

Sientra, Inc.
Form 10-Q
August 07, 2018

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2018

OR

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

For the transition period from _____ to _____

Commission file number: 001-36709

SIENTRA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware 20-5551000

(State or Other Jurisdiction of (I.R.S. Employer
Incorporation or Organization) Identification No.)

420 South Fairview Avenue, Suite 200 93117

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Santa Barbara, California

(Zip Code)

(Address of Principal Executive Offices)

(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

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a 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 August 2, 2018, the number of outstanding shares of the registrant's common stock, par value \$0.01 per share, was 28,427,655.

SIENTRA, INC.

FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2018

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“Sientra”, “Sientra Platinum20”, “Sientra Full Circle”, “OPUS”, “Allox”, “Allox2”, “BIOCORNEUM”, “Dermaspan”, “Softsp”, “Silishield”, “miraDry”, “Miramar Labs”, “miraDry and Design”, “miraDry Fresh”, “bioTip”, “The Sweat Stops Here”, “Drop”, “miraWave”, “miraSmooth”, “miraFresh”, and “ML Stylized mark” are trademarks of our company. Our logo and our other trade names, trademarks and service marks appearing in this document are our property. Other trade names, trademarks and service marks appearing in this document are the property of their respective owners. Solely for convenience, our trademarks and trade names referred to in the document, appear without the TM or the (R) symbol, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the rights of the applicable licensor to these trademarks and trade names.

PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

SIENTRA, INC.

Condensed Consolidated Balance Sheets

(In thousands, except per share and share amounts)

(Unaudited)

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 112,619	\$ 26,588
Accounts receivable, net of allowances of \$1,393 and \$4,816 at June 30, 2018 and December 31, 2017, respectively	16,330	6,569
Inventories, net	22,487	20,896
Prepaid expenses and other current assets	6,516	1,512
Total current assets	157,952	55,565
Property and equipment, net	2,247	4,763
Goodwill	12,507	12,507
Other intangible assets, net	17,646	18,803
Other assets	708	575
Total assets	\$ 191,060	\$ 92,213
Liabilities and Stockholders' Equity		
Current liabilities:		
Current portion of long-term debt	\$ 6,663	\$ 24,639
Accounts payable	11,637	5,811
Accrued and other current liabilities	22,337	13,474
Legal settlement payable	—	1,000
Customer deposits	6,025	5,423
Sales return liability	4,882	—
Total current liabilities	51,544	50,347
Long-term debt	28,032	—
Deferred and contingent consideration	6,070	12,597
Warranty reserve and other long-term liabilities	2,500	1,646
Total liabilities	88,146	64,590
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, \$0.01 par value – Authorized 10,000,000 shares; none issued or outstanding	—	—
Common stock, \$0.01 par value — Authorized 200,000,000 shares; issued 28,390,271 and 19,474,702 and outstanding 28,317,544 and 19,401,975 shares at June 30, 2018 and	284	194

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December 31, 2017 respectively		
Additional paid-in capital	419,811	307,159
Treasury stock, at cost (72,727 shares at June 30, 2018 and December 31, 2017)	(260)	(260)
Accumulated deficit	(316,921)	(279,470)
Total stockholders' equity	102,914	27,623
Total liabilities and stockholders' equity	\$ 191,060	\$ 92,213

See accompanying notes to condensed consolidated financial statements.

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SIENTRA, INC.

Condensed Consolidated Statements of Operations

(In thousands, except per share and share amounts)

(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2018	2017	2018	2017
Net sales	\$ 17,554	\$ 8,169	\$ 32,229	\$ 15,658
Cost of goods sold	6,660	2,621	12,756	4,942
Gross profit	10,894	5,548	19,473	10,716
Operating expenses:				
Sales and marketing	15,477	6,163	30,733	13,119
Research and development	2,301	1,573	5,052	4,766
General and administrative	10,014	8,022	19,514	14,458
Legal settlement	—	10,000	—	10,000
Total operating expenses	27,792	25,758	55,299	42,343
Loss from operations	(16,898)	(20,210)	(35,826)	(31,627)
Other income (expense), net:				
Interest income	40	37	80	59
Interest expense	(867)	(185)	(1,521)	(194)
Other income (expense), net	(303)	(4)	(184)	4
Total other income (expense), net	(1,130)	(152)	(1,625)	(131)
Loss before income taxes	(18,028)	(20,362)	(37,451)	(31,758)
Income tax expense	—	29	—	54
Net loss	\$ (18,028)	\$ (20,391)	\$ (37,451)	\$ (31,812)
Basic and diluted net loss per share attributable to				
common stockholders	\$ (0.73)	\$ (1.07)	\$ (1.69)	\$ (1.68)
Weighted average outstanding common shares used				
for net loss per share attributable to common				
stockholders:				
Basic and diluted	24,761,117	19,132,052	22,202,565	18,953,500

See accompanying notes to condensed consolidated financial statements.

SIENTRA, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$(37,451)	\$(31,812)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,700	1,159
Provision for doubtful accounts	489	27
Provision for warranties	572	119
Provision for inventory	709	(50)
Amortization of acquired inventory step-up	106	417
Change in fair value of warrants	164	83
Change in fair value of deferred consideration	18	(14)
Change in fair value of contingent consideration	1,708	463
Change in deferred revenue	(161)	—
Amortization of debt discount and issuance costs	85	144
Stock-based compensation expense	5,686	3,182
Loss on disposal of property and equipment	—	12
Deferred income taxes	—	54
Changes in assets and liabilities, net of effects from acquisitions:		
Accounts receivable	(6,343)	47
Inventories	(2,405)	1,716
Prepaid expenses, other current assets and other assets	(2,518)	(2,395)
Insurance recovery receivable	33	9,277
Accounts payable	4,230	(1,264)
Accrued and other liabilities	1,643	4,648
Legal settlement payable	(1,000)	(900)
Customer deposits	602	(697)
Sales return liability	976	—
Net cash used in operating activities	(31,157)	(15,784)
Cash flows from investing activities:		
Purchase of property and equipment	(160)	(1,580)
Net cash used in investing activities	(160)	(1,580)
Cash flows from financing activities:		
Proceeds from exercise of stock options	410	1,096
Proceeds from issuance of common stock under ESPP	391	324
Tax payments related to shares withheld for vested restricted stock units (RSUs)	(1,297)	(569)
Net proceeds from issuance of common stock	107,850	—
Gross borrowings under the Term Loan	10,000	—

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Gross borrowings under the Revolving Loan	12,109	5,000
Repayment of the Revolving Loan	(12,109)	—
Deferred financing costs	(6)	(204)
Net cash provided by financing activities	117,348	5,647
Net increase (decrease) in cash and cash equivalents	86,031	(11,717)
Cash and cash equivalents at:		
Beginning of period	26,588	67,212
End of period	\$112,619	\$55,495
Supplemental disclosure of cash flow information:		
Interest paid	\$1,347	\$50
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment in accounts payable and accrued liabilities	\$1,741	\$461
Deferred follow-on offering costs in accounts payable and accrued liabilities	299	—

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. (“Sientra”, the “Company,” “we,” “our” or “us”), 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 pre-market approval, or PMA, assets. Following this acquisition, the Company focused on completing the clinical trials to gain FDA approval to offer its silicone gel breast implants in the United States.

In March 2012, the Company 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 miraDry

On June 11, 2017, Sientra entered into an Agreement and Plan of Merger, or the Merger Agreement, with miraDry, (formerly Miramar Labs), pursuant to which Sientra commenced a tender offer to purchase all of the outstanding shares of miraDry’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 Review of Vesta Manufacturing

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 site-change pre-market approval, or PMA supplement, to the FDA for the manufacture of the Company’s PMA-approved breast implants at the Vesta manufacturing facility. On January 30, 2018, the Company announced the FDA has granted approval of the site-change pre-market approval, or PMA, supplement for the Company’s contract manufacturer, Vesta, to manufacture its silicone gel breast implants. In support of the move to the Vesta manufacturing facility, the Company also implemented new manufacturing process improvements which, in consultation with the FDA, required three (3) additional PMA submissions. In addition to approving the manufacturing site-change supplement, the FDA has approved our three (3) process enhancement submissions on January 10, 2018, January 19, 2018 and April 17, 2018.

d. Follow-On Offering

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

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 consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 13, 2018 and Form 10-K/A filed on April 30, 2018, or the Annual Report. The results for the three and six months ended June 30, 2018 are not necessarily indicative of results to be expected for the year ending December 31, 2018, any other interim periods, or any future year or period.

b. Liquidity

Since the Company's inception, it has incurred significant net operating losses and the Company anticipates that losses will continue in the near term. The Company expects its operating expenses will continue to grow as they expand operations. The Company will need to generate significant net sales to achieve profitability. To date, the Company has funded operations primarily with proceeds from the sales of preferred stock, borrowings under term loans, sales of products since 2012, and the proceeds from the sale of common stock in public offerings.

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. As of June 30, 2018, the Company had cash and cash equivalents of \$112.6 million. Since inception, the Company has incurred recurring losses from operations and cash outflows from operating activities. The continuation of the Company as a going concern is dependent upon many factors including liquidity and the ability to raise capital. The Company received FDA approval of their PMA supplement on April 17, 2018 and was then able to access a \$10.0 million term loan pursuant to an amendment to the credit agreement with MidCap Financial Trust, or MidCap. In addition, in February 2018, the Company entered into an At-The-Market Equity Offering Sales Agreement with Stifel, Nicolaus & Company, Incorporated, or Stifel, as sales agent pursuant to which the Company may sell, from time to time, through Stifel, shares of our common stock having an aggregate gross offering price of up to \$50 million. As of June 30, 2018, we have not sold any common stock pursuant to the sales agreement. Further, on May 7, 2018, the Company completed a public offering of its common stock, raising approximately \$107.6 million in net proceeds after deducting underwriting discounts and commissions and other offering expenses.

The Company believes that its cash and cash equivalents will be sufficient to fund its operations for at least the next 12 months. To fund ongoing operating and capital needs, the Company may need to raise additional capital in the future through the sale of equity securities and incremental debt financing.

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

Revenue Recognition

The Company recognizes revenue when the Company transfers control of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled to in exchange for those goods or services. See Note 3 - Revenue for further discussion.

There have been no other changes to the accounting policies during the three and six months ended June 30, 2018, 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 May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606). Topic 606 supersedes the revenue recognition requirements in Topic 605 Revenue Recognition (Topic 605) and requires entities to recognize revenue when control of the promised goods or services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. The Company adopted Topic 606 in the first quarter of 2018 to all contracts using the modified retrospective method. The adoption of Topic 606 did not have a material impact on the Company’s historical net losses and, therefore, no adjustment was made to the opening balance of retained earnings. The comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods.

In accordance with Topic 606 disclosure requirements, the impact of adoption on our condensed consolidated balance sheet was as follows (in thousands):

	As Reported December 31, 2017	Total Adjustment	Adjusted January 1, 2018
Balance Sheet			
Assets			
Accounts receivable, net of allowances	\$ 6,569	3,906	10,475
Liabilities			
Sales return liability	\$ —	3,906	3,906

	As Reported June 30, 2018	Total Adjustment	Amounts Under Previous Standards
Balance Sheet			
Assets			
Accounts receivable, net of allowances	\$ 16,330	(4,882)	11,448
Liabilities			
Sales return liability	\$ 4,882	(4,882)	—

Additionally, in accordance with Topic 606, the balance of breast product inventory estimated to be returned as of June 30, 2018 is included in the components of the Company's inventory as "finished goods – right of return" in Note 9b - Inventories. Prior to the adoption of Topic 606, the inventory impact of estimated returns for breast products was included in the "finished goods" inventory balance and was not separately disclosed.

The adoption of Topic 606 did not have a material impact on our condensed consolidated statement of operations.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows – Classifications of Certain Cash Receipts and Cash Payments (Topic 230). The standard update addresses eight specific cash flow issues not currently addressed by GAAP, with the objective of reducing the existing diversity in practice of how these cash receipts and payments are presented and classified in the statement of cash flows. The ASU requires a retrospective approach to adoption. The Company adopted the ASU in the first quarter of 2018. The adoption of this ASU did not have a material impact on the Company's condensed consolidated financial statements.

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 Company adopted the ASU in the first quarter of 2018 on prospective basis. The adoption of this ASU did not have a material impact on the Company's condensed consolidated financial statements.

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 Accounting Standard Codification, or ASC, 718. The Company adopted the ASU in the first quarter of 2018 on a prospective basis. The adoption of this ASU did not have a material impact on the Company's condensed consolidated financial statements.

Recently Issued Accounting Standards

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) which supersedes FASB Accounting Standard Codification Leases (Topic 840). The standard is intended to increase the transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. This accounting standard update will be effective for the Company beginning in fiscal year 2019. The Company is currently evaluating the impact that adoption of the standard will have on the financial statements and related disclosures.

In February 2018, the FASB issued ASU 2018-02, Income Taxes (Topic 740), which allows for an entity to elect to reclassify the income tax effects on items within accumulated other comprehensive income resulting from U.S. Tax Cuts and Jobs Act to retained earnings. The guidance is effective for fiscal years beginning after December 15, 2018 with early adoption permitted, including interim periods within those years. The Company does not expect to elect to reclassify the income tax effects under ASU 2018-05, as it does not have a material impact on the condensed consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, Compensation - Stock Compensation (Topic 718), to simplify the accounting for non-employee share-based payment transactions by expanding the scope of ASC Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. Under the new standard, most of the guidance on stock compensation payments to non-employees would be aligned with the requirements for share-based payments granted to employees. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those years, with early adoption permitted. The Company is currently evaluating the impact that adoption of the standard will have on the financial statements and related disclosures.

f.Reclassifications

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

3.Revenue

Revenue Recognition

The Company generates revenue primarily through the sale and delivery of promised goods or services to customers and recognizes revenue when control is transferred to customers, in an amount that reflects the consideration the

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Company expects to be entitled to in exchange for the goods or services. Sales prices are documented in the executed sales contract or purchase order prior to the transfer of control to the customer. Customers may enter into a separate extended service agreement to purchase an extended warranty for miraDry products from the Company whereby the payment is due at the inception of the agreement. Revenue for extended service agreements are recognized ratably over the term of the agreements.

The Company also leverages a distributor network for selling the miraDry System internationally. The Company recognizes revenue when control of the goods or services is transferred to the distributors. Standard terms in these agreements do not allow for trial periods, right of return, refunds, payment contingent on obtaining financing or other terms that could impact the customer's payment obligation.

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

For Breast Products, with the exception of the Company's BIOCORNEUM scar management products, the Company allows for the return of products from customers within six months after the original sale, which is accounted for as variable consideration. Appropriate reserves are established for anticipated sales returns based on the expected amount calculated with historical experience, recent gross sales and any notification of pending returns. The estimated sales return is recorded as a reduction of revenue and as a refund liability in the same period revenue is recognized. Actual sales returns in any future period are inherently uncertain and thus may differ from the estimates. If actual sales returns differ significantly from the estimates, an adjustment to revenue in the current or subsequent period would be recorded. The Company has established an allowance for sales returns of \$4.9 million and \$3.9 million as of June 30, 2018 and December 31, 2017, respectively, recorded as "sales return liability" on the condensed consolidated balance sheet under Topic 606 as of June 30, 2018 and recorded in "accounts receivable, net of allowances," at December 31, 2017 on the condensed consolidated balance sheet, as indicated above in "Recently Adopted Accounting Standards."

Sales tax, value-added tax, and other taxes the Company may collect concurrent with revenue-producing activities are excluded from the measurement of the transaction price and thus from revenue.

Arrangements with Multiple Performance Obligations

The Company has determined that the delivery of each unit of product in the Company's revenue contracts with customers is a separate performance obligation. The Company's revenue contracts may include multiple products, each of which is considered a separate performance obligation. For such arrangements, the Company allocates revenue to each performance obligation based on its relative standalone selling price. The Company generally determines standalone selling prices based on observable prices or using an expected cost plus margin approach when an observable price is not available. The Company invoices customers once products are shipped or delivered to customers depending on the negotiated shipping terms.

Practical Expedients and Policy Election

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

The Company does not adjust accounts receivable for the effects of any significant financing components as customer payment terms are generally shorter than one year.

The Company has elected to account for shipping and handling activities performed after a customer obtains control of the products as activities to fulfill the promise to transfer the products to the customer. Shipping and handling activities are largely provided to customers free of charge for the Breast Products segment. The associated costs were \$0.6 million and \$0.5 million for the six months ended June 30, 2018 and 2017. The associated costs were \$0.3 million and \$0.2 million for the three months ended June 30, 2018 and 2017. These costs are viewed as part of the

Company's marketing programs and are recorded as a component of sales and marketing expense in the condensed consolidated statement of operations as an accounting policy election. For the miraDry segment, shipping and handling charges are typically billed to customers and recorded as revenue. The shipping and handling costs incurred are recorded as a component of cost of goods sold in the condensed consolidated statement of operations. The associated costs were \$0.1 million and \$0.2 million for the three and six months ended June 30, 2018, respectively.

4. Acquisitions

a. Acquisition of miraDry

On June 11, 2017, Sientra entered into the Merger Agreement with miraDry, pursuant to which Sientra commenced a tender offer to purchase all of the outstanding shares of miraDry'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 indicated to reduce underarm sweat, odor and hair of all colors, to Sientra's aesthetics portfolio. The Company did not record any professional fees related to the acquisition for the three and six months ended June 30, 2018. The Company recorded \$0.4 million in professional fees related to the acquisition for the three and six months ended June 30, 2017. The aggregate acquisition date fair value of the consideration transferred was approximately \$29.6 million, consisting of the following (in thousands):

	Fair Value
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	\$29,572

The Company funded the cash consideration, including the debt payoff amount with cash on hand. The cash consideration included the payoff of miraDry'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 miraDry, 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 miraDry 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 6. 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 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	\$29,572

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 methods 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
	\$14,800		

The Company retained an independent third-party appraiser to assist management in its valuation and the purchase price has been finalized.

Unaudited Pro Forma Information

The following unaudited pro forma financial information presents combined results of operations for each of the periods presented, as if miraDry had been acquired as of the beginning of fiscal year 2017. 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 condensed consolidated results of operations of the combined business had the merger actually occurred at the beginning of fiscal year 2017 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, except per share amounts):

	Three Months Ended June 30, 2017 Pro Forma	Six Months Ended June 30, 2017 Pro Forma
Net sales	\$ 13,709	\$ 25,012
Net loss	(23,935)	(44,566)
Pro forma loss per share attributable to ordinary shares - basic and diluted	\$ (1.25)	\$ (2.35)

5. Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, customer deposits and sales return liability are reasonable estimates of their fair value because of the short maturity of these items. The fair value of the common stock warrant liability and contingent consideration are discussed in Note 6. The fair value of the debt is based on the amount of future cash flows associated with the instrument discounted using the Company's estimated market rate. As of June 30, 2018, the carrying value of the long-term debt was not materially different from the fair value.

6. 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 contingent consideration for future royalty payments related to the acquisition of BIOCORNEUM, the contingent consideration for future milestone payments for the acquisition of the tissue expander portfolio and the contingent consideration for the future milestone payments related to the acquisition of miraDry using a 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 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 June 30, 2018 and December 31, 2017 and indicate the level of the fair value hierarchy utilized to determine such fair value (in thousands):

	Fair Value Measurements as of June 30, 2018 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Liability for common stock warrants	\$ —	—	358	358
Liability for contingent consideration	—	—	14,027	14,027
	\$ —	—	14,385	14,385

	Fair Value Measurements as of December 31, 2017 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Liability for common stock warrants	\$ —	—	194	194
Liability for contingent consideration	—	—	12,319	12,319
	\$ —	—	12,513	12,513

The liability for common stock warrants and the current portion of contingent consideration is included in “accrued and other current liabilities” and the long-term liabilities for the contingent consideration are included in “deferred and contingent consideration” in the condensed consolidated balance sheet. The following table provides a rollforward of the aggregate fair values of the Company's common stock warrants and contingent consideration for which fair value is determined by Level 3 inputs (in thousands):

Warrant Liability	
Balance, December 31, 2017	\$ 194
Change in fair value of warrant liability	164

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Balance, June 30, 2018	\$ 358
Contingent Consideration Liability	
Balance, December 31, 2017	\$ 12,319
Change in fair value of contingent consideration	1,708
Balance, June 30, 2018	\$ 14,027

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 contingent consideration are recognized in “general and administrative” expense in the condensed consolidated statement of operations.

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7. Product Warranties

The Company offers a product replacement and limited warranty program for the Company's silicone gel breast implants, and a product warranty for the Company's miraDry Systems and consumable bioTips. For implant surgeries taking place after May 1, 2018, the breast implant product replacement and limited warranty program provides lifetime no-charge replacement implants for covered rupture events, and no-charge replacement breast implants for other covered events that occur within twenty years of the implant surgery. For certain covered events, the Company will also reimburse patients for certain out-of-pocket expenses incurred by patients within twenty years of the implant surgery, up to a maximum amount of \$5,000. For implants occurring prior to May 1, 2018, 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 provides a standard product warranty for the miraDry system and 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):

	Six Months Ended June 30,	
	2018	2017
Beginning balance as of January 1	\$ 1,642	\$ 1,378
Warranty costs incurred during the period	(231)	—
Changes in accrual related to warranties issued during the period	568	110
Changes in accrual related to pre-existing warranties	4	9
Balance as of June 30	\$ 1,983	\$ 1,497

8. Net Loss Per Share

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net loss (in thousands)	\$ (18,028)	\$ (20,391)	\$ (37,451)	\$ (31,812)
Weighted average common shares outstanding, basic				
and diluted	24,761,117	19,132,052	22,202,565	18,953,500
Net loss per share attributable to common stockholders	\$ (0.73)	\$ (1.07)	\$ (1.69)	\$ (1.68)

The Company excluded the following potentially dilutive securities, outstanding as of June 30, 2018 and 2017, from the computation of diluted net loss per share attributable to common stockholders for the three and six months ended June 30, 2018 and 2017 because they had an anti-dilutive impact due to the net loss attributable to common stockholders incurred for the periods.

	June 30,	
	2018	2017
Stock options to purchase common stock	2,011,503	1,663,890
Warrants for the purchase of common stock	47,710	47,710
	2,059,213	1,711,600

9. Balance Sheet Components

a. Allowance for Doubtful Accounts

The Company has established an allowance for doubtful accounts of \$1.4 million and \$0.9 million as of June 30, 2018 and December 31, 2017, respectively, recorded net against accounts receivable in the balance sheet.

b. Inventories

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

	June 30, 2018	December 31, 2017
Raw materials	\$1,807	\$ 1,642
Work in progress	2,015	3,956
Finished goods	17,456	15,298
Finished goods - right of return	1,209	—
	\$22,487	\$ 20,896

c. Prepaid Expenses and Other Current Assets

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

	June 30, 2018	December 31, 2017
Prepaid expenses	\$ 2,245	\$ 1,040
Assets held for sale	2,674	—
Other current assets	1,597	472
Total	\$ 6,516	\$ 1,512

Under the terms of the manufacturing agreement with Vesta, upon the commencement of Contract Year One (as defined in the agreement) which occurred following FDA-approval of all submissions related to the site-change PMA supplement for the Vesta manufacturing facility Vesta is obligated to purchase the manufacturing equipment and tooling that Sientra had originally purchased for the manufacture of Sientra's breast implant inventory at Vesta's manufacturing facility. The Company expects Vesta to purchase the equipment in the third quarter of 2018. The net book value of \$2.7 million is in "assets held for sale" in "prepaid expenses and other current assets" at June 30, 2018 and "property and equipment, net" at December 31, 2017 for the Breast Products segment.

d. Property and Equipment

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

	June 30, 2018	December 31, 2017
Leasehold improvements	\$402	\$ 402
Manufacturing equipment and toolings	1,586	4,260
Computer equipment	411	387
Software	901	797
Office equipment	156	142
Furniture and fixtures	816	816
	4,272	6,804
Less accumulated depreciation	(2,025)	(2,041)
	\$2,247	\$ 4,763

Depreciation expense for the three months ended June 30, 2018 and 2017 was \$0.3 million and \$0.2 million, respectively. Depreciation expense for the six months ended June 30, 2018 and 2017 was \$0.6 million and \$0.3 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 six months ended June 30, 2018 were as follows (in thousands):

	Breast Products	miraDry	Total
Balances as of December 31, 2017			
Goodwill	\$ 19,156	\$ 7,629	\$ 26,785
Accumulated impairment losses	(14,278)	—	(14,278)
Goodwill, net	\$ 4,878	\$ 7,629	\$ 12,507
Balances as of June 30, 2018			
Goodwill	\$ 19,156	\$ 7,629	\$ 26,785
Accumulated impairment losses	(14,278)	—	(14,278)
Goodwill, net	\$ 4,878	\$ 7,629	\$ 12,507

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

	Average Amortization Period (in years)	June 30, 2018 Gross Carrying Amount	Accumulated Amortization	Intangible Assets, net
Intangibles with definite lives				
Customer relationships	11	\$ 11,240	\$ (2,672)	\$ 8,568
Trade names - finite life	14	5,800	(378)	5,422

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Developed technology	15	3,000	(217)	2,783
Distributor relationships	9	500	(85)	415
Non-compete agreement	2	80	(72)	8
Regulatory approvals	1	670	(670)	—
Acquired FDA non-gel product approval	11	1,713	(1,713)	—
Total definite-lived intangible assets		\$23,003	\$ (5,807)	\$ 17,196
Intangibles with indefinite lives					
Trade names - indefinite life	—	450	—		450
Total indefinite-lived intangible assets		\$450	\$ —		\$ 450

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	Average Amortization Period (in years)	December 31, 2017 Gross Carrying Amount	Accumulated Amortization	Intangible Assets, net
Intangibles with definite lives				
Customer relationships	11	\$ 11,240	\$ (1,859)	\$ 9,381
Trade names - finite life	14	5,800	(216)	5,584
Developed technology	15	3,000	(95)	2,905
Distributor relationships	9	500	(40)	460
Non-compete agreement	2	80	(57)	23
Regulatory approvals	1	670	(670)	—
Acquired FDA non-gel product approval	11	1,713	(1,713)	—
Total definite-lived intangible assets		\$23,003	\$ (4,650)	\$ 18,353
Intangibles with indefinite lives				
Trade names - indefinite life	—	450	—	450
Total indefinite-lived intangible assets		\$450	\$ —	\$ 450

Amortization expense for the three months ended June 30, 2018 and 2017 was \$0.6 million and \$0.4 million, respectively. Amortization expense for the six months ended June 30, 2018 and 2017 was \$1.2 million and \$0.9 million, respectively. The following table summarizes the estimated amortization expense relating to the Company's definite-lived intangible assets as of June 30, 2018 (in thousands):

Period	Amortization Expense
Remainder of 2018	\$ 1,151
2019	2,321
2020	2,209
2021	1,996
2022	1,762
Thereafter	7,757
	\$ 17,196

f. Accrued and Other Current Liabilities

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

	June 30, 2018	December 31, 2017
Payroll and related expenses	\$4,156	\$ 3,579
Accrued commissions	3,179	3,297

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Accrued equipment	35	1,091
Deferred and contingent consideration, current portion	9,230	977
Audit, consulting and legal fees	406	920
Accrued sales and marketing expenses	569	794
Other	4,762	2,816
	\$22,337	\$ 13,474

10. 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.

Under the terms of the Term Loan Credit Agreement, as of July 25, 2017, MidCap funded \$25.0 million to the Company, or 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. On April 18, 2018, the Company amended the Term Loan Credit Agreement pursuant to which the parties agreed to adjust the date by which the Company must obtain FDA approval of its PMA supplement in order to access the March 2018 Term Loan until April 30, 2018. In April 2018, upon FDA approval of the Company's PMA supplement, MidCap funded the \$10.0 million March Term Loan. 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 a portion of the \$25.0 million of proceeds from the Closing Date Term Loan 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 remainder of 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 June 30, 2018 was 1.98%, 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 June 30, 2018, there was \$35.0 million outstanding related to the Term Loans. As of June 30, 2018, the unamortized debt issuance costs on the Term Loans was approximately \$0.1 million current portion and approximately \$0.2 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 paid an origination fee of 0.50% of the Revolving Loan amount of \$10.0 million on the closing date. The Company classifies the amounts borrowed under the

Revolving Loan as short term because it is the Company's intention to use the line of credit to borrow and pay back funds over short periods of time. As of June 30, 2018, there were no borrowings outstanding under the Revolving Loan. As of June 30, 2018, the unamortized debt issuance costs related to the Revolving Loan was approximately \$0.1 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 June 30, 2018 and 2017 was \$34,000 and \$48,000, respectively. The amortization of debt issuance costs for both the six months ended June 30, 2018 and 2017 was \$0.1 million, and was 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.

Future Principal Payments of Debt

The future schedule of principal payments for the outstanding Term Loans as of June 30, 2018 was as follows (in thousands):

Fiscal Year	
2019	\$ 11,666
2020	11,667
2021	11,667
2022	—
2023	—
Thereafter	—
Total	\$ 35,000

11. Stockholders’ Equity

a. Authorized Stock

The Company’s Amended and Restated Certificate of Incorporation authorizes the Company to issue 210,000,000 shares of common and preferred stock, consisting of 200,000,000 shares of common stock with \$0.01 par value and 10,000,000 shares of preferred stock with \$0.01 par value. As of June 30, 2018 and December 31, 2017, 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 June 30, 2018, 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 June 30, 2018, a total of 244,977 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 June 30, 2018, inducement grants for 624,735 shares of common stock have been awarded, and 327,912 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:

	Option Shares	Weighted average exercise price	Weighted average remaining contractual term (year)
Balances at December 31, 2017	2,179,787	\$ 7.60	7.27
Exercised	(61,203)	6.70	
Forfeited	(69,896)	9.99	
Balances at June 30, 2018	2,048,688	\$ 7.54	6.72

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 related to stock options was \$0.4 million

and \$0.5 million for the three months ended June 30, 2018 and 2017, respectively. Stock-based compensation expense related to stock options was \$0.8 million and \$1.2 million for the six months ended June 30, 2018 and 2017, respectively. As of June 30, 2018, there was \$1.8 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 1.59 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 to employees 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. RSUs issued to non-employees generally vest either monthly or annually over the service term.

Activity related to RSUs is set forth below:

	Number of shares	Weighted average grant date fair value
Balances at December 31, 2017	928,552	\$ 9.12
Granted	1,327,746	11.89
Vested	(366,116)	8.86
Forfeited	(106,330)	10.90
Balances at June 30, 2018	1,783,852	\$ 11.13

Stock-based compensation expense for RSUs for the three months ended June 30, 2018 and 2017 was \$2.6 million and \$1.2 million, respectively. Stock-based compensation expense for RSUs for the six months ended June 30, 2018 and 2017 was \$4.6 million and \$1.8 million respectively. As of June 30, 2018, there was \$16.4 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 2.20 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 purchase date. A total of 255,500 shares of common stock were initially reserved for issuance under the ESPP, subject to certain annual increases.

During the six months ended June 30, 2018, employees purchased 62,491 shares of common stock at a weighted average price of \$6.26 per share. As of June 30, 2018, the number of shares of common stock available for future issuance was 627,080.

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 June 30, 2018 and 2017. Stock-based compensation expense related to the ESPP was \$0.3 million and \$0.2 million for the six months ended June 30, 2018 and 2017, respectively.

12. 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. Tax expense was \$0 and \$29,000 for the three months ended June 30, 2018 and 2017, respectively. Tax expense was \$0 and \$54,000 for the six months ended June 30, 2018 and 2017, respectively.

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13. Segment Information

Reportable Segments

The Company has two reportable segments: Breast Products and miraDry. The Breast Products 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 miraDry. See Note 4 – Acquisitions for additional details. miraDry has been included in the condensed 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, net operating loss and net assets by reportable segment for the periods presented (in thousands):

	Three Months Ended June 30, 2018		Six Months Ended June 30, 2017	
Net sales				
Breast Products	\$9,412	\$8,169	\$17,954	\$15,658
miraDry	8,142	—	14,275	—
Total net sales	\$17,554	\$8,169	\$32,229	\$15,658

	Three Months Ended June 30, 2018		Six Months Ended June 30, 2017	

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Loss from operations				
Breast Products	\$12,444	\$20,210	\$25,238	\$31,627
miraDry	4,454	—	10,588	—
Total loss from operations	\$16,898	\$20,210	\$35,826	\$31,627

	June 30, 2018	December 31, 2017
Assets		
Breast Products	\$157,404	\$59,365
miraDry	33,656	32,848
Total assets	\$191,060	\$92,213

14. 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 \$0.3 million and \$0.1 million for the three months ended June 30, 2018 and 2017, respectively. Rent expense was \$0.6 million and \$0.3 million for the six months ended June 30, 2018 and 2017, 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 "prepaid expenses and other current assets" on the accompanying condensed consolidated balance sheets.

miraDry Class Action Litigation

On August 3, 2017, a lawsuit styled as a verified class action on the part of the former stockholders of miraDry was filed in the Court of Chancery for the State of Delaware against the former board of directors of miraDry, or the Defendants, alleging breach of their fiduciary duties in connection with the Company's acquisition of miraDry. On August 30, 2017, the Defendants moved to dismiss the verified class action complaint for failure to state a claim upon which relief can be granted. On November 11, 2017 the parties notified the Court that they had reached an agreement to settle the matter pending completion of confirmatory discovery regarding the fairness of the settlement and obtaining approval from the court. Under the terms of the proposed settlement, in exchange for a full and final settlement and release of all claims, the Defendants (and/or their indemnitors and/or insurers) agreed to pay a settlement consideration of \$0.4 million. The miraDry Merger Agreement contained a holdback amount expected to

be used for the settlement and associated costs of the miraDry Class Action litigation and is included in the Company's "deferred and contingent consideration, current portion" component of "accrued and other current liabilities" on the condensed consolidated balance sheet.

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 paid an additional \$1.0 million on June 29, 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, 2017 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, 2017, filed with the Securities and Exchange Commission on March 13, 2018 and 10-K/A filed on April 30, 2018, 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," "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 miraDry (formerly Miramar Labs) pursuant to which we commenced a tender offer to purchase all of the outstanding shares of miraDry's common stock. Pursuant to the transaction, which closed on July 25, 2017 we added the miraDry System, the only FDA cleared device to reduce underarm sweat, odor and hair of all colors to our aesthetics portfolio. Following our acquisition of miraDry in July 2017, we began selling the miraDry System and bioTips. As a result of the miraDry acquisition, we determined that we will conduct our business in two operating segments: Breast Products and miraDry. The Breast Products segment focuses on sales of our breast implants, tissue expanders and scar management products under the brands OPUS, 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.

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

We sell both our Breast Products and miraDry products in the U.S. through a direct sales organization, which as of June 30, 2018, consisted of 94 employees, including 77 sales representatives and 17 sales managers. Additionally, we also sell our miraDry System in several international markets where we leverage a combination of distributor relationships and direct sales efforts.

Our Markets

The global market for aesthetic procedures is significant. The American Society for Aesthetic Plastic Surgery, or ASAPS, estimates that U.S. consumers spent approximately \$15 billion on approximately 13 million aesthetic procedures in 2016, including both surgical and non-invasive cosmetic treatments.

Breast Products

Breast augmentation surgery remains the leading aesthetic surgical procedure by dollars and number of procedures in the United States, with over 333,000 primary breast augmentation procedures performed in the United States in 2017, according to ASAPS. Based on the number of procedures reported by ASAPS and American Society of Plastic Surgeons, or ASPS, and our estimates of average selling prices, implant mix and implants per procedure, we estimate the size of our current and potential breast markets to be approximately \$1.5 billion on a global basis, with the size of our addressable U.S. market (based on our currently available breast products, including scar management products) estimated at approximately \$700 million.

We sell our breast implants and tissue expanders exclusively to board-certified and board-admissible plastic surgeons, as determined by the American Board of Plastic Surgery, who we refer to as Plastic Surgeons. These surgeons have completed the extensive multi-year plastic surgery residency training required by the American Board of Plastic Surgery. While aesthetic procedures are performed by a wide range of medical professionals, including dermatologists, otolaryngologists, obstetricians, gynecologists, dentists and other specialists, the majority of aesthetic surgical procedures are performed by Plastic Surgeons. Plastic Surgeons are thought leaders in the medical aesthetics industry. According to the American Board of Plastic Surgery, there are approximately 6,500 board-certified plastic surgeons in the United States. In addition, our Breast Products segment is also supported by Multi Specialty Consultants, or MSCs, that sell scar management products directly to physicians, and we have recently expanded our sales channel to include a dedicated national accounts team focused on selling our tissue expanders to hospitals.

miraDry

According to the ASAPS, cosmetic procedures have increased by 35% over the past five years with nonsurgical procedures up 39%. Laser and light-based hair removal continues to be the largest volume among non-invasive and non-injectable procedures. As an emerging market, energy-based procedures for sweat and odor reduction are not currently tracked by ASAPS data. No one treatment procedure is offered by all physicians, and treatments vary in terms of the treatment goal and desired effect. As a result, the total aesthetic market as reported by ASAPS does not represent the market potential for miraDry or any other single product or treatment, but illustrates that each year patients elect to have millions of aesthetic procedures. We believe several factors are contributing to the ongoing

growth in aesthetic procedures, including:

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

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

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

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

Our Competitive Strengths

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

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

Breast Products

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

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

Innovative services that deliver an improved customer experience. Our customer service offerings are intended to accommodate and anticipate the needs of our Plastic Surgeons so they can focus on providing better services to their patients. Historically, we have provided an industry-leading ten year limited warranty that provided patients with a cash reimbursement for certain out of pocket costs related to revision surgeries in a covered event; a lifetime no charge implant replacement program for covered ruptures; and our industry first C3 Program through which we

offered no charge replacement implants to breast augmentation patients who experienced capsular contracture within the first five years after implantation with our smooth or textured breast implants. On April 25, 2018, we announced our new Sientra Platinum20 Warranty, which we believe provides an industry-leading policy of no-charge replacement implants, as well as financial assistance, for certain qualifying events occurring within twenty years of the initial procedure. We also offer specialized educational initiatives and a streamlined ordering, shipping and billing process.

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

miraDry

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

Patient satisfaction. miraDry allows most patients to achieve noticeable and measurable aesthetic results without the pain, expense, downtime, and risks associated with invasive and minimally-invasive procedures for sweat, odor and hair reduction. In addition, unlike many other non-invasive procedures, patients are not required to undergo multiple or recurring treatment procedures to obtain aesthetic results. According to RealSelf.com, a leading online community helping people make confident choices in elective cosmetic procedures, as of January 16, 2018, the miraDry procedure received a 90% "worth it" rating from patients.

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

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

Our Strategy

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

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

Selectively pursue acquisitions and expand into new markets. We may continue to selectively pursue domestic and international acquisitions of businesses or technologies that may allow us to leverage our relationships with Plastic Surgeons and our existing commercial infrastructure to provide us with new or complementary products or technologies, and allow us to compete in new geographic markets or market segments or to increase our market share. For example, we began selling BIOCORNEUM directly to physicians in the United States after we acquired the rights to do so, in addition to rights relating to certain other specified sales channels from Enaltus in March 2016. We began selling the AlloX2 and Dermaspan lines of breast tissue expanders, and the Softspan line of general tissue expanders, after we acquired these product lines from Specialty Surgical Products, or SSP, in November 2016. We began selling the miraDry System and bioTips after the acquisition of miraDry in July 2017 and, based on our commissioned survey of over 2,000 consumers, we believe the market for these products represents a growing and demographically diverse opportunity to drive sales.

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

Highly optimized, experienced and fully trained sales force. We maintain separate sales forces within our Breast Products and miraDry segments. As of June 30, 2018, our combined worldwide sales force consisted of 105 sales representatives and directors in addition to our distributor network. Our Breast Products sales force primarily consists of Plastic Surgery Consultants, or PSCs, focused on selling all breast products and tissue expanders exclusively to board certified and board admissible plastic surgeons. Additionally, our Breast Products segment is also supported by MSCs that sell scar management products directly to physicians. Our miraDry sales force is a bifurcated organization that is split between Area Sales Managers, or ASMs, who focus on system sales, and Practice Development Managers, or PDMs, who focus on high margin consumable bioTip sales, assisting practices to market miraDry to patients, undergo product training and drive system utilization. We have continued to hire high quality, experienced sales representatives and sales management personnel in all categories and train the sales organization to optimize performance in their respective roles. We believe our sales force will continue to generate increased customer adoption and patient awareness momentum in the marketplace.

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

Increase our international presence. There is strong global demand for aesthetic procedures outside of North America. We intend to increase our market penetration outside of North America and build global brand recognition. We have received regulatory approval or are otherwise free to market miraDry in numerous international markets. We intend to seek regulatory approval to market miraDry in additional international markets, as well as grow our international sales and marketing organization to focus on increasing sales and market share, as well as strengthening our customer relationships. As part of this strategy, we are and intend to continue to opportunistically deploy a direct sales force in select international markets.

Our Products

Breast Products

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

Our breast implants were approved by the FDA in 2012, based on three-year data from our recently completed, 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). According to a recent publication by the Plastic and Reconstructive Surgery Journal, our clinical trial represents the largest gel breast implant pivotal trial in the United States and examined the long-term safety and effectiveness of gel breast implants. The study included a large magnetic resonance imaging, or MRI, cohort, with 571 patients. The MRI cohort is a subset of study patients that underwent regular MRI screenings in addition to the other aspects of the clinical trial protocol prior to FDA approval. Post-approval, all patients in the long-term clinical trial were subject to serial MRI screenings as part of the clinical protocol. The clinical data we collected over a ten year follow up period demonstrated rupture rates, capsular contracture rates and reoperation rates that were comparable to, or better than, those of our competitors, at similar time points. In addition to our pivotal study, our clinical data is supported by our completed five-year Continued Access Study of 2,497 women in the United States. We have also commissioned a number of bench studies run by independent laboratories that we believe further demonstrate the advantages of our breast implants over those of our competitors.

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

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

We sell our silicone gel breast implants and tissue expanders exclusively to Plastic Surgeons. We seek to provide Plastic Surgeons with differentiated services, including enhanced customer service offerings and a twenty year limited warranty that provides patients with cash reimbursement for certain out of pocket costs related to revision surgeries in a covered event; a lifetime no charge implant replacement program for covered ruptures; and the industry's first policy of no charge replacement implants to patients who experience covered capsular contracture, double capsule and late-forming seroma events within twenty years of the initial implant procedure.

miraDry Products

In July 2017, we completed our acquisition of miraDry, following which we began selling the miraDry System, the only FDA cleared device indicated to reduce underarm sweat, odor and hair of all colors through the precise and non-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 has been cleared by the FDA as indicated for use in the treatment of primary axillary hyperhidrosis, or a condition characterized by abnormal sweating in excess of that required for regulation of body temperature, plus unwanted underarm hair removal, and permanent reduction of underarm hair of all colors for Fitzpatrick skin types I – IV. Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime. When used for the treatment of primary axillary hyperhidrosis, the miraDry System may reduce underarm odor. In addition, the miraDry System received CE mark approval for the treatment of primary axillary hyperhidrosis and approval in several other countries.

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

The miraDry System consists of a console and a handheld device which uses consumable single-use bioTips. The miraDry System has a global footprint, and we estimate that over 1,000 systems and over 125,000 bioTips have been sold to date. The miraDry procedure is not technique-dependent, does not require significant training or skill for the healthcare provider, and the user-interface guides the provider through each step of the procedure for each treatment. We sell our miraDry System and consumable single-use bioTips only to physicians, consisting of dermatologists, plastic surgeons, aesthetic specialists and physicians specializing in the treatment of hyperhidrosis. Aesthetic specialists are physicians who elect to offer aesthetic procedures as a significant part of their practices but are generally not board-certified dermatologists or plastic surgeons. Physicians can market the miraDry procedure as a premium, highly-differentiated, non-surgical sweat reduction procedure. We are approved to sell the miraDry System in over 40 international markets outside of North America, including countries in Asia, Europe, the Middle East and South America.

The miraDry segment generated net sales of \$8.1 million and \$14.3 million for the three and six months ended June 30, 2018, respectively. With the acquisition of miraDry, 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.

Intellectual Property

Our Breast Products patent portfolio presently consists of two (2) pending U.S. patent application, as well as several in-licensed patent rights, and our miraDry patent portfolio presently consists of approximately twenty (20) granted or allowed U.S. patents, eighty-six (86) granted or allowed foreign counterparts patents, nine (9) pending or published U.S. patent applications, and thirty-three (33) pending or published foreign counterpart patent applications. Our Breast Products trademark portfolio presently consists of approximately twelve (12) worldwide registered trademarks and thirteen (13) pending worldwide trademark applications and our miraDry trademark portfolio presently consists of approximately ninety (90) worldwide registered trademarks and seven (7) pending worldwide trademark applications.

Components of Operating Results

Net Sales

We recognize revenue on breast implants and tissue expanders, net of sales discounts and estimated returns, as the customer has a standard six-month window to return purchased breast implants and tissue expanders. Our Breast Products segment net sales include sales of silicone gel breast implants, tissue expanders and BIOCORNEUM. Net sales for our miraDry segment for the three and six months ended June 30, 2018 include net sales of the miraDry System and consumable bioTips, as a result of the acquisition of miraDry on July 25, 2017.

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

Cost of Goods Sold and Gross Margin

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

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

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

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

Sales and Marketing Expenses

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

Research and Development Expenses

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

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

General and Administrative Expenses

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

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

Other Income (Expense), net

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

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, other than the implementation of ASU 2014-09 (Topic 606) Revenue from Contracts with Customers, as discussed in Note 2 of the unaudited condensed consolidated financial statements included in this Form 10-Q.

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 unaudited condensed consolidated financial statements.

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Results of Operations

Comparison of the Three Months Ended June 30, 2018 and 2017

The following table sets forth our results of operations for the three months ended June 30, 2018 and 2017:

	Three Months Ended June 30, 2018 2017 (In thousands)	
Statement of operations data		
Net sales	\$17,554	\$8,169
Cost of goods sold	6,660	2,621
Gross profit	10,894	5,548
Operating expenses		
Sales and marketing	15,477	6,163
Research and development	2,301	1,573
General and administrative	10,014	8,022
Legal settlement	—	10,000
Total operating expenses	27,792	25,758
Loss from operations	(16,898)	(20,210)
Other income (expense), net		
Interest income	40	37
Interest expense	(867)	(185)
Other income (expense), net	(303)	(4)
Total other income (expense), net	(1,130)	(152)
Loss before income taxes	(18,028)	(20,362)
Income tax expense	—	29
Net loss	\$(18,028)	\$(20,391)

Net Sales

Net sales increased \$9.4 million, or 114.6%, to \$17.6 million for the three months ended June 30, 2018 as compared to \$8.2 million for the three months ended June 30, 2017. Net sales of our Breast Products segment was \$9.4 million, an increase of \$1.2 million for the three months ended June 30, 2018, as compared to \$8.2 million for the three months ended June 30, 2017, driven primarily by an increase in sales of Alloxx2 and Dermapan breast tissue expanders. The miraDry segment contributed \$8.1 million of net sales for the three months ended June 30, 2018, as a result of the acquisition of miraDry on July 25, 2017.

As of June 30, 2018, our U.S. sales organization included 77 sales representatives as compared to 37 sales representatives as of June 30, 2017. The increase is primarily attributed to the acquisition of miraDry and the subsequent headcount increase of the miraDry sales representatives. Additionally, we also sell our miraDry System in several international markets where we leverage a combination of distributor relationships and direct sales efforts.

Cost of Goods Sold and Gross Margin

Cost of goods sold increased \$4.1 million, or 157.7%, to \$6.7 million for the three months ended June 30, 2018, as compared to \$2.6 million for the three months ended June 30, 2017. The increase was primarily due to an increase in net sales and the acquisition of miraDry on July 25, 2017. The miraDry segment contributed \$3.7 million to cost of goods sold for the three months ended June 30, 2018, as a result of the acquisition of miraDry on July 25, 2017.

The gross margins for the three months ended June 30, 2018 and 2017 were 61.9% and 67.9%, 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 \$9.3 million, or 150.0%, to \$15.5 million for the three months ended June 30, 2018, as compared to \$6.2 million for the three months ended June 30, 2017. The increase was primarily due to the addition of miraDry, higher employee-related costs as a result of increased sales and headcount, an increase in marketing expenses and an increase in marketing initiatives. The miraDry segment increased sales and marketing expenses by \$7.2 million for the three months ended June 30, 2018 as a result of the acquisition of miraDry on July 25, 2017.

Research and Development Expenses

R&D expenses increased \$0.7 million, or 43.8%, to \$2.3 million for the three months ended June 30, 2018, as compared to \$1.6 million for the three months ended June 30, 2017. The increase was primarily due to an increase in consulting expenses. The miraDry segment increased R&D expenses by \$0.3 million for the three months ended June 30, 2018, as a result of the acquisition of miraDry on July 25, 2017.

General and Administrative Expenses

G&A expenses increased \$2.0 million, or 25.0%, to \$10.0 million for the three months ended June 30, 2018, as compared to \$8.0 million for the three months ended June 30, 2017. The increase was primarily due to the addition of miraDry. The miraDry segment increased G&A expenses by \$1.4 million for the three months ended June 30, 2018 as a result of the acquisition of miraDry on July 25, 2017. The Breast Products segment increase is primarily related to an increase in contingent consideration fair value adjustments, consulting expenses, stock-based compensation and variable compensation, offset by a decrease in legal expenses.

Legal Settlement Expenses

The Company had no legal settlement expenses for the three months ended June 30, 2018. The \$10 million expense for the three months ended June 30, 2017 was related to the settlement of the Silimed Litigation in 2017.

Other Income (Expense), net

Other income (expense), net for the three months ended June 30, 2018 was primarily associated with expenses related to the change in fair value of warrants and interest and amortization of debt issuance costs associated with our Credit Agreements. Other income (expense), net for the three months ended June 30, 2017 was primarily associated with expenses related to warrants and amortization of issuance costs associated with the Loan Agreement.

Income Tax Expense

Income tax expense is associated with a deferred tax liability associated with indefinite-lived intangible assets from the BIOCORNEUM acquisition and the tissue expander portfolio acquisition that cannot offset deferred tax assets. Income tax expense for the three months ended June 30, 2018 and 2017 was \$0 and \$29,000, respectively.

Comparison of the Six Months Ended June 30, 2018 and 2017

The following table sets forth our results of operations for the six months ended June 30, 2018 and 2017:

	Six Months Ended	
	June 30,	
	2018	2017
	(In thousands)	
Statement of operations data		
Net sales	\$32,229	\$15,658
Cost of goods sold	12,756	4,942
Gross profit	19,473	10,716
Operating expenses		
Sales and marketing	30,733	13,119
Research and development	5,052	4,766
General and administrative	19,514	14,458
Legal settlement	—	10,000
Total operating expenses	55,299	42,343
Loss from operations	(35,826)	(31,627)
Other income (expense), net		
Interest income	80	59
Interest expense	(1,521)	(194)
Other income (expense), net	(184)	4
Total other income (expense), net	(1,625)	(131)
Loss before income taxes	(37,451)	(31,758)
Income tax expense	—	54
Net loss	\$(37,451)	\$(31,812)

Net Sales

Net sales increased \$16.5 million, or 105.6%, to \$32.2 million for the six months ended June 30, 2018 as compared to \$15.7 million for the six months ended June 30, 2017. Net sales of our Breast Products increased \$2.3 million to \$18.0 million for the six months ended June 30, 2018, as compared to \$15.7 million for the six months ended June 30, 2017, driven primarily by an increase in sales of our Allox2 and Dernaspan breast tissue expanders and our BIOCORNEUM scar management product. The miraDry segment contributed \$14.3 million to net sales for the six months ended June 30, 2018, as a result of the acquisition of miraDry on July 25, 2017.

Cost of Goods Sold and Gross Margin

Cost of goods sold increased \$7.9 million, or 159.0%, to \$12.8 million for the six months ended June 30, 2018, as compared to \$4.9 million for the six months ended June 30, 2017. The increase was primarily due to an increase in net sales and the acquisition of miraDry on July 25, 2017. The miraDry segment contributed \$7.4 million to cost of goods sold for the six months ended June 30, 2018, as a result of the acquisition of miraDry on July 25, 2017.

The gross margins for the six months ended June 30, 2018 and 2017 were 60.6% and 68.4%, 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 \$17.6 million, or 134.4%, to \$30.7 million for the six months ended June 30, 2018, as compared to \$13.1 million for the six months ended June 30, 2017. The increase is primarily due to the addition of miraDry, higher employee-related costs as a result of increased sales and headcount, an increase in marketing expenses and an increase in marketing initiatives. The miraDry segment increased sales and marketing expenses by \$13.7 million for the six months ended June 30, 2018, as a result of the acquisition of miraDry on July 25, 2017.

Research and Development Expenses

Research and development expenses increased \$0.3 million, or 6.3%, to \$5.1 million for the six months ended June 30, 2018, as compared to \$4.8 million for the six months ended June 30, 2017. The increase was primarily due to the addition of miraDry, offset by a decrease in consulting expenses. The miraDry segment increased research and development expenses by \$0.9 million for the six months ended June 30, 2018, as a result of the acquisition of miraDry on July 25, 2017.

General and Administrative Expenses

G&A expenses increased \$5.0 million, or 34.5%, to \$19.5 million for the six months ended June 30, 2018, as compared to \$14.5 million for the six months ended June 30, 2017. The increase was primarily due to the addition of miraDry, an increase in consulting expenses, stock-based compensation, contingent consideration fair value adjustments, and bad debt expense, offset by a decrease in legal expenses. The miraDry segment increased G&A expenses by \$2.8 million for the six months ended June 30, 2018, as a result of the acquisition of miraDry on July 25, 2017.

Legal Settlement Expenses

The Company had no legal settlement expenses for the six months ended June 30, 2018. The \$10 million expense for the six months ended June 30, 2017 was related to the settlement of the Silimed Litigation in 2017.

Other Income (Expense), net

Other income (expense), net for the six months ended June 30, 2018 was primarily associated with expenses related to the warrants and interest and amortization of debt issuance costs associated with the Credit Agreements. Other income (expense), net for the six months ended June 30, 2017 was primarily associated with expenses related to warrants and amortization of issuance costs associated with the Loan Agreement.

Income Tax Expense

Income tax expense is 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 six months ended June 30, 2018 and 2017 was \$0 and \$54,000, 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, raising approximately \$77.0 million in net proceeds. In September 2015, we completed a follow-on public offering of common stock raising approximately \$61.4 million in net proceeds.

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

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

See Note 10 to the condensed consolidated financial statements for a full description of our long-term debt and revolving line of credit.

In February 2018, we entered into an At-The-Market Equity Offering Sales Agreement with Stifel, Nicolaus & Company, Incorporated, or Stifel, as sales agent pursuant to which we may sell, from time to time, through Stifel shares of our common stock having an aggregate gross offering price of up to \$50 million. As of June 30, 2018, we have not sold any common stock pursuant to the sales agreement.

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

As of June 30, 2018, we had \$112.6 million in cash and cash equivalents. Our historical cash outflows have primarily been associated with research and development activities, activities relating to commercialization and increases in working capital, including the expansion of our sales force and marketing programs. In addition, we have used cash to fund the acquisitions of miraDry, BIOCORNEUM and our tissue expander portfolio.

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

Cash Flows

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

	Six Months Ended	
	June 30,	
	2018	2017
Net cash (used in) provided by:		
Operating activities	\$(31,157)	\$(15,784)
Investing activities	(160)	(1,580)
Financing activities	117,348	5,647
Net change in cash and cash equivalents	\$86,031	\$(11,717)

Cash used in operating activities

Net cash used in operating activities was \$31.2 million during the six months ended June 30, 2018, as compared to \$15.8 million during the six months ended June 30, 2017. The increase in cash used in operating activities between the six months ended June 30, 2018 and 2017 was primarily associated with higher net loss for the six months ended June 30, 2018, an increase in accounts receivable due to the timing of sales and collections and the timing of insurance recovery payments received as compared to the six months ended June 30, 2017.

Cash used in investing activities

Net cash used in investing activities was \$0.2 million during the six months ended June 30, 2018 as compared to \$1.6 million during the six months ended June 30, 2017. The decrease in cash used in investing activities between the six months ended June 30, 2018 and 2017 was due to a decrease in property and equipment purchases.

Cash provided by financing activities

Net cash provided by financing activities was \$117.3 million during the six months ended June 30, 2018 as compared to \$5.6 million during the six months ended June 30, 2017. The increase in cash provided by financing activities was primarily the result of proceeds from the public follow-on offering and proceeds from borrowings under the Credit Agreements for the six months ended June 30, 2018.

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

- the ability of the Vesta facility to meet capacity to meet customer requirements;
- net sales generated by our Breast Products and miraDry segments, and any other future products that we may develop and commercialize;
- costs associated with expanding our sales force and marketing programs;
- cost associated with developing and commercializing our proposed products or technologies;
- expenses we incur in connection with potential litigation or governmental investigations;
- cost of obtaining and maintaining regulatory clearance or approval for our current or future products;
- cost of ongoing compliance with regulatory requirements, including compliance with Sarbanes-Oxley;
- anticipated or unanticipated capital expenditures; and
- unanticipated G&A expenses.

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

- support of our sales and marketing efforts related to our current and future products;
- new product acquisition and development efforts;
- facilities expansion needs;
- 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 June 30, 2018, 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, except as it relates to the timing of payments and interest under our obligations under our Credit Agreements. See Note 10 for further discussion regarding our long-term debt and revolving loan.

Scheduled contractual obligations for the future payments of our term loan debt obligations as of June 30, 2018 were as follows (in thousands):

	Payments Due by Period				
	Total (in thousands)	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Term loan principle obligations	\$35,000	\$ 5,833	\$ 29,167	\$ —	\$ —

Off-Balance Sheet Arrangements

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

ITEM 3: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of June 30, 2018, we had \$112.6 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 of June 30, 2018, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer, or CEO, and Chief Financial Officer, or CFO, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, the CEO and CFO concluded that the Company’s disclosure controls and procedures were effective as of such date.

Changes in Internal Control over Financial Reporting

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. Information regarding certain legal proceedings is provided in this Quarterly Report in Note 14 of the Condensed Consolidated Financial Statements.

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

The report of our independent registered public accounting firm included in our Annual Report contains an explanatory paragraph with respect to our liquidity.*

As of June 30, 2018, we had cash and cash equivalents of approximately \$112.6 million. Since inception, we have incurred recurring operating losses and cash outflows from operations activities. We believe that we have the ability to continue as a going concern for at least 12 months from the date our condensed consolidated financial statements are issued. There can be no assurance, however, that we will not need to raise additional capital to continue to fund operations which could negatively impact our ability to continue as a going concern.

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

Since our inception, we have incurred significant net operating losses. As of June 30, 2018, we had an accumulated deficit of \$316.9 million. To date, we have financed our operations primarily through sales of preferred stock, borrowings under our term loans, sales of our products since 2012, our initial public offering and follow-on public offerings of our common stock. We have devoted substantially all of our resources to the acquisition and clinical development of our products, the commercial launch of our products, the development of a sales and marketing team and the assembly of a management team to manage our business.

For the six months ended June 30, 2018, our net loss was \$37.5 million. The extent of our future operating losses and the timing of profitability are uncertain, especially in light of our inventory supply issues. We will need to generate significant sales to achieve profitability, and we might not be able to do so. Even if we do generate significant sales, we might not be able to achieve, sustain or increase profitability on a quarterly or annual basis in the future. If our sales grow more slowly than we have forecasted, or if our operating expenses exceed our forecasts, our financial performance and results of operations will be adversely affected.

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

We have recently completed a series of business and product acquisitions including our acquisition of miraDry and our product acquisitions, including BIOCORNEUM and our tissue expanders portfolio. As a result of these acquisitions, we have undergone substantial changes to our business and product offerings in a short period of time. In addition, in the future, we may consider other opportunities to partner with or acquire other businesses, products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base or advance our business strategies.

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

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

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

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

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

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

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

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

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

Commercial sales of the miraDry System commenced in the United States in 2012. We expect that the net sales we generate from our miraDry System and bioTips will represent high margin sales (on a gross margin basis) and account for a substantial amount of our net sales for the next several years, with high margin consumables comprising a sizable percentage of our miraDry segment's net sales. Accordingly, our success depends on the acceptance among physicians and patients of the miraDry procedure as a preferred treatment for being sweat-bothered. Although we have received FDA clearance to market the miraDry procedure for the treatment of primary axillary hyperhidrosis and permanent hair reduction 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. We expect to derive a substantial portion of sales from the miraDry Systems and the sale of our consumable bioTip products, which represent higher margin products (e.g., 50% - 90% gross margin) within our product portfolio. As a result, any failure of this product to achieve meaningful market acceptance will harm our business, sales, profitability and future prospects.

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

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

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

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

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

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

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

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

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

- our products may not be manufactured in accordance with agreed upon specifications or in compliance with regulatory requirements or cGMP, or the manufacturing facilities may not be able to maintain compliance with regulatory requirements or cGMP, which could negatively affect the safety or efficacy of our products or cause delays in shipments of our products;
- we may not be able to timely respond to unanticipated changes in customer orders, and if orders do not match forecasts, we may have excess or inadequate inventory of materials and components;
- our products may be mishandled while in production or in preparation for transit;
- we are subject to transportation and import and export risk, particularly given the global nature of our supply chain;
- the third-party manufacturer may discontinue manufacturing and supplying products to us for risk management reasons;
- the third-party manufacturer may lose access to critical services and components, resulting in an interruption in the manufacturing or shipment of our products;
 - the third-party manufacturer may encounter financial or other hardships unrelated to us and our demand for products, which could inhibit our ability to fulfill our orders;
- there may be delays in analytical results or failure of analytical techniques that we depend on for quality control and release of products;
- natural disasters, labor disputes, financial distress, lack of raw material supply, issues with facilities and equipment or other forms of disruption to business operations affecting our manufacturer or its suppliers may occur;
- latent defects may become apparent after products have been released and which may result in a recall of such products; and
- there are inherent risks if we contract with manufacturers located outside of the United States, including the risks of economic change, recession, labor strikes or disruptions, political turmoil, new or changing tariffs or trade barriers, new or different restrictions on importing or exporting, civil unrest, infrastructure failure, cultural differences in doing business, lack of contract enforceability, lack of protection for intellectual property, war and terrorism.

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

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

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

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

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

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

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

- greater financial and human resources for sales, marketing and product development;
- established relationships with health care providers and third-party payors;
- established reputations and name recognition among health care providers and other key opinion leaders in the plastic surgery industry;

in some cases, an established base of long-time customers;
greater financial resources and economies-of-scale to put additional pricing pressure on competing products;
products supported by long-term clinical data;
larger and more established distribution networks;
greater ability to cross-sell products; and
more experience in conducting research and development, manufacturing, performing clinical trials and obtaining regulatory approval or clearance.

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

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

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

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

In January 2011, the FDA issued a Safety Communication indicating that there was a possible association between saline and silicone gel breast implants and anaplastic large-cell lymphoma, or BIA-ALCL. Since our FDA approval in 2012, Sientra's breast-implant product labeling, which is approved by the FDA, has been required to contain a description of BIA-ALCL as a possible, 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 train Plastic Surgeons on the safe and appropriate use of our breast products. If we become unable to attract potential new Plastic Surgeon customers to our education and training programs, we may be unable to achieve our expected growth.

There is a learning process involved for Plastic Surgeons to become proficient in the use of our anatomically-shaped products. It is critical to the success of our commercialization efforts to train a sufficient number of Plastic Surgeons and provide them with adequate instruction in the appropriate use of our products via preceptorships and additional demonstration surgeries. This training process may take longer than expected and may therefore affect our ability to increase sales. Following completion of training, we rely on the trained Plastic Surgeons to advocate the benefits of our products in the marketplace. Convincing Plastic Surgeons to dedicate the time and energy necessary for adequate training is challenging, and we cannot assure you that we will be successful in these efforts. If Plastic Surgeons are not properly trained, they may misuse or ineffectively use our products. This may also result in, among other things, unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us, any of which could have an adverse effect on our business and reputation.

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

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

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

There have been a number of legislative and regulatory proposals to change the healthcare system, reduce the costs of healthcare and change medical reimbursement policies. Doctors, clinics, hospitals and other users of our products may decline to purchase our products to the extent there is uncertainty regarding coverage from government or commercial payors. Further proposed legislation, regulation and policy changes affecting third-party reimbursement are likely.

Among other things, Congress has in the past proposed changes to and the repeal of the Patient Protection and Affordable Care and Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the Affordable Care Act), and lawsuits have been brought challenging aspects of the law at various points. There have been repeated recent attempts by Congress to repeal or replace the Affordable Care Act. Some of the provisions of the ACA have yet to be implemented, and there have been legal and political challenges to certain aspects of the ACA. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal and replace all or part of the ACA. While Congress has previously been successful at passing comprehensive repeal legislation through both Chambers of Congress, it had then been vetoed by former

President Obama; however full repeal legislation is unlikely in the current political climate. Furthermore, the Tax Cuts and Jobs Act passed in December of 2017 included a provision that would repeal one of the primary pillars of the law, the ACA's individual mandate penalty that essentially assessed a monetary penalty or fine on certain individuals who fail to maintain qualifying health coverage for all or part of a year. Congress may consider other legislation to repeal or replace elements of the ACA on a provision-by-provision basis. We are unable to predict what legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future at the state or federal level, or what effect such legislation or regulation may have on us. Denial of coverage and reimbursement of our products, or the revocation or changes to coverage and reimbursement policies, could have a material adverse effect on our business, results of operations and financial condition.

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, 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 other procedures and could have an adverse effect on consumer spending. This shift could have an adverse effect on our net sales and profitability. Furthermore, consumer preferences and trends may shift due to a variety of factors, including changes in demographic and social trends, public health initiatives and product innovations, which may reduce consumer demand for our products.

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

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

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

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

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

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

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

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

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

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

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

Our corporate headquarters and certain other facilities are located in Santa Barbara, California, which in the past has experienced both severe earthquakes and wildfires. Earthquakes, wildfires or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects.

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

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

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

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

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

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

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

As of June 30, 2018, we had approximately 206 full-time employees. Our management and personnel, and the systems and facilities we currently have in place, may not be adequate to support future growth. Effectively executing our growth strategy requires that we increase net sales through sales and marketing activities, recruit and retain additional employees and continue to improve our operational, financial and management controls, reporting systems and procedures. If we are not able to effectively expand our organization in these ways, we may not be able to successfully execute our growth strategy, and our business, financial condition and results of operations may suffer.

We are subject to political, economic and regulatory risks associated with doing business outside of the United States.*

As a result of our acquisition of miraDry, we now face new risks inherent in conducting business internationally, including compliance with international and U.S. laws and regulations that apply to international operations. We are able to market and sell the miraDry System in over 40 international markets outside of North America, including countries in Asia, Europe, the Middle East and South America. In addition, we may seek to market and sell the miraDry System in additional countries, as well as seek approval to market and sell our breast products in international markets, in the future. These laws 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, including tax law changes and compliance with other tax laws;
- compliance with complex transfer pricing regulations administered by taxing authorities in various jurisdictions resulting from our intercompany arrangements, if any;
- 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.*

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

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

There is no guarantee that we will be able to pay the principal and interest under the Credit Agreements or that future working capital, borrowings or equity financing will be available to repay or refinance any amounts outstanding under the Credit Agreements. Our obligations under the Credit Agreements are secured by a perfected security interest in all of our tangible and intangible assets (including our intellectual property assets), except for certain customary excluded property and all of our and our subsidiaries capital stock, with certain limited exceptions. In addition, we may enter into debt agreements in the future that may contain similar or more burdensome terms and covenants, including financial covenants.

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

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

- the length of time it took 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 miraDry, BIOCORNEUM and our tissue expander portfolio;
- the impact of the buying patterns of patients and seasonal cycles in consumer spending;
- our ability to drive increased sales of breast implant products, miraDry System and bioTips;
- our ability to establish and maintain an effective and dedicated sales organization;
- pricing pressure applicable to our products, including adverse third-party coverage and reimbursement outcomes;
- results of clinical research and trials on our existing products;
- the impact of the past regulatory inquiries of Silimed on our brand and reputation;
- timing of our research and development activities and initiatives;
- the mix of our products sold due to different profit margins among our products;
- timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;
- the ability of our suppliers to timely provide us with an adequate supply of products;
- the evolving product offerings of our competitors;
- regulatory approvals and legislative changes affecting the products we may offer or those of our competitors;
- increased labor and related costs;
- interruption in the manufacturing or distribution of our products;
- the effect of competing technological, industry and market developments;
- changes in our ability to obtain regulatory clearance or approval for our products; and
- our ability to expand the geographic reach of our sales and marketing efforts.

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

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

As of June 30, 2018, we had federal net operating loss carryforwards, or NOLs, of approximately \$334 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. In addition, starting in 2018, the deduction for NOLs is limited to 80% of our income. As a result of these limitations, we may not be able to utilize a material portion of the NOLs reflected on our condensed consolidated balance sheet and for this reason, we have fully reserved against the value of our NOLs on our condensed consolidated 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.

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

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

take as a result of the Tax Cuts and Jobs Act different from that presently contemplated.

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Risks Related to Our Intellectual Property and Potential Litigation

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

Our success depends in part on our ability to protect our intellectual property rights. We rely on a combination of trademarks, trade secrets, confidential information, copyrights, patent rights and other intellectual property rights to protect our intellectual property. In addition, to protect our trade secrets, confidential information and other intellectual property rights, we have entered into confidentiality agreements with third parties, and confidential information and invention assignment agreements with employees, consultants and advisors. However, these agreements may not provide sufficient protection or adequate remedies for violation of our rights in the event of unauthorized use or disclosure of confidential and proprietary information. Without additional protection under the patent or other intellectual property laws, such unauthorized use or disclosure may enable competitors to duplicate or surpass our technological achievements. Moreover, the laws of certain foreign countries do not recognize intellectual property rights or protect them to the same extent as do the laws of the United States. Failure to protect our proprietary rights could seriously impair our competitive position.

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

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

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

- redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and/or infeasible; or
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all.

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

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

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

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

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

As a supplier of medical devices, we are and may be subject to warranty or product liability claims alleging that the use of our products has resulted in adverse health effects or other litigation in the ordinary course of business that may require us to make significant expenditures to defend these claims or pay damage awards. The breast implant industry has a particularly significant history of product liability litigation. The risks of litigation exist even with respect to products that have received or in the future may receive regulatory approval for commercial sale, such as our Breast Products. In addition, 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 ten years of implantation. In April 2018, we announced our Platinum20 product replacement and limited warranty program, which we believe provides an industry-leading program of no-charge replacement implants for covered rupture events that occur during the lifetime of the patient, and no-charge replacement implants for other covered events that occur within twenty years of the implant procedure, as well as financial assistance for certain qualifying events that occur within twenty years of the implant procedure.

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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 and may receive stock awards as compensation for services provided, could be subject to challenge under one or more of such laws. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and/or criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, exclusion from governmental health care programs, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

We recently settled a securities class action lawsuit and have reached an agreement-in-principle with the SEC. If we are unable to finalize the settlement with the Securities and Exchange Commission (the "SEC") or if we are subject to additional claims, our insurance may not be sufficient to cover additional expenses incurred.*

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

In March 2018, we reached an agreement-in-principle with the Staff of the Division of Enforcement, or the Staff, of the SEC to settle, without admitting or denying, charges arising out of the SEC's investigation into alleged false and misleading statements or omissions made in connection with the 2015 offering. Those charges include alleged violations of Section 10 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Rule 10b-5 promulgated thereunder, and Sections 17(a)(1)-(3) of the Securities Act. The agreement-in-principle is subject to review and approval by the Commissioners of the SEC. While there is no monetary component to the agreement-in-principle, there can be no assurances that the Commissioners of the SEC will approve the agreement-in-principle in its current form, or at all, or that the SEC will not take alternative enforcement actions, including monetary fines,

trading suspensions, asset freezes, etc. There are a wide array of potential remedies available to the Commissioners, and if the Commissioners do not approve the agreement-in-principle in its current form, or if the Commissioners decide to take alternative enforcement actions, we may be subject to protracted litigation, significant legal costs, distraction of our management, and potential monetary damages, which could have a material adverse effect on our business, financial condition and results of operations, and significantly impact the price of our common stock.

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

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

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

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

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

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

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

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

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

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

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

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory authority. The FDA or other regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or other regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or other regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

In addition, even after we have obtained the proper regulatory clearance or approval to market a product, the FDA has the power to require us to conduct post-marketing studies. For example, we are required to continue to study and report clinical results to the FDA on our silicone gel breast implants. We completed and submitted the Final Report to FDA for our 10-year pivotal study in March 2018. Clinical data is ongoing for our second or “new enrollment” post-approval study. Failure to conduct required studies in a timely manner could result in the revocation of the PMA approval or 510(k) clearance for the product that is subject to such a requirement and could also result in the recall or withdrawal of the product, which would prevent us from generating sales from that product in the United States.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

one of our distributors could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Similar regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert management attention and financial resources and could cause the price of our stock to decline, expose us to product liability or other claims and harm our reputation with customers. Such events could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. A recall involving our silicone gel breast implants could be particularly harmful to our business, financial and operating results. Companies are required to maintain certain

records of recalls, even if they are not reportable to the FDA or similar foreign governmental authorities. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA or foreign governmental authorities. If the FDA or foreign governmental authorities disagree with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA or a foreign governmental authority could take enforcement action for failing to report the recalls when they were conducted.

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

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

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

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