
**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): **February 8, 2016**

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 8.01. Other Events.

On February 8, 2016, Sientra, Inc. issued a press release and mailed a letter to surgeons announcing the return of its products to the market. A copy of the press release is filed as Exhibit 99.1 and is incorporated herein by reference, and a copy of the letter is filed as Exhibit 99.2 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 February 8, 2016.
99.2	Letter of Sientra, Inc. dated February 8, 2016.

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: February 8, 2016

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

INDEX TO EXHIBITS

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99.1	Press Release of Sientra, Inc. dated February 8, 2016.
99.2	Letter of Sientra, Inc. dated February 8, 2016.



Sientra Announces Return of All Products to U.S. Market

SANTA BARBARA, Calif., February 8, 2016 – Sientra, Inc. (NASDAQ:SIEN) (“Sientra” or the “Company”), a medical aesthetics company, today announced all of its medical devices, including all Sientra breast implant products, will return to the U.S. market beginning March 1, 2016.

Sientra is taking this action subsequent to the completion of extensive independent, third-party testing and analyses of its products in the U.S. Under worst-case testing conditions, the products exhibit a high safety margin compared to numerous U.S. and international standards for medical device and materials safety. The conclusive results of our testing indicate no anticipated significant safety concerns with the use of Sientra products, including our breast implants, consistent with their approval status since 2012.

Jeffrey Nugent, Chairman and Chief Executive Officer of Sientra, said, “We are extremely pleased to return our products to the U.S. market where we can once again provide choice to board-certified plastic surgeons. Our decision to place the voluntary hold on Sientra products was difficult, but we felt it was the responsible action to take at the time amid the speculation, to ensure that Sientra products remain a safe choice for our customers and their patients. Following the results of independent, third-party testing, we are more confident than ever in the safety of our devices, and specifically our breast implant products, which are further supported by our 9-year clinical study data to be published in April of 2016. In terms of the confirmation of our manufacturing supply initiatives, we are confident that our resupply process will be in place in sufficient time to assure our customers of uninterrupted supply.”

Sientra has also sent a letter to its surgeons informing them of the Company’s market re-entry plans. A copy of that letter can be found in the Investor Relations section of Sientra’s web site.

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 exact date that Sientra’s products will return to the U.S. market, the interpretation of the results of the third-party independent testing of Sientra’s products, actions that the FDA may take in response to such matters and the timing and availability of sources of supply. 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. 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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IR@Sientra.com



Subject line: Sientra Products are Returning to the Market
Date of Email: February 8, 2016
Sent to: Sientra Board-Certified Plastic Surgeons List

Dear Valued Board-Certified Plastic Surgeon,

Sientra Products are Returning to the Market

As a trusted partner to Sientra, I want to reach out to you with important news. We are excited to announce today that ALL of our medical devices, including our Sientra Silicone Gel Breast Implants, will be **returning to market** beginning March 1, 2016. We are taking this action subsequent to the extensive independent testing and analyses that have been performed on Sientra breast implants over the past four months. Placing the voluntary hold on Sientra products was a difficult but responsible decision that provided the necessary time to confirm that Sientra implants continue to be a safe choice for you and your patients, as our breast implants have been since they first entered the U.S. market in 2012. That safety is further supported by our 9-year clinical study data to be published in April of this year.

With the work completed, we want to provide you with some information related to the independent tests and their findings to assure you that we are more confident than ever in the safety of our products, including Sientra breast implants. Importantly, our results found that under worst-case conditions, Sientra products exhibited a high safety margin compared to numerous U.S. and international standards for medical device and materials safety. There are no anticipated significant safety concerns with the use of our products beyond those associated with all breast implants. As a result of our work, we have never been more confident in the safety and clinical efficacy of Sientra products.

And now we are moving forward.

Over the next few weeks we are turning our attention to restarting our commercial activities. This process will take place over the coming weeks and months, during which time we will be laser-focused on a controlled, predictable approach to resuming our commercial operations. We owe it to our loyal customer base to ensure that our re-entry occurs with the same high-level of Sientra customer service for which we have become known.

We are proud to once again bring choice to plastic surgeons in the U.S., and to deliver our unique value proposition that begins with our commitment to the specialty of plastic surgery. Since we entered the US market in 2012, we have remained steadfast in our focus and dedication to the boardcertified plastic surgeon community. We therefore wish to stress, notwithstanding anything you may have heard to the contrary, that Sientra's innovative, high quality breast implants will remain available exclusively to board-certified plastic surgeons. All of us at Sientra understand the difficulty this situation placed on your practice. We want to express our deepest apologies for that inconvenience, and trust that our recommitment to the specialty is a strong first step in regaining your confidence.



We will also move forward with our strategic plans to secure a robust, redundant, supply chain for Sientra implants. Those efforts have been in place for a considerable period of time. As a company known for its innovative approach to products, service, and marketing programs, we are now applying that same forward-thinking focus to our manufacturing operations. Efforts in this regard have been underway, and we are now confident that our resupply process will assure our customers of an uninterrupted supply.

Finally, I want to personally thank you for your patience, understanding and support over the past several months. This is an exciting milestone in the Company's history and the entire Sientra team is fully prepared to resume the high-level of service and care that you have come to expect from us, and we are committed to exceeding your high expectations going forward.

I am confident that we have a bright future ahead of us at Sientra, thanks in no small part to the support of our dedicated plastic surgeon customers, and I look forward to keeping you informed of our progress.

Respectfully,

Jeffrey Nugent
Chairman and Chief Executive Officer
Sientra, Inc.

Note to our Customers:

As always, please familiarize yourself with Sientra's *Directions for Use* to resolve any questions or concerns with the use of Sientra breast implants. You should also use best surgical practices, including the standard practice of washing surgical pockets and the surface of the implant with an antibiotic solution prior to insertion. In addition, please review the patient labeling with your patients to ensure they understand the risk/benefit relationship of undergoing breast implant surgery with Sientra Silicone Gel Breast Implants. Consistent with standard patient follow-up, please advise your patients who have received Sientra implants to contact you if they experience any complications.

Health care professionals may report adverse reactions or quality problems they experience using these or any medical products to MedWatch: The FDA Safety Information and Adverse Event Reporting Program either online at <http://www.fda.gov/Safety/MedWatch/default.htm>, by regular mail or by FAX.