocated expenses for the two segments.

The following tables present the net sales and net operating loss by reportable segment for the periods presented (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Net sales:				
Breast Product	\$ 7,655	\$ 6,531	\$ 23,313	\$ 14,246
miraDry®	2,164	—	2,164	—
Total net sales	<u>\$ 9,819</u>	<u>\$ 6,531</u>	<u>\$ 25,477</u>	<u>\$ 14,246</u>
	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Loss from operations				
Breast Product	\$ (11,253)	\$ (9,774)	\$ (42,878)	\$ (31,921)
miraDry®	(2,602)	—	(2,602)	—
Total loss from operations	<u>\$ (13,855)</u>	<u>\$ (9,774)</u>	<u>\$ (45,480)</u>	<u>\$ (31,921)</u>

### **13. Commitments and Contingencies**

#### ***a. Operating Leases***

The Company's leases for its general office facilities are in Santa Barbara, California and Santa Clara, California, with leases expiring February 2020 and May 2019, respectively. The Company also leases additional industrial space for warehouse, research and development and additional general office use. Rent expense was \$0.2 million and \$0.1 million for the three months ended September 30, 2017 and 2016, respectively. Rent expense was \$0.5 million and \$0.4 million for the nine months ended September 30, 2017 and 2016, 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.

#### ***Class Action Shareholder Litigation***

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 naming the Company and certain of its officers as defendants for allegedly false and misleading statements concerning the Company's business, operations, and prospects. 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 naming 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 for allegedly false and misleading statements in the Company's offering documents associated with the follow-on offering concerning its business, operations, and prospects. On September 13, 2016, the parties to the actions pending in the San Mateo Superior Court and the United States District Court for the Central District of California signed a memorandum of understanding that sets forth the material deal points of a settlement that covers both actions and includes class-wide relief. Following a final fairness hearing in the federal court, on May 23, 2017, the federal court extended an order granting final approval of the settlement and dismissing the federal court action with prejudice. Following a final fairness hearing in the state court, on May 31, 2017, the state court entered an order granting final approval of the settlement and dismissing the state court action with prejudice.

As a result of these developments, the Company determined a probable loss had been incurred and recognized a net charge to earnings of approximately \$1.6 million for the nine months ended September 30, 2016 within general and administrative expense which was comprised of the loss contingency of approximately \$10.9 million, net of expected insurance proceeds of approximately \$9.4 million. In the first quarter of 2017, the Company received \$9.3 million in insurance proceeds and paid the \$10.9 million loss contingency. The remaining insurance proceeds receivable is classified as "insurance recovery receivable" on the accompanying condensed consolidated balance sheets.

#### ***Silimed Litigation***

On July 27, 2017, the Company entered into a settlement agreement, or the Settlement Agreement, with Silimed to settle outstanding litigations with Silimed. Pursuant to the Settlement Agreement, in exchange for a mutual release of claims and covenants not to sue or pursue certain litigation, Sientra paid Silimed a lump sum of \$9.0 million on September 7, 2017 and agreed to further pay \$1.0 million on or by July 1, 2018. In addition, should the Company enter into international markets using certain breast implant specifications, the Company has agreed to make royalty payments of \$12.50 on each of its net sales of such products, up to a maximum royalty of \$5.0 million. (See Part II – Item 1. Legal Proceedings – Silimed Litigation.)

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.

## 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 consolidated 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, 2016 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, 2016, filed with the Securities and Exchange Commission on March 14, 2017, or the Annual Report. 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," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in Part II, Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q and in our other filings with the SEC. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements.*

### **Overview**

We are a medical aesthetics company committed to making a difference in patients' lives by enhancing their body image, growing their self-esteem and restoring their confidence. We were founded to provide greater 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 tissue expanders exclusively to board-certified and board-admissible plastic surgeons and tailor our customer service offerings to their specific needs, which we believe helps secure their loyalty and confidence.

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

We sell our products in North America through a direct sales organization, which as of September 30, 2017, consisted of 63 employees, including 53 sales representatives and 10 sales managers. We leverage a distributor network for sales outside of North America.

We have two reporting segments: Breast Product and miraDry®. The Breast Product segment focuses on sales of our breast implants, tissue expanders and scar management products under the brands Sientra®, AlloX2 ® , Dermaspan™ , Softspan™ and BIOCORNEUM® . The miraDry® segment focuses on sales of the miraDry® System, consisting of a console and a handheld device which uses consumable single-use bioTips™.

## **Breast Product Segment**

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

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

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

We sell our silicone gel breast implants and tissue expanders exclusively to board-certified and board-admissible plastic surgeons, as determined by the American Board of Plastic Surgery, who we refer to as Plastic Surgeons. 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.

We continue to focus on our efforts on securing and qualifying an alternate manufacturing supplier. In July 2017, we entered into a Settlement Agreement with Silimed, our previous contract manufacturer. On August 9, 2016, we announced our collaboration with Vesta Intermediate Funding, Inc., or Vesta, a Lubrizol Lifesciences company, pursuant to which we are working with Vesta towards establishing a dedicated contract manufacturing facility for our breast implants. On March 14, 2017, we announced that we had executed a definitive manufacturing agreement with Vesta for the manufacture and supply of our breast implants and that we had submitted a PMA supplement to the FDA for the manufacturing of our PMA-approved breast implants by Vesta.

## **miraDry<sup>®</sup> Segment**

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

The miraDry® System MD4000 has been cleared by the FDA as indicated for use in the treatment of primary axillary hyperhidrosis, or a condition characterized by abnormal sweating in excess of that required for regulation of body temperature, plus unwanted underarm hair removal, and permanent reduction of underarm hair of all colors for Fitzpatrick skin types I – IV. Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime. When used for the treatment of primary axillary hyperhidrosis, the miraDry® System MD4000 may reduce underarm odor. In addition, the miraDry® System received CE mark approval for the treatment of primary axillary hyperhidrosis and approval in several other countries.

The miraDry® System provides patients with a non-invasive and durable procedure to selectively ablate underarm sweat glands for both severely hyperhidrotic patients and those that are bothered by their underarm sweat. The miraDry® System is clinically proven to reduce sweat in one or more procedures of approximately 60-minutes, allowing most patients to achieve immediately noticeable and durable results without the pain, expense, downtime, or repeat visits associated with surgical and other minimally-invasive procedures. The sweat glands in the treated area are ablated through targeted heating of the tissue, and because the body does not regenerate sweat glands, we believe the results will be lasting, although some patients may need to repeat the miraDry® procedure to achieve the lasting results.

The miraDry® System consists of a console and a handheld device which uses consumable single-use bioTips™. The miraDry® procedure is not technique-dependent, does not require significant training or skill for the treatment provider, and the user-interface guides the provider through each step of the procedure for each treatment. We sell our miraDry® System and consumable single-use bioTips™ only to physicians, consisting of dermatologists, plastic surgeons, aesthetic specialists and physicians specializing in the treatment of hyperhidrosis. Aesthetic specialists are physicians who elect to offer aesthetic procedures as a significant part of their practices but are generally not board-certified dermatologists or plastic surgeons. Physicians can market the miraDry® procedure as a premium, highly-differentiated, non-surgical sweat reduction procedure. Based on our commercial data, we believe physicians can recoup their capital expenditures within 12 months on average, assuming modest use of the miraDry® System, even though the cost of the miraDry® procedure is not reimbursed by any third party payors. We are approved to sell the miraDry® System in over 40 international markets outside of North America, including countries in Asia, Europe, the Middle East and South America.

We generated net sales of \$2.2 million for the three and nine months ended September 30, 2017 from the acquisition date on July 25, 2017. With the acquisition of Miramar, we expect net sales, cost of goods sold, sales and marketing, general and administrative, and research and development expenses to increase in 2018 when compared to 2017 and prior periods.

## **Components of Operating Results**

### ***Net Sales***

We recognize revenue on breast implants and tissue expanders, net of sales discounts and estimated returns, as the customer has a standard six-month window to return purchased breast implants and tissue expanders. Our Breast Product segment net sales for the nine months ended September 30, 2017 and 2016 reflects the combined effect of the temporary hold on sales and implanting of breast products manufactured by Silimed until March 1, 2016, our controlled re-entry to market designed to optimize our supply of breast implant inventory, the commercial introductions of our scar management products as of March 2016, our tissue expander portfolio as of November 2016. Net sales for our miraDry® segment include net sales of the miraDry® System and consumable bioTips™ as of the acquisition date of July 25, 2017.

We expect that, in the future, our net sales will fluctuate on a quarterly basis due to a variety of factors, including seasonality of breast augmentation procedures and purchase of miraDry® procedures. We believe that aesthetic procedures are subject to seasonal fluctuation due to patients planning their procedures leading up to the summer season and in the period around the winter holiday season.

### ***Cost of Goods Sold and Gross Margin***

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

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

We provide a commercial warranty on our silicone gel breast implants and a standard warranty on our miraDry® Systems, hand pieces and bioTips™. The estimated warranty costs are recorded at the time of sale. In addition, the inventory fair market value associated with non-cash purchase accounting adjustments and royalty costs related to both the SSP and Miramar acquisitions are recorded at the time of sale.

### ***Sales and Marketing Expenses***

Our sales and marketing expenses primarily consist of salaries, bonuses, benefits, incentive compensation, stock-based compensation and travel for our sales, marketing and customer support personnel. Our sales and marketing expenses also include expenses for trade shows, our no-charge customer shipping program 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 Manufacturing Practices (“cGMP”), 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, incentive compensation 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, facilities and information technologies expenses.

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

### ***Other Income (Expense), net***

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

### ***Income Taxes***

Income tax expense consists of an estimate for income taxes based on the projected income tax expense for the period ended September 30, 2017. We operate in several tax jurisdictions and are subject to taxes in each jurisdiction in which we conduct business. To date, we have incurred cumulative net losses and maintain a full valuation allowance on our net deferred tax assets due to the uncertainty surrounding realization of such assets. However, as a result of the BIOCORNEUM® and tissue expander portfolio acquisitions, we have deferred tax liabilities associated with indefinite-lived intangible assets that cannot be considered sources of income to support the realization of the deferred tax assets, and have provided for tax expense and a corresponding deferred tax liability associated with these indefinite-lived intangible assets.

### **Critical Accounting Policies and Significant Judgments and Estimates**

The preparation of our unaudited condensed consolidated 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 the Annual Report. There have been no material changes to our critical accounting policies and estimates from those disclosed in the Annual Report.

### **Recent Accounting Pronouncements**

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

## Results of Operations

### Comparison of the Three Months Ended September 30, 2017 and 2016

The following table sets forth our results of operations for the three months ended September 30, 2017 and 2016:

	Three Months Ended September 30,	
	2017	2016
(unaudited, in thousands)		
<b>Statement of operations data</b>		
Net sales	\$ 9,819	\$ 6,531
Cost of goods sold	3,484	1,814
Gross profit	6,335	4,717
<b>Operating expenses</b>		
Sales and marketing	7,981	5,137
Research and development	2,911	2,052
General and administrative	9,298	5,684
Legal settlement	—	1,618
Total operating expenses	20,190	14,491
Loss from operations	(13,855)	(9,774)
<b>Other income (expense), net</b>		
Interest income	54	16
Interest expense	(409)	(105)
Other income (expense), net	(155)	(52)
Total other income (expense), net	(510)	(141)
Loss before income taxes	(14,365)	(9,915)
Income taxes	16	48
Net loss	\$ (14,381)	\$ (9,963)

### Net Sales

Net sales increased \$3.3 million, or 50.3%, to \$9.8 million for the three months ended September 30, 2017 as compared to \$6.5 million for the three months ended September 30, 2016. Net sales of our breast implants and tissue expanders increased \$1.3 million to \$6.3 million for the three months ended September 30, 2017, as compared to \$5.0 million for the three months ended September 30, 2016, primarily due to increased sales of tissue expanders as a result of the acquisition from SSP in November 2016. The acquisition of Miramar contributed \$2.2 million of net sales since the acquisition on July 25, 2017.

As of September 30, 2017, our sales organization included 53 sales representatives as compared to 38 sales representatives as of September 30, 2016. The increase is primarily attributed to the acquisition of Miramar.

### Cost of Goods Sold and Gross Margin

Cost of goods sold increased \$1.7 million, or 92.1%, to \$3.5 million for the three months ended September 30, 2017, as compared to \$1.8 million for the three months ended September 30, 2016. This increase was primarily due to an increase in sales volume driven by increased sales of breast implants and tissue expanders as a result of the acquisition from SSP in November 2016. The acquisition of Miramar increased cost of goods by \$1.4 million since the acquisition on July 25, 2017.

The gross margins for the three months ended September 30, 2017 and 2016 were 64.5% and 72.2%, respectively. The decrease is primarily due to the inclusion of miraDry®, which carries a lower margin than Breast Products.

### ***Sales and Marketing Expenses***

Sales and marketing expenses increased \$2.9 million, or 55.4%, to \$8.0 million for the three months ended September 30, 2017, as compared to \$5.1 million for the three months ended September 30, 2016. The increase is primarily due to the higher employee related costs as a result of increased sales and headcount. The acquisition of Miramar increased sales and marketing expenses by \$1.9 million since the acquisition on July 25, 2017.

### ***Research and Development Expenses***

Research and development expenses increased \$0.8 million, or 41.9%, to \$2.9 million for the three months ended September 30, 2017, as compared to \$2.1 million for the three months ended September 30, 2016. The increase was primarily due to a \$0.4 million increase in employee related costs. The acquisition of Miramar increased research and development expenses by \$0.5 million since the acquisition on July 25, 2017.

### ***General and Administrative Expenses***

G&A expenses increased \$3.6 million, or 63.6%, to \$9.3 million for the three months ended September 30, 2017, as compared to \$5.7 million for the three months ended September 30, 2016. The increase consisted primarily of an increase in acquisition related costs. The acquisition of Miramar increased general and administrative expenses by \$1.0 million since the acquisition on July 25, 2017.

### ***Legal Settlement Expenses***

The Company did not have any legal settlement expenses for the three months ended September 30, 2017. For the three months ended September 30, 2016, the Company had legal settlement expenses of \$1.6 million for the settlement of the Class Action Shareholder Litigation which was comprised of a loss contingency of approximately \$10.9 million, net of expected insurance proceeds of approximately \$9.4 million.

### ***Other Income (Expense), net***

Other income (expense), net for the three months ended September 30, 2017 was primarily associated with expenses related to the change in fair value of warrants and amortization of issuance costs associated with our Credit Agreements. Other income (expense), net for the three months ended September 30, 2016 was primarily associated with interest income on cash held in a money market account and expense recognized for the change in fair value of warrants.

### ***Income Tax Expense***

Income tax expense for the three months ended September 30, 2017 was associated with a deferred tax liability associated with indefinite-lived intangible assets from the BIOCORNEUM® acquisition and the tissue expander portfolio acquisition from SSP that cannot offset deferred tax assets. Income tax expense for the three months ended September 30, 2017 and 2016 was \$16,000 and \$48,000, respectively.

**Comparison of the Nine Months Ended September 30, 2017 and 2016**

The following table sets forth our results of operations for the nine months ended September 30, 2017 and 2016:

	Nine Months Ended September 30,	
	2017	2016
(unaudited, in thousands)		
<b>Statement of operations data</b>		
Net sales	\$ 25,477	\$ 14,246
Cost of goods sold	8,427	4,319
Gross profit	17,050	9,927
<b>Operating expenses</b>		
Sales and marketing	21,100	16,533
Research and development	7,677	7,370
General and administrative	23,753	16,327
Legal settlement	10,000	1,618
Total operating expenses	62,530	41,848
Loss from operations	(45,480)	(31,921)
<b>Other income (expense), net</b>		
Interest income	112	47
Interest expense	(603)	(118)
Other income (expense), net	(151)	(54)
Total other income (expense), net	(642)	(125)
Loss before income taxes	(46,122)	(32,046)
Income taxes	70	48
Net loss	\$ (46,192)	\$ (32,094)

**Net Sales**

Net sales increased \$11.3 million, or 79%, to \$25.5 million for the nine months ended September 30, 2017 as compared to \$14.2 million for the nine months ended September 30, 2016. Net sales of our breast implants and tissue expanders increased \$7.8 million to \$18.9 million for the nine months ended September 30, 2017, as compared to \$11.1 million for the nine months ended September 30, 2016, as a result of our controlled re-entry to market designed to optimize our supply of breast implant inventory after the voluntary hold on the sale and implanting of all Sientra devices manufactured by Silimed between October 9, 2015 and March 1, 2016. Net sales of breast implants and tissue expanders for the nine months ended September 30, 2017 also included sales of the tissue expander portfolio we acquired from SSP as of November 2016. Net sales of our scar management products increased \$1.1 million to \$3.8 million for the nine months ended September 30, 2017 as compared to \$2.7 million for the nine months ended September 30, 2016 as a result of integrating scar management products into our product mix after our acquisition of BIOCORNEUM® in March 2016. The acquisition of Miramar contributed \$2.2 million of net sales since the acquisition on July 25, 2017.

As of September 30, 2017, our total sales organization included 53 sales representatives as compared to 38 sales representatives as of September 30, 2016. The increase is primarily attributed to the acquisition of Miramar.

### ***Cost of Goods Sold and Gross Margin***

Cost of goods sold increased \$4.1 million, or 95%, to \$8.4 million for the nine months ended September 30, 2017, as compared to \$4.3 million for the nine months ended September 30, 2016. This increase was primarily due to an increase in sales volume driven by our controlled re-entry of breast implants into the marketplace after the voluntary hold on the sale and implanting of all Sientra devices manufactured by Silimed between October 9, 2015 and March 1, 2016, along with an increase in sales volume of our scar management products after the acquisition of BIOCORNEUM® in March 2016 and sales of our tissue expander portfolio we acquired from SSP in November 2016. The acquisition of Miramar increased cost of goods by \$1.4 million since the acquisition on July 25, 2017.

The gross margins for the nine months ended September 30, 2017 and 2016 were 66.9% and 69.7%, respectively. The decrease is primarily due to the inclusion of miraDry®, which carries a lower margin than Breast Products.

### ***Sales and Marketing Expenses***

Sales and marketing expenses increased \$4.6 million, or 27.6%, to \$21.1 million for the nine months ended September 30, 2017, as compared to \$16.5 million for the nine months ended September 30, 2016. The increase is primarily due to the increase in employee related costs as a result of increased sales and headcount. The acquisition of Miramar increased sales and marketing expenses by \$1.9 million since the acquisition on July 25, 2017.

### ***Research and Development Expenses***

Research and development expenses increased \$0.3 million, or 4.2%, to \$7.7 million for the nine months ended September 30, 2017, as compared to \$7.4 million for the nine months ended September 30, 2016. The acquisition of Miramar increased research and development expenses by \$0.5 million since the acquisition on July 25, 2017.

### ***General and Administrative Expenses***

G&A expenses increased \$7.5 million, or 45.5%, to \$23.8 million for the nine months ended September 30, 2017, as compared to \$16.3 million for the nine months ended September 30, 2016. The increase consisted primarily of an increase in employee related costs, an increase in acquisition related costs, and an increase in amortization and change in fair market value of contingent consideration related to acquisitions. The acquisition of Miramar increased general and administrative expenses by \$1.0 million since the acquisition on July 25, 2017.

### ***Legal Settlement Expenses***

The Company had legal settlement expenses of \$10.0 million for the nine months ended September 30, 2017 for the settlement of the Silimed Litigations. The Company had legal settlement expenses of \$1.6 million for the nine months ended September 30, 2016 for the settlement of the Class Action Shareholder Litigation which was comprised of a loss contingency of approximately \$10.9 million, net of expected insurance proceeds of approximately \$9.4 million .

### ***Other Income (Expense), net***

Other income (expense), net for the nine months ended September 30, 2017 was primarily associated with expenses related to the change in fair value of warrants and amortization of issuance costs associated with our Credit Agreements. Other income (expense), net for the nine months ended September 30, 2016 was primarily associated with interest income on cash held in a money market account and expense recognized for the change in fair value of warrants.

### ***Income Tax Expense***

Income tax expense for the nine months ended September 30, 2017 was associated with a deferred tax liability associated with indefinite-lived intangible assets from the BIOCORNEUM® acquisition and the tissue expander portfolio acquisition from SSP that cannot offset deferred tax assets. Income tax expense for the nine months ended September 30, 2017 and 2016 was \$0.1 million and \$48,000, respectively.

## 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.

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.

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

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

See Note 9 to the unaudited financial statement for a full description of our long-term debt and revolving line of credit.

As of September 30, 2017, we had \$37.6 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, 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. In addition, we have used cash to fund the acquisitions of Miramar, BIOCORNEUM® and the tissue expander portfolio from SSP. We believe that our available cash on hand, along with the availability under the Credit Agreements will be sufficient to satisfy our liquidity requirements for at least the next 12 months from the date our condensed consolidated financial statements are issued.

However, we expect that uncertainty regarding expenses we may continue to incur in connection with establishing new manufacturing capacity with Vesta or any other third-party manufacturer for our breast implants, and our uncertainty regarding the amount of additional expenses we may incur in connection with regulatory inquiries, as well as expenses we may incur defending against litigation claims, may have a material effect on our future cash outflows and our liquidity. As a result, we may be required to make or increase our borrowings under the Credit Agreements, as well as seek additional funds in the future from public or private offerings of our capital stock or from other sources.

## 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:

	Nine Months Ended September 30,	
	2017	2016
	(unaudited, in thousands)	
<b>Net cash (used in) provided by:</b>		
Operating activities	\$ (35,702)	\$ (27,507)
Investing activities	(19,628)	(7,675)
Financing activities	25,759	1,663
Net change in cash and cash equivalents	<u>\$ (29,571)</u>	<u>\$ (33,519)</u>

### *Cash used in operating activities*

Net cash used in operating activities was \$35.7 million during the nine months ended September 30, 2017 as compared to \$27.5 million during the nine months ended September 30, 2016. The increase in cash used in operating activities between the nine months ended September 30, 2017 and 2016 was primarily associated with an increase in net loss and the \$9.9 million payment to Silimed related to the settlement of the lawsuit, offset by collection of \$9.3 million in insurance recovery and a decrease in accrued liabilities due to the timing of payments as compared to the nine months ended September 30, 2016.

### *Cash used in investing activities*

Net cash used in investing activities was \$19.6 million during the nine months ended September 30, 2017, primarily due to the \$18.5 million net cash outflow for the acquisition of Miramar. Net cash used in investing activities was \$7.7 million during the nine months ended September 30, 2016 and was primarily due to the \$6.8 million cash outflow for the acquisition of BIOCORNEUM®.

### *Cash provided by financing activities*

Net cash provided by financing activities was \$25.8 million during the nine months ended September 30, 2017 as compared to \$1.7 million during the nine months ended September 30, 2016. The increase in cash provided by financing activities was primarily the result of \$25.0 million in proceeds from borrowings under the Term Loans and an increase in proceeds from exercise of employee stock options, offset by tax payments related to shares withheld for vested RSUs for the nine months ended September 30, 2017.

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

- the timing to qualify Vesta with the FDA and the timing and availability of any alternative manufacturing sources, and costs associated with procuring and qualifying such manufacturing capacity;
- net sales generated by our Breast Product and miraDry® segments, and any other future products that we may develop and commercialize;
- costs associated with expanding our sales force and marketing programs;
- cost associated with developing and commercializing our proposed products or technologies;
- expenses we incur in connection with potential litigation or governmental investigations;
- cost of obtaining and maintaining regulatory clearance or approval for our current or future products;

- cost of ongoing compliance with regulatory requirements;
- anticipated or unanticipated capital expenditures; and
- unanticipated G&A expenses.

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

- support of our sales and marketing efforts related to our current and future products;
- new product acquisition and development efforts ;
- facilities expansion needs;
- investment in inventory required to meet customer demands; and
- expenses we incur in connection with defending against litigation.

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 September 30, 2017, except as discussed below, 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 the Annual Report.

On July 25, 2017, we borrowed \$25.0 million pursuant to the Term Loan Credit Agreement with Midcap and the other lenders party thereto. See Note 9 to the unaudited financial statement for timing of debt payment obligations.

### ***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 September 30, 2017, we had \$37.6 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. We have established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

## **ITEM 4: CONTROLS AND PROCEDURES**

### **Evaluation of Disclosure 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 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 chief 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 we disclosed in our Annual Report, we identified a material weakness in our internal control over financial reporting related to the Company not maintaining sufficiently trained resources with knowledge of internal control over financial reporting as it relates to accounting for significant unusual transactions, including coordination with external service providers. As a result, we did not have in place effective management review controls over business combinations, specifically key assumptions, financial data and calculations used to measure the fair value of acquired assets and liabilities, including contingent consideration prepared by its external service provider.

As described in our Annual Report, we are taking steps to remediate this material weakness in internal control over financial reporting; however, additional time will be required to assess and ensure remediation of these processes and procedures. Our goal is to remediate the identified material weakness by the end of 2017.

Because of the material weakness in our internal control over financial reporting as previously disclosed, our chief executive officer and chief financial officer concluded that, as of September 30, 2017, 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, were not effective. Our management, including our chief executive officer and chief financial officer, has concluded that, notwithstanding the material weakness in our internal control over financial reporting, the condensed consolidated financial statements in this Quarterly Report on Form 10-Q fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with U.S. GAAP.

### **Changes in Internal Control over Financial Reporting**

We are taking actions to remediate the material weakness relating to our internal control over financial reporting, as described above. Except as otherwise described herein, there was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q 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**

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

#### ***Silimed Litigation***

On July 27, 2017, the Company entered into a settlement agreement, or the Settlement Agreement, with Silimed to settle outstanding litigation with Silimed. Pursuant to the Settlement Agreement, in exchange for a mutual release of claims and covenants not to sue or pursue certain litigation, Sientra paid Silimed a lump sum of \$9.0 million and

agreed to pay \$1.0 million on or by July 1, 2018. In addition, should the Company enter into international markets using certain breast implant specifications, the Company has agreed to make royalty payments of \$12.50 on each of its net sales of such products, up to a maximum royalty of \$5.0 million.

## **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 the Annual Report.*

### **Risks Relating to Our Business and Our Industry**

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

As a result of our acquisition of Miramar, and our prior acquisitions of new products including BIOCORNEUM® and tissue expanders from SSP, we have undergone substantial changes in a short period of time and our business has changed and broadened in size and the scope of products we offer. In addition, we may consider other opportunities to partner with or acquire other businesses, products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base or advance our business strategies.

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

- distracting management from day-to-day operations;
- potential incompatibility of corporate cultures;
- an inability to achieve synergies as planned;
- risks associated with the assumption of contingent or other liabilities of acquisition targets;
- adverse effects on existing business relationships with suppliers or customers;
- inheriting and uncovering previously unknown issues, problems and costs from the acquired company;
- uncertainties associated with entering new markets in which we have limited or no experience;
- increased legal and accounting costs relating to the partnership or acquisition or compliance with regulatory matters;
- delays between our expenditures to acquire new products, technologies or businesses and the generation of revenues from those acquired products, technologies or businesses;

- realization of assets and settlement of liabilities at amounts equal to estimated fair value as of the acquisition date of any acquisition or disposition;
- costs and delays in implementing common systems and procedures (including technology, compliance programs, financial systems, distribution and general business operations, among others); and
- increased difficulties in managing our business due to the addition of international locations.

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

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

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

Since our inception, we have incurred significant net operating losses. As of September 30, 2017, we had an accumulated deficit of \$261.6 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.

For the nine months ended September 30, 2017, our net loss was \$46.2 million. The extent of our future operating losses and the timing of profitability are uncertain, especially in light of our inventory supply issues. We will need to generate significant sales to achieve profitability, and we might not be able to do so. Even if we do generate significant sales, we might not be able to achieve, sustain or increase profitability on a quarterly or annual basis in the future. If our sales grow more slowly than we have forecasted, or if our operating expenses exceed our forecasts, our financial performance and results of operations will be adversely affected.

***Our future profit ability depends on the success of our Breast Product and miraDry® System and procedures.\****

Our Breast Products have historically accounted for substantially all of our net sales and we expect our Breast Products to continue to be a substantial majority of our net sales. In connection with the Miramar acquisition, we invested a significant amount of assets to acquire the miraDry® System for the treatment of primary axillary hyperhidrosis, or a condition characterized by abnormal sweating in excess of that required for regulation of body temperature, and which we refer to as being “sweat-bothered”, plus unwanted underarm hair removal, and permanent reduction of underarm hair of all colors for Fitzpatrick skin types I – IV. When used for the treatment of primary axillary hyperhidrosis, the miraDry® System may also reduce underarm odor.

Our inability to manage our inventory supply issues, the inability to qualify Vesta or another third party as an alternate manufacturer, the potential loss of market acceptance of our Breast Products, or any adverse rulings by regulatory authorities, any adverse publicity or other adverse events relating to us or our Breast Products, or the introduction of competitive products by our competitors and other third parties, would adversely affect our business, financial condition and results of operations.

***We may not be able to procure and qualify a new manufacturer for our silicone gel breast implants and other products previously manufactured by Silimed.\****

Our manufacturing contract with Silimed expired on its terms on April 1, 2017, and we did not renew it. Moreover, our existing inventory of breast implants that were previously manufactured by Silimed is limited.

Although we have entered into a definitive manufacturing agreement with Vesta, Vesta has not yet been qualified as a manufacturer to source our implants. We recently submitted a PMA supplement to the FDA for the manufacturing of our PMA-approved implants by Vesta, but the timing of when we may obtain FDA approval, if any, could be subject to delays, some of which are beyond our control. Moreover, Vesta, or any other alternate manufacturer, would need to be qualified with the FDA, which is an expensive and time-consuming process. Any delays or our inability to qualify Vesta or negotiate a manufacturing agreement and qualify another alternate manufacturer could result in a supply interruption, which would materially adversely 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 Breast Product market.\****

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

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

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

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

- our products may not be manufactured in accordance with agreed upon specifications or in compliance with regulatory requirements or cGMP, or the manufacturing facilities may not be able to maintain compliance with regulatory requirements or cGMP, which could negatively affect the safety or efficacy of our products or cause delays in shipments of our products;
- we may not be able to timely respond to unanticipated changes in customer orders, and if orders do not match forecasts, we may have excess or inadequate inventory of materials and components;

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

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

***We invested a significant amount of assets in the acquisition of the miraDry® System, which has a limited commercial history. If the market acceptance for the miraDry® System fails to grow significantly, our business and future prospects will be harmed. \****

Commercial sales of the miraDry® System commenced in the United States in 2012 and in Japan in 2011 for the treatment of primary axillary hyperhidrosis, or a condition characterized by abnormal sweating in excess of that required for regulation of body temperature, and which we refer to as being “sweat-bothered”, plus unwanted underarm hair removal, and permanent reduction of underarm hair of all colors for Fitzpatrick skin types I – IV. When used for the treatment of primary axillary hyperhidrosis, the miraDry® System may also reduce underarm odor. We expect that the revenues we generate from sales of our miraDry® System and bioTips™ will account for a substantial amount of our revenues for the next several years. Accordingly, our success depends on the acceptance among physicians and patients of the miraDry® procedure as a preferred treatment for being sweat-bothered. Although we have received FDA clearance to market the miraDry® procedure for the treatment of primary axillary hyperhidrosis in the United States and are approved or are otherwise free to market the miraDry® procedure in over 40 international markets, the degree of market acceptance of the miraDry® procedure by physicians and patients is unproven. We believe that market acceptance of the miraDry® procedure will depend on many factors, including:

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

We cannot guarantee that the miraDry® System will achieve broad market acceptance among physicians and patients. Because we expect to derive a substantial portion of sales from the miraDry® Systems and the sale of our consumable bioTip™ products, any failure of this product to achieve meaningful market acceptance will harm our business and future prospects.

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

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

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

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

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

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

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

Our industry is intensely competitive and subject to rapid change from the introduction of new products, technologies and other activities of industry participants. Our Breast Product 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 our breast implants 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 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 and followed, health regulators believe there is an association between breast implants and a rare form of lymphoma called anaplastic large-cell lymphoma.\****

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

As of August 23, 2017, the FDA updated its recommendations on BIA-ALCL and subsequently requested all breast implant manufacturers to revise their physician and patient labeling with the most up-to-date information. The FDA still describes BIA-ALCL as "rare" and states: "we have strengthened our understanding of this condition and concur with the World Health Organization designation of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) as a rare T-cell lymphoma that can develop following breast implants. The exact number of cases remains difficult to determine due to significant limitations in world-wide reporting and lack of global implant sales data. At this time, most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with

textured surfaces rather than those with smooth surfaces.” The FDA noted it does not recommend prophylactic breast implant removal in a patient without symptoms or other abnormality.

Further studies or clinical experience may indicate that breast implants, including our products, expose individuals to a more substantial risk of developing BIA-ALCL or other unexpected complications than currently anticipated. As a result, we may be exposed to increased regulatory scrutiny, negative publicity and lawsuits from any individual who may develop BIA-ALCL after using our products, any of which could have a significant negative impact on our results of operations or financial condition. Moreover, if long-term results and clinical experience indicate that our products cause unexpected or serious complications, we could be subject to mandatory product recalls, suspension or withdrawal of regulatory clearances and approvals and significant legal liability.

***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, expand our miraDry® System and develop and market new products that respond to customer needs and preferences and achieve market acceptance, we may experience a decrease in demand for our products and our business could suffer.\****

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

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

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

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

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

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

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

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

Our corporate headquarters and 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 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 September 30, 2017, we had approximately 171 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.

***Our acquisition of Miramar has exposed us to risks and challenges associated with conducting business internationally.\****

As a result of our acquisition of Miramar, we now face new risks inherent in conducting business internationally, including compliance with international and U.S. laws and regulations that apply to international operations. These laws and regulations are complex, and there is a risk that some provisions may be breached by us, for example through fraudulent or negligent behavior of individual employees, our failure to comply with certain formal documentation requirements, or otherwise. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, requirements to obtain export licenses, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, our business and our operating results.

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

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

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

## Risks Related to Our Financial Results

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

We recently entered into the Credit Agreements with MidCap Financial Trust and the other lenders party thereto and borrowed \$25 million thereunder. Our indebtedness and other financial obligations could:

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

There is no guarantee that we will be able to pay the principal and interest under the Credit Agreements or that future working capital, borrowings or equity financing will be available to repay or refinance any amounts outstanding under the Credit Agreements. In addition, we may enter into debt agreements in the future that may contain similar or more burdensome terms and covenants, including financial covenants. See Liquidity and Capital Resources for additional detailed discussion of our outstanding indebtedness.

### *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 timing to qualify Vesta with the FDA and the availability of any alternative manufacturing sources to supply our silicone gel breast implants and certain other products;
- our ability to integrate and achieve the anticipated benefits of our acquisitions of the Miramar, BIOCORNEUM® and the tissue expanders from SSP;
- 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 past regulatory inquiries of Silimed on our brand and reputation;
- timing of our research and development activities and initiatives;
- the mix of our products sold due to different profit margins among our products;
- 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;
- our ability to expand the geographic reach of our sales and marketing efforts.

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

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

As of September 30, 2017, we had \$37.6 million in cash and cash equivalents. We believe that our available cash on hand, along with access to funds under our Credit Agreements, will be sufficient to satisfy our liquidity requirements for at least the next 12 months. However, the planned growth of our business, including our manufacturing agreement with Vesta, our acquisition of Miramar, 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 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 on our future cash outflows and our financial condition.

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

- the timing to qualify Vesta with the FDA and the availability of any alternative manufacturing sources and costs associated with procuring and qualifying such manufacturing capacity;
- net sales generated by our silicone gel breast implants, tissue expanders, miraDry® 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 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;
- anticipated or unanticipated capital expenditures; and
- unanticipated general and administrative expenses.

As a result of these and other factors, we do not know whether and the extent to which we may be required to raise additional capital. We may in the future seek additional capital from public or private offerings of our capital stock, borrowings under term loans or other sources. 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, 2016, we had federal net operating loss carryforwards, or NOLs, of approximately \$171.0 million, which begin expiring in 2027, if not utilized to offset taxable income. In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. In general, an “ownership change” occurs if there is a cumulative change in our ownership by “5% shareholders” that exceeds 50 percentage points over a rolling three-year period. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we undergo one or more ownership changes in connection with future transactions in our stock, our ability to utilize NOLs could be further limited by Section 382 of the Code. 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. We rely on a combination of trademarks, trade secrets, confidential information, copyrights, patent rights and other intellectual property rights to protect our intellectual property. In addition, to protect our trade secrets, confidential information and other intellectual property rights, we have entered into confidentiality agreements with third parties, and confidential information and invention assignment agreements with employees, consultants and advisors. However, these agreements may not provide sufficient protection or adequate remedies for violation of our rights in the event of unauthorized use or disclosure of confidential and proprietary information. Without additional protection under the patent or other intellectual property laws, such unauthorized use or disclosure may enable competitors to duplicate or surpass our technological achievements. Moreover, the laws of certain foreign countries do not recognize intellectual property rights or protect them to the same extent as do the laws of the United States. Failure to protect our proprietary rights could seriously impair our competitive position.

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

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

- stop making, selling or using products or technologies that allegedly infringe the asserted intellectual property;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others;

- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing;
- pay the attorney fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;
- redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and/or infeasible; or
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all.

Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, negatively impact shareholder value and harm our reputation. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages (which may be increased up to three times of awarded damages) and/or substantial royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations and financial condition.

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

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

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

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

As a supplier of medical devices, we are and may be subject to warranty or product liability claims alleging that the use of our products has resulted in adverse health effects or other litigation in the ordinary course of business that may require us to make significant expenditures to defend these claims or pay damage awards. The breast implant

industry has a particularly significant history of product liability litigation. The risks of litigation exist even with respect to products that have received or in the future may receive regulatory approval for commercial sale, such as our Breast Products. In addition, 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.

**Risks Related to Our Legal and Regulatory Environment**

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

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

- the federal Anti-Kickback Statute, which applies to our business activities, including our marketing practices, educational programs, pricing policies and relationships with healthcare providers, by prohibiting, among other things, knowingly and willfully soliciting, receiving, offering or providing any remuneration (including any bribe, kickback or rebate) directly or indirectly, overtly or covertly, in cash or in kind, intended to induce or in return for the purchase or recommendation of any good, facility, item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare or Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to commit a violation. Rather, if "one purpose" of the remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. In addition, following passage of the PPACA violations of the federal Anti-Kickback Statute became per se violations of the False Claims Act;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government payors that are false or fraudulent, or making a false statement to decrease or conceal an obligation to pay or transmit money or property to the federal government, and which may apply to entities that provide coding and billing advice to customers;

- HIPAA, and its implementing regulations, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- and, HIPAA, as amended by HITECH, also imposes certain regulatory and contractual requirements on certain types of people and entities subject to the law and their business associates regarding the privacy, security 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 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, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

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

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

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical trials;

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

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

Before we can market or sell a new regulated product or a significant modification to an existing product in the United States, we must obtain either clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or FDCA, or an approval of a PMA application unless the device is specifically exempt from pre-market review. In the 510(k) clearance process, the FDA must determine that a proposed device is “substantially equivalent” to a device legally on the market, known as a “predicate” device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on specific data, including, but not limited to, pre-clinical, clinical trial, and other product data. The PMA process is typically required for devices for which the 510(k) process cannot be used and that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. Modifications to products that are approved through a PMA application generally need FDA approval. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). The FDA’s 510(k) clearance process usually takes from three to 12 months, but may last longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA until an approval is obtained.

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

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

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

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

The FDA could also reclassify some or all of our products that are currently classified as Class II to Class III requiring additional controls, clinical studies and submission of a PMA for us to continue marketing and selling those products. We cannot guarantee that the FDA will not reclassify any of our Class II devices into Class III and require us to submit a PMA for FDA review and approval of the safety and effectiveness of our product. Any delay in, or failure to receive or maintain clearance or approval for our products under development could prevent us from generating sales from these products or achieving profitability. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could dissuade some surgeons from using our products and adversely affect our reputation and the perceived safety and 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 could result in the revocation of the PMA approval or 510(k) clearance for the product that is subject to such a requirement and could also result in the recall or withdrawal of the product, which would prevent us from generating sales from that product in the United States.

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

- warning letters;
- fines;
- injunctions;
- civil penalties;
- termination of distribution;
- recalls or seizures of products;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- refusal of the FDA or other regulator to grant future clearances or approvals;

- withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products; and/or
- in the most serious cases, criminal penalties.

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

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

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

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or pre-market approval of new products or modified products;
- withdrawing 510(k) clearances or pre-market approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

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

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

We currently only have FDA clearance to market the miraDry® System in the United States for the treatment of primary hyperhidrosis of the axilla, or the underarm, and for hair reduction procedures in the axilla. This clearance restricts our ability to market or advertise the miraDry® System for other specific body areas, and other conditions such as underarm odor, which could limit physician adoption and patient demand for the miraDry® System. We believe that future applications using the miraDry® System could be used to treat other body areas, such as the feet and hands, where patients experience sweat-bothered symptoms. Developing and promoting these new treatment applications for our miraDry® System is an element of our growth strategy, but we cannot predict when or if we will receive the clearances required to implement these additional products and applications. In addition, we will be required to conduct additional clinical trials or studies to support our applications, which may be time-consuming

and expensive, and may produce results that do not result in submission of, or FDA clearances for, new treatment applications. In the event that we do not obtain additional FDA clearances, our ability to promote the miraDry® System in the United States will be limited. Because we anticipate that sales in the United States will continue to be a significant portion of our business for the foreseeable future, ongoing restrictions on our ability to market the miraDry® System in the United States could harm our business and limit our revenue growth.

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

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

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

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

In the United States, our silicone gel breast implants are marketed pursuant to a PMA order issued by the FDA in March 2012, and our tissue expanders are marketed pursuant to pre-market clearance under Section 510(k) of the FDCA. Any modifications to a PMA-approved or 510(k)-cleared device that could significantly affect its safety or effectiveness, including significant design and manufacturing changes, or that would constitute a major change in its intended use, manufacture, design, components, or technology requires a new 510(k) clearance or, possibly, approval of a new PMA application or PMA supplement. For example, on March 14, 2017, we announced that we had submitted a PMA supplement to the FDA for the manufacturing of our PMA-approved breast implants by Vesta. 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 Effectuated or PMA Annual Report. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have modified some of our 510(k) cleared products, and have determined based on our review of the applicable FDA guidance that in certain instances the changes did not require new 510(k) clearances or PMA approvals. If the FDA disagrees with our determination and requires us to seek new 510(k) clearances or PMA approvals for modifications to our previously cleared or approved products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. Furthermore, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. Delays in receipt or failure to receive approvals, the loss of previously received approvals, or the failure to comply with any other existing or future regulatory requirements, could reduce our sales, profitability and future growth prospects.

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

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious injury or death. Manufacturers may also, under their own initiative, recall a product if any material deficiency in a device is found or withdraw a product to improve device performance or for other reasons. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Similar regulatory

agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert management attention and financial resources and could cause the price of our stock to decline, expose us to product liability or other claims and harm our reputation with customers. Such events could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. A recall involving our silicone gel breast implants could be particularly harmful to our business, financial and operating results. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA or similar foreign governmental authorities. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA or foreign governmental authorities. If the FDA or foreign governmental authorities disagree with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA or a foreign governmental authority could take enforcement action for failing to report the recalls when they were conducted.

In addition, under the FDA's medical device reporting regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall. We are also required to follow detailed record-keeping requirements for all firm-initiated medical device corrections and removals, and to report such corrective and removal actions to FDA if they are carried out in response to a risk to health and have not otherwise been reported under the medical device reporting regulations. Depending on the corrective action we take to 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.

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

Our educational and promotional activities and training methods must comply with FDA and other applicable laws, including the prohibition of the promotion of a medical device for a use that has not been cleared or approved by the FDA. Use of a device outside of its cleared or approved indications is known as "off-label" use. Physicians may

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

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

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

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

To the extent we sell our products internationally, market acceptance may depend, in part, upon the availability of coverage and reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government-sponsored healthcare and private insurance. We may not obtain international coverage and reimbursement approvals in a timely manner,

if at all. Our failure to receive such approvals would negatively impact market acceptance of our products in the international markets in which those approvals are sought.

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

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

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

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, if impaneled, 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.

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 January, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the PPACA. The Budget Resolution is not a law; however, it is widely viewed as the first step toward the passage of repeal legislation. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Recently, Congress and the new administration have proposed and taken various steps to revise, repeal, or delay

implementation of various aspects of PPACA. Congress also could consider subsequent legislation to replace elements of the PPACA that are repealed. We cannot predict how the PPACA, its possible repeal, or any legislation that may be proposed to replace the PPACA will impact our business.

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 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 currently do not have Health Canada's approval to market our breast implant products in Canada and we must receive our ISO certification before Health Canada will review and approve our application to market. 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 HITECH, govern the collection, dissemination, security, use and confidentiality of health information that identifies specific patients. HIPAA and HITECH require our surgeon and hospital customers to comply with certain standards for the use and disclosure of health information within their companies and with third parties. The Privacy Standards and Security Standards under HIPAA establish a set of standards for the protection of individually identifiable health information by health plans, health care clearinghouses and certain health care providers, referred to as Covered Entities, and the Business Associates with whom Covered Entities enter into service relationships pursuant to which individually identifiable health information may be exchanged. Notably, whereas HIPAA previously directly regulated only these Covered Entities, HITECH, which was signed into law as part of the stimulus package in February 2009, makes certain of HIPAA's privacy and security standards also directly applicable to Covered Entities' Business Associates. As a result, both Covered Entities and Business Associates are now subject to significant civil and criminal penalties for failure to comply with Privacy Standards and Security Standards.

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

We are not currently 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 or value-added tax (VAT) audit could have a material adverse effect on our results of operations and financial condition.\****

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

#### **Risks Related to Our Common Stock**

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

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

- a determination that our products are not in compliance with regulatory requirements, or our facilities, or those of our third-party manufacturers are not maintained in compliance with regulatory requirements;

- the timing and availability of alternative manufacturing sources to supply our silicone gel breast implants, tissue expanders and certain other products;
- a slowdown in the medical device industry, the aesthetics industry or the general economy;
- actual or anticipated quarterly or annual variations in our results of operations or those of our competitors;
- changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;
- actual or anticipated changes in our growth rate relative to our competitors;
- changes in earnings estimates or recommendations by securities analysts;
- fluctuations in the values of companies perceived by investors to be comparable to us;
- announcements by us or our competitors of new products or services, significant contracts, commercial relationships, capital commitments or acquisitions;
- competition from existing technologies and products or new technologies and products that may emerge;
- the entry into, modification or termination of agreements with our sales representatives or distributors;
- developments with respect to intellectual property rights;
- sales, or the anticipation of sales, of our common stock by us, our insiders or our other stockholders, including upon the expiration of contractual lock-up agreements;
- our ability to develop and market new and enhanced products on a timely basis;
- our ability to integrate and achieve the anticipated benefits of our acquisitions of Miramar, BIOCORNEUM® and the tissue expanders from SSP;
- 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 do not anticipate paying any cash dividends in the foreseeable future, and accordingly, stockholders must rely on stock appreciation for any return on their investment.\****

We do not anticipate declaring any cash dividends to holders of our common stock in the foreseeable future. In addition, our ability to pay cash dividends is currently prohibited by our Credit Agreements. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors and will depend on then-

existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

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

As of November 3, 2017, our executive officers, directors and principal stockholders beneficially owned approximately 41% of our outstanding voting stock. As a result, these stockholders have the ability to influence us through their ownership position and may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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

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

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

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

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

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

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

In connection with the preparation and audit of our 2016 financial statements, we identified certain deficiencies in our internal controls over financial reporting that we concluded to be a material weakness and that our internal control over financial reporting was not effective as of December 31, 2016. The material weakness resulted from the inadequate design and operation of internal controls related to the accounting for significant unusual transactions.

We are in the process of improving policies and procedures and designing more effective controls to remediate this material weakness, but our remediation efforts are not complete and are ongoing. If our remedial measures are insufficient to address the material weakness, or if additional material weaknesses or significant deficiencies in our internal control are discovered or occur in the future, it may materially adversely affect our ability to report our financial condition and results of operations in a timely and accurate manner and impact investor confidence in our Company.

Due to the above referenced material weakness in our internal control over financial reporting, we may be unable to comply with the SOX 404 internal controls requirements. Additionally, for as long as we remain an “emerging growth company” as defined in the JOBS Act, we intend to utilize the provision exempting us from the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting. The process of becoming fully compliant with Section 404 may divert internal resources and will take a significant amount of time and effort to complete, and may result in additional deficiencies and material weaknesses being identified by us or our independent registered public accounting firm. We may experience higher than anticipated operating expenses, as well as increased independent registered public accounting firm fees during the implementation of any required changes and thereafter. Completing documentation of our internal control system and financial processes, remediation of control deficiencies and management testing of internal controls will require substantial effort by us. If our internal control over financial reporting or our related disclosure controls and procedures are not effective, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that our officers, directors or the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. As of November 3, 2017, we had approximately 19,395,285 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.

Holders of an aggregate of approximately 5,413,124 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.

As of November 3, 2017, options to purchase an aggregate of 3,285,353 shares of our common stock were outstanding under our 2007 Plan, our 2014 Plan and our Inducement Plan and an additional 365,469 shares of common stock are reserved for issuance under our 2014 Plan and our Inducement Plan. 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.

As of September 30, 2017, the number of shares of common stock reserved for issuance under our 2014 plan was 2,789,442. The number of shares of our common stock reserved for issuance under the 2014 Plan automatically increases on January 1 of each year, 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, 2017, 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, 2016, or 743,947 shares.

As of September 30, 2017, the number of shares of common stock reserved for issuance under our ESPP was 770,549. The number of shares of our common stock reserved for issuance under the ESPP automatically 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, 2017, 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, 2016, or 185,986 shares.

Pursuant to the Inducement Plan that our board of directors approved in March 2016, our compensation committee of the board of directors is authorized to grant stock options or restricted stock units which may be exercised or settled, as applicable, to new employees as inducements material to such new employees entering into employment with us in accordance with NASDAQ Marketplace Rule 5635(c)(4). Since the inception of the Inducement Plan, options to purchase 330,000 shares had been awarded by the compensation committee and the number of shares available for future grant was 34,000 shares. The number of shares that may be granted under the Inducement Plan may be increased in the future by our board of directors.

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

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

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;

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

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

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

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

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

### **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***

None.

## **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

## **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

None.

## ITEM 6. EXHIBITS

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

<u>Number</u>	<u>Description</u>
10.1	<a href="#"><u>Credit and Security Agreement (Revolving Loan) by and between the Registrant and the other borrowers thereto and Midcap Financial Trust and the additional lenders thereto, dated July 25, 2017 (incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 9, 2017).</u></a>
10.2	<a href="#"><u>Credit and Security Agreement (Term Loan) by and between the Registrant and the other borrowers thereto and Midcap Financial Trust and the additional lenders thereto, dated July 25, 2017 (incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 9, 2017).</u></a>
10.3#	<a href="#"><u>Amended and Restated Consulting Agreement by and between Registrant and Keith J. Sullivan, dated August 4, 2017 (incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 9, 2017).</u></a>
10.4	<a href="#"><u>Assignment and License Agreement, dated December 31, 2008, by and between Miramar Labs, Inc. and The Foundry, Inc. (incorporated by reference to Miramar Laboratories, Inc.'s Registration Statement on Form S-1 filed with the Securities and Exchange Commission on October 14, 2016).</u></a>
10.5	<a href="#"><u>Assignment and License Clarification Letter, dated June 10, 2010, by and between Miramar Labs, Inc. and The Foundry, LLC (incorporated by reference to Miramar Laboratories, Inc.'s Registration Statement on Form S-1 filed with the Securities and Exchange Commission on October 14, 2016).</u></a>
10.6	<a href="#"><u>Asset Purchase Agreement, dated January 18, 2008, by and between Miramar Labs, Inc. and Jan Wallace (incorporated by reference to Miramar Laboratories, Inc.'s Registration Statement on Form S-1 filed with the Securities and Exchange Commission on October 14, 2016).</u></a>
10.7	<a href="#"><u>Lease Agreement, dated December 16, 2013, by and between Miramar Labs, Inc. and DWF III Walsh Bowers, LLC (incorporated by reference to Miramar Laboratories, Inc.'s Registration Statement on Form S-1 filed with the Securities and Exchange Commission on October 14, 2016).</u></a>
10.8 †	<a href="#"><u>Supply Agreement dated, November 13, 2014, by and between Miramar Labs, Inc. and Broadband Wireless, LLC (incorporated by reference to Miramar Laboratories, Inc.'s Registration Statement on Form S-1 filed with the Securities and Exchange Commission on October 14, 2016).</u></a>
10.9 †	<a href="#"><u>Contract Manufacturing Service Agreement dated, November 6, 2012, by and between Miramar Labs, Inc. and Healthcare Technology International Limited (incorporated by reference to Miramar Laboratories, Inc.'s Registration Statement on Form S-1 filed with the Securities and Exchange Commission on October 14, 2016).</u></a>
31.1	<a href="#"><u>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.</u></a>
31.2	<a href="#"><u>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.</u></a>
32.1	<a href="#"><u>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.</u></a>
32.2	<a href="#"><u>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.</u></a>

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<b>Number</b>	<b>Description</b>
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.

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

† Confidential treatment granted. Portions of this exhibit (indicated by asterisks) have been omitted and this exhibit has been filed separately with the SEC.

## SIGNATURES

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

SIENTRA, INC.

November 7, 2017

By: /s/ Jeffrey Nugent  
Jeffrey Nugent  
Chief Executive Officer

November 7, 2017

By: /s/ Patrick F. Williams  
Patrick F. Williams  
Chief Financial Officer and Treasurer

## CERTIFICATION OF CHIEF EXECUTIVE OFFICER

## PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jeffrey Nugent, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Sientra, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13(a)-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2017

/s/ Jeffrey Nugent

Jeffrey Nugent

*Chief Executive Officer*

## CERTIFICATION OF CHIEF FINANCIAL OFFICER

## PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Patrick F. Williams, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Sientra, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13(a)-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2017

/s/ Patrick F. Williams

Patrick F. Williams

*Chief Financial Officer*

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**

**PURSUANT TO 18 U.S.C. SECTION 1350,**

**AS ADOPTED PURSUANT TO**

**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Jeffrey Nugent, Chief Executive Officer of Sientra, Inc. (the "Company"), hereby certifies that to the best of his knowledge:

- (1) The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2017, to which this Certification is attached as Exhibit 32.1 (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 2017

/s/ JEFFREY NUGENT

Jeffrey Nugent

*Chief Executive Officer*

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Sientra, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

**CERTIFICATION OF CHIEF FINANCIAL OFFICER**

**PURSUANT TO 18 U.S.C. SECTION 1350,**

**AS ADOPTED PURSUANT TO**

**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Patrick F. Williams, Chief Financial Officer of Sientra, Inc. (the "Company"), hereby certifies that to the best of his knowledge:

- (1) The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2017, to which this Certification is attached as Exhibit 32.2 (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 2017

/s/ PATRICK F. WILLIAMS

Patrick F. Williams

*Chief Financial Officer*

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Sientra, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.