
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 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): September 19, 2018

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

420 South Fairview Avenue, Suite 200
Santa Barbara, CA 93117
(Address of principal executive offices, with 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.):

- 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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.

Item 8.01 Other Events.

On September 19, 2018, the Securities and Exchange Commission (the “SEC”) issued an order (the “Order”) approving the terms proposed by Sientra, Inc. (“Sientra” or the “Company”) to the SEC in an Offer of Settlement (the “Settlement Offer”) previously disclosed in Sientra’s Current Report on Form 8-K, dated March 23, 2018 (the “Prior 8-K”). As disclosed in the Prior 8-K, pursuant to the Settlement Offer, Sientra agreed to settle, without admitting or denying, charges arising out of the SEC’s previously disclosed investigation into alleged false and misleading statements or omissions made in connection with its follow-on public offering that closed on September 23, 2015. Those charges included alleged violations of Section 10 of the Securities and Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder, and Sections 17(a)(1)-(3) of the Securities Act of 1933, as amended.

The Order approves the Settlement Offer and fully and finally disposes of the investigation of the Company by the SEC without any monetary component as previously disclosed. It also contains an order prohibiting future violations of the securities laws.

Neither Sientra nor any current Sientra officers or directors admitted or denied or were required to admit or deny the allegations. The SEC does not allege that either Sientra or any current Sientra officers or directors acted with an intent to deceive investors.

The foregoing description of the Order does not purport to be complete and is qualified in its entirety by reference to the Order. The Order is filed as Exhibit 10.1 hereto and is incorporated herein by reference.

Item 9.01 Exhibits.

Exhibit No.	Description
10.1	<u>Order Instituting Cease-and-Desist Proceedings Pursuant to Section 8A of the Securities Act of 1933 and Section 21c of the Securities Exchange Act of 1934, Making Findings, and Imposing a Cease-And-Desist Order dated September 19, 2018.</u>

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 hereunto duly authorized.

SIENTRA, INC.

Date: September 20, 2018

By: /s/ Jeffrey M. Nugent

Jeffrey M. Nugent

Chairman of the Board of Directors and Chief Executive Officer

UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

SECURITIES ACT OF 1933
Release No. 10555 / September 19, 2018

SECURITIES EXCHANGE ACT OF 1934
Release No. 84208 / September 19, 2018

ADMINISTRATIVE PROCEEDING
File No. 3-18795

In the Matter of
SIENTRA, INC.,
Respondent.

ORDER INSTITUTING
CEASE-AND-DESIST PROCEEDINGS PURSUANT TO SECTION
8A OF THE SECURITIES ACT OF 1933 AND SECTION 21C OF
THE SECURITIES EXCHANGE ACT OF 1934, MAKING
FINDINGS, AND IMPOSING A CEASE-AND-DESIST ORDER

I.

The Securities and Exchange Commission (“Commission”) deems it appropriate that cease-and-desist proceedings be, and hereby are, instituted pursuant to Section 8A of the Securities Act of 1933 (“Securities Act”) and Section 21C of the Securities Exchange Act of 1934 (“Exchange Act”), against Sientra, Inc. (“Sientra” or “Respondent”).

II.

In anticipation of the institution of these proceedings, Respondent has submitted an Offer of Settlement (the “Offer”) which the Commission has determined to accept. Solely for the purpose of these proceedings and any other proceedings brought by or on behalf of the Commission, or to which the Commission is a party, and without admitting or denying the findings herein, except as to the Commission’s jurisdiction over it and the subject matter of these proceedings, which are admitted, Respondent consents to the entry of this (“Order”), as set forth below.

III.

On the basis of this Order and Respondent's Offer, the Commission finds ¹ that:

Summary

These proceedings arise from the fraudulent concealment of damaging news about Sientra's former sole-source contract manufacturer before it closed a more than \$60 million follow-on offering in September 2015. Sientra sells silicone breast implants in the United States, and, at the relevant time pertinent to these proceedings, those implants were made by a privately-held Brazilian company called Silimed Industria de Implantes Ltda. ("Silimed"). Just three days before the close of Sientra's follow-on offering, its then-CEO at the time, Hani Zeini ("Zeini"), learned that Silimed's CE certification—a sign of regulatory compliance that is required to sell products in the European Union—had been suspended. Zeini learned this directly from Silimed's CEO. But instead of disclosing this bad news before Sientra's stock offering closed, Zeini concealed it and made sure that Sientra's board of directors and key players, including Sientra's general counsel, Sientra's outside counsel, and the underwriters for the offering, did not learn about the CE certificate suspension prior to closing. One day after the offering closed, news of the suspension became public, and Sientra issued a Form 8-K disclosing the suspension. On that news, Sientra's stock price fell 52.6% from \$20.58 to \$9.70, per share, in a single day's trading.

Respondent

1. Sientra, Inc., a Delaware corporation based in Santa Barbara, California, is a medical aesthetics company whose primary products include silicone gel breast implants. Sientra's stock is registered under Section 12(b) of the Exchange Act and traded on the NASDAQ global select market (ticker symbol: SIEN).

Facts

2. Sientra is a medical aesthetics company whose primary products, at the time of the events relevant to this proceeding, were silicone gel breast implants. At all times relevant here, Sientra's sole supplier of breast implants was Silimed. The implants Silimed made for Sientra were manufactured at Silimed's facility in Brazil, and were sold by Sientra in the United States. Silimed also manufactured its own brand of implants at the same facility in Brazil, and marketed and sold those implants in foreign markets outside of the United States, including countries in the European Union. In order to sell its breast implants in the European Union, Silimed was required to have a "CE certificate," which reflected that the implants complied with certain regulatory requirements.

3. In September 2015, Sientra carried out a follow-on offering of its common stock for about \$61.4 million. Sientra filed its initial registration statement on Form S-1 with the Commission on September 3, which it amended on September 14 (the "Registration Statement"). On September 14, Sientra entered into a purchase agreement with the underwriters for the offering. That agreement contained representations that the Registration Statement and the prospectus on

¹ The findings herein are made pursuant to Respondent's Offer of Settlement and are not binding on any other person or entity in this or any other proceeding.

Form 424B3 (the “Prospectus”), which it filed with the Commission on September 18, did not omit any material information. The offering closed on September 23, 2015.

4. In its Registration Statement and Prospectus, Sientra stated that “there are inherent risks in contracting with manufacturers located outside of the United States such as in Brazil” and that “any negative publicity concerning our products could harm our business reputation and negatively impact our financial results.”

5. Sientra’s Registration Statement and Prospectus also expressly incorporated by reference the “Risk Factors” sections in Sientra’s annual report on Form 10-K for the year ended December 31, 2014, and in its quarterly reports on Forms 10-Q for the quarters ended March 31 and June 30, 2015. There, Sientra warned that its future profitability depended on its breast implant products, and that it relied on Silimed as its “sole source” manufacturer of all of its products. Sientra further stated in its 2014 annual report: “In addition, our reliance on Silimed involves a number of other risks, including among other things that... our products may not be manufactured in accordance with agreed upon specifications or in compliance with regulatory requirements, or its manufacturing facilities may not be able to maintain compliance with regulatory requirements, which could negatively affect the safety or efficacy of our products or cause delays in shipments of our products.”

6. On September 20, 2015, three days before the close of Sientra’s follow-on offering, Sientra’s then-CEO, Hani Zeini, learned that the CE certificate for the Silimed brand of breast implants had been suspended following an audit of Silimed’s manufacturing facility.

7. From September 20, 2015, through the close of the follow-on offering on September 23, 2015, Sientra’s then-CEO, Zeini, concealed the fact that Silimed’s CE certificate had been suspended from other individuals at Sientra working on the offering, including Sientra’s then-general counsel, and from the outside professionals working on the offering, including Sientra’s outside counsel and the underwriters.

8. On September 22, 2015, Zeini signed the officer’s closing certificate on behalf of Sientra. Through the certificate, Sientra represented that “the representations and warranties of [Sientra] in the Purchase Agreement are true and correct as if made at and as of the Closing Date, and [Sientra] has complied with all the agreements and satisfied all the conditions on its part to be performed or satisfied at or prior to the Closing Date.”

9. On September 22, 2015, Zeini directed Sientra’s then-general counsel to close the follow-on offering, but did not tell the general counsel that Silimed’s CE certificate had been suspended.

10. On September 23, 2015, Sientra’s then-general counsel participated in a final due diligence call on behalf of Sientra. During the due diligence call, counsel for the underwriters asked eleven questions directed to Sientra’s management about “any material updates or changes” since the last due diligence call. In response to at least two of these questions asking about “[a]ny material developments with your relationships with contractual parties and particularly, Silimed,” or “[a]ny other information that has not been made known to us that may be deemed material to an

investor or that would make the disclosure in the Prospectus untrue or misleading.” Sientra should have disclosed the fact that Silimed’s CE certificate had been suspended. Instead, Sientra’s then-general counsel, acting on behalf of Sientra, and at the direction of its then-CEO, Zeini, responded to both of these questions by stating “no.” Sientra did not disclose the fact that Silimed’s CE certificate had been suspended on the call.

11. On September 23, 2015, Sientra closed the follow-on offering, selling three million shares for net proceeds of \$61,397,000, without disclosing the fact the Silimed’s CE certificate had been suspended.

12. The suspension of Silimed’s CE certificate was material information that would have been important to Sientra’s investors and to the underwriters.

13. On September 24, 2015, Sientra filed a current report on Form 8-K disclosing that it had issued a letter, dated September 24, to its plastic surgeon customers regarding the suspension of Silimed’s CE certificate.

14. Based on this news, Sientra’s stock price fell from \$20.58 to \$9.70 by the close of business on September 24, a decline of 52.63%.

Violations

15. As a result of the conduct described above, Sientra violated Section 17(a) of the Securities Act, which prohibits fraudulent conduct in the offer and sale of securities.

16. Also as a result of the conduct described above, Sientra violated Section 10(b) of the Exchange Act and Rule 10b-5 thereunder, which prohibit fraudulent conduct in connection with the purchase or sale of securities.

Sientra’s Remedial Efforts and Cooperation

In determining to accept the Offer, the Commission considered remedial acts promptly undertaken by Sientra and cooperation afforded the Commission staff. The independent members of Sientra’s board of directors swiftly hired outside counsel to perform an internal investigation just days after Sientra issued its current report on Form 8-K on September 24, 2015. After a prompt investigation, counsel for Sientra’s independent board members presented their findings to the independent members of the board and then self-reported the matter to the Commission. On November 12, 2015, the independent board members asked Zeini to resign. Thereafter, Sientra and its board of directors have cooperated with the Commission’s staff in its investigation. During the investigation, Sientra voluntarily waived the attorney client privilege for certain communications among its former general counsel, Zeini and other Sientra employees between September 20 and 27, 2015.

IV.

Undertakings

In connection with this action and any related judicial or administrative proceeding or investigation commenced by the Commission or to which the Commission is a party, Respondent (i) agrees to use its best efforts to cause its officers, employees, and directors to be interviewed by the Commission staff at such times and places as the staff requests upon reasonable notice; (ii) will accept service by mail or facsimile transmission of notices or subpoenas issued by the Commission for documents or testimony at depositions, hearings, or trials, or in connection with any related investigation by Commission staff; (iii) appoints its undersigned attorneys as agents to receive service of such notices and subpoenas; (iv) with respect to such notices and subpoenas, waives the territorial limits on service contained in Rule 45 of the Federal Rules of Civil Procedure and any applicable local rules, provided that the party requesting the interview or testimony reimburses the travel, lodging, and subsistence expenses at the then-prevailing U.S. Government per diem rates; and (v) consents to personal jurisdiction over it in any United States District Court for purposes of enforcing any such subpoena.

In determining whether to accept Respondent's Offer, the Commission has considered these undertakings.

V.

In view of the foregoing, the Commission deems it appropriate and in the public interest to impose the sanctions agreed to in Respondent's Offer.

Accordingly, it is hereby ORDERED that:

Pursuant to Section 8A of the Securities Act and Section 21C of the Exchange Act, Respondent cease and desist from committing or causing any violations and any future violations of Section 17(a) of the Securities Act and Section 10(b) of the Exchange Act and Rule 10b-5, thereunder.

By the Commission.

Brent J. Fields
Secretary