
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of Earliest Event Reported): **October 27, 2015**

SIENTRA, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36709
(Commission
File Number)

20-5551000
(IRS Employer
Identification No.)

420 South Fairview Avenue, Suite 200
Santa Barbara, CA 93117
(Address of Principal Executive Offices and Zip Code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02. Results of Operations and Financial Condition.

The information set forth in Item 8.01 regarding the cash position of Sientra, Inc. (the “*Company*”) as of September 30, 2015 is incorporated by reference into this Item 2.02.

Item 2.04. Triggering Events That Accelerate or Increase a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement.

The information set forth in Item 8.01 regarding the Loan Agreement (as defined below) is incorporated by reference into this Item 2.04.

Item 8.01. Other Events.

On October 28, 2015, the Company issued a press release regarding the recent fire at Silimed’s manufacturing facilities and other business updates, including that, as previously disclosed, the Company has multiple term loans outstanding under an Amended and Restated Loan and Security Agreement, dated June 30, 2014, by and between Oxford Finance LLC (“*Oxford*”) and the Company (the “*Loan Agreement*”), and on October 27, 2015, Oxford issued a notice to the Company indicating that, in connection with the recent events involving Silimed and the Company, certain events of default have occurred and continue to exist under the Loan Agreement. On October 28, 2015, the Company repaid all principal, interest, other amounts and obligations owed to Oxford under the term loans for a total of \$24.5 million, following which the Company has no outstanding debt obligations. The Company remains well funded with cash and cash equivalents as of September 30, 2015 of \$148.9 million prior to the payment of all amounts due and owed under the Loan Agreement. A copy of the press release is filed as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Sientra, Inc. dated October 28, 2015.

SIGNATURES

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

SIENTRA, INC.

Dated: October 28, 2015

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

INDEX TO EXHIBITS

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Sientra Provides Business Update

SANTA BARBARA, Calif., October 28, 2015-- Sientra, Inc. (NASDAQ:SIEN), a medical aesthetics company, today provided an update regarding its business, including additional details regarding its contract manufacturer, Silimed.

Update on Fire at Silimed's Manufacturing Facility

Sientra's management team is in contact with Silimed regarding the facts related to a fire on October 22, 2015 at one of Silimed's two buildings in Rio de Janeiro, Brazil. Based on these preliminary discussions with Silimed, the Company can confirm that the fire occurred in the building where Sientra's breast implants are primarily manufactured (building F2).

However, Silimed has indicated to the Company that a smaller production facility in Silimed's second building (building F1), which was not impacted by the fire, has the potential to be modified for breast implant manufacturing. In order to commence the manufacturing of breast implants, certain areas in this facility would need to be reconfigured and receive certification and approval by appropriate regulatory bodies.

The Company is working with Silimed to assess this option and the associated timeframe, but does not have any additional update at this time. Fire officials have not yet allowed anyone access to building F2, and therefore, information regarding its status is currently limited. Over the coming weeks, the Company expects to have a more comprehensive understanding of the near and long-term capabilities of Silimed's manufacturing operations including:

- The operational state of building F2, including the status of equipment that is used to manufacture breast implants; and
- The potential feasibility, production capacity and timing related to Silimed's ability to manufacture breast implants in building F1.

As the fire investigation winds down and Silimed is allowed additional access, the Company will work with Silimed to seek additional clarity on these points.

Repayment of Term Loan

As previously disclosed, the Company has multiple term loans outstanding under an Amended and Restated Loan and Security Agreement, dated June 30, 2014, between Oxford and the Company. On October 27, 2015, Oxford issued a notice to Sientra indicating that, in connection with the recent events involving Silimed and the Company, certain events of default have occurred and continue to exist under the Loan Agreement. On October 28, 2015, Sientra repaid all principal, interest, other amounts and obligations owed to Oxford under the term loans for a total of \$24.5 million, following which the Company has no outstanding debt obligations.

Sientra remains well funded with cash and cash equivalents as of September 30, 2015 of \$148.9 million prior to the payment of all amounts due and owed under the Loan Agreement. Sientra will provide further detail on its financial position during the Company's upcoming third quarter earnings call.

Long-Term Manufacturing Supply

The Sientra management team and board are focused on the long-term manufacturing needs of the Company and are evaluating the best way to meet its manufacturing and supply requirements going forward. This review is underway and being conducted with a strong sense of urgency.



The review includes the previously mentioned options with Silimed, as well as potential alternative manufacturing arrangements to ensure that Sientra can continue to provide surgeons and patients with its compelling value proposition and differentiated products well into the future.

Update on Regulatory Review

As previously announced, Sientra is conducting a comprehensive, independent review into the suspension of Silimed's CE certificate for all medical devices manufactured by Silimed as well as the Brazilian ANVISA action.

Out of an abundance of caution, and to allow for Sientra to conduct this review, the Company previously disclosed that it had decided to voluntarily suspend the sales of Silimed manufactured products. It is important to note that while breast implants have stringent standards for manufacturing and robust quality systems, there is no specific or defined standard for particles on breast implants. In addition, no reports of adverse events and no risks to patient health have been identified in connection with implanting the Silimed-manufactured products. Furthermore, no regulatory authorities have found that there is a need to explant these devices or adopt any specific procedure or action for patients who have received them.

Sientra's ongoing review, conducted with the assistance of independent experts in quality management systems, Good Manufacturing Practices (GMP) and data-based risk assessment, includes:

- Documentation related to the matter in question;
- Procedures for manufacturing Sientra's products;
- Environmental monitoring;
- Data, testing and analysis conducted by or on behalf of Silimed; and
- Potential corrective actions implemented by Silimed to resolve the non-conformities identified in order to reinstate Silimed's GMP compliance.

Sientra has also initiated its own testing of its existing finished goods inventory, a central component to the risk assessment analysis. Based on historical demand patterns and evaluation, the Company believes its current inventory supply is approximately 12 months.

Sientra believes that the outcome of this detailed review process will enable the Company to accurately assess the steps required in order to reintroducing its products in the U.S. market, following consultation with and clearance from the U.S. Food and Drug Administration (FDA). The Company has been in continuous communication with the FDA and expects to provide its findings to the FDA by the end of calendar year 2015. However, Sientra cannot speculate on the FDA's timing or decision making process.

About Sientra

Headquartered in Santa Barbara, California, Sientra is 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. The Company was founded to provide greater choice to board-certified plastic surgeons and patients in need of medical aesthetics products. The Company has developed a broad portfolio of products with technologically differentiated characteristics, supported by independent laboratory testing and strong clinical trial outcomes. The Company sells its breast implants and breast tissue expanders exclusively to board-certified and board-admissible plastic surgeons and tailors its customer service offerings to their specific needs. The Company also offers a range of other aesthetic and specialty products.



Forward-looking Statements

This press release contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, relating to, among other things, the future performance of Sientra that are based on management’s current assumptions and expectations of future events and involve risks and uncertainties. Forward-looking statements include, but are not limited to, statements regarding: the effects of the fire at Silimed’s manufacturing facilities and the ability for Sientra’s breast implants to be manufactured at building F1; the availability of alternative sources of supply; Sientra’s cash position following the repayment of all amounts due and owed under the Oxford Loan and Security Agreement; the results and timing of Sientra’s independent review of the matters discussed in this release; Sientra’s current inventory supply; and the actions that the FDA may take in response to such matters and as a result of Sientra’s independent review. Such statements are subject to risks and uncertainties. The Company’s business, strategy, operations or financial performance, and actual results may differ materially from those predicted or implied. Factors that could cause or contribute to such differences include, but are not limited to, Sientra’s reliance on the sale of its breast products, the Company’s reliance on sole-source manufacturing by Silimed, Sientra’s uncertainty regarding the resolution of the regulatory inquiries of Silimed’s medical devices and the delay of the Company’s sales pending such resolution, Sientra’s ability to find an alternative solution for its long-term manufacturing supply needs and the Company’s uncertainty regarding the extent of the damage of the fire at Silimed’s manufacturing facility and when Silimed may be able to resume manufacturing Sientra’s breast implants. All statements other than statements of historical fact are forward-looking statements. The words “believe,” “may,” “might,” “could,” “will,” “aim,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “plan,” or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes are intended to identify estimates, projections and other forward-looking statements.

More information about factors that could cause actual results to differ materially from those contemplated in this press release can be found under the captions “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in the Company’s most recent Quarterly Report on Form 10-Q at <http://investors.sientra.com/financial-info/sec-filings/default.aspx> or the SEC’s website at www.sec.gov. Undue reliance should not be placed on the forward-looking statements in this release, which are based on information available to the Company on the date hereof, and except to the extent required by law, Sientra assumes no obligation to update such statements.

Contact

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