
**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): August 25, 2020

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.01 per share	SIEN	The Nasdaq Stock Market LLC

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

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 August 25, 2020, Sientra, Inc. (the “Company”) issued a press release announcing a that it has received approval from Japan’s Pharmaceutical and Medical Device Agency for the Company’s OPUS line of implants. A copy of the press release is furnished as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits**(d) Exhibits**

Exhibit No.	Description
99.1	Press release, dated August 25, 2020.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: August 25, 2020

By: /s/ Jeffrey M. Nugent
Jeffrey M. Nugent
Chairman of the Board of Directors and Chief
Executive Officer



Sientra Receives Regulatory Approval to Market OPUS® Breast Implants in Japan

Marks First Regulatory approval of Sientra Breast Implants Outside of the U.S.

Santa Barbara, CA – August 25, 2020 – Sientra, Inc. (NASDAQ: SIEN) (“Sientra” or the “Company”), a diversified global medical aesthetics company, announced today that it has received approval from Japan’s Pharmaceutical and Medical Device Agency (“PDMA”) to market the Company’s entire OPUS line of breast implants in Japan.

Sientra will market the complete portfolio of OPUS breast implants in Japan through its local partner Medical U&A, Inc. (“Medical U&A”), a leading provider of surgical and medical devices in the fields of plastic and reconstructive surgery. Medical U&A will sell Sientra’s implants through a dedicated sales force to over 2,000 hospitals and clinics across Japan.

Jeff Nugent, Chairman and Chief Executive Officer of Sientra, said, “The approval of our OPUS line of implants in Japan represents a major milestone for Sientra, representing our first approval for our breast products outside of the U.S. With this approval, Sientra’s implants will be one of only two breast implants approved by the PDMA, which reinforces our clinically proven safety profile.”

Jeff continued, “In an era when safety and trust are paramount, Sientra upholds the highest standards for both patients and providers. With our latest generation of clinically supported and FDA approved implants sold only to highly qualified surgeons in the U.S. and now Japan, we believe Sientra consistently provides patients with safe and beautiful outcomes.”

Shojiro Matsuda, Chief Executive Officer of Medical U&A, said “Many patients in Japan have long-awaited Sientra’s breast implants. In response to the demands of patients and healthcare professionals, and with the full cooperation of Sientra, we submitted the regulatory application and obtained approval in only six months. We are very pleased to be able to distribute these highly differentiated Sientra products that contribute to the quality of life of Japanese patients.”

About Sientra

Headquartered in Santa Barbara, California, Sientra is a diversified global medical aesthetics company and a leading partner to aesthetic physicians. The Company offers a suite of products designed to make a difference in patients’ lives by enhancing their body image, growing their self-esteem, and restoring their confidence. Sientra has developed a broad portfolio of products with

technologically differentiated characteristics, supported by independent laboratory testing and strong clinical trial outcomes. The Company's Breast Products Segment includes its OPUS® breast implants, the first fifth generation breast implants approved by the FDA for sale in the United States, its ground-breaking Allox2® breast tissue expander with patented dual-port and integral drain technology, and BIOCORNEUM® the #1 performing, preferred and recommended scar gel of plastic surgeons(*). The Company's miraDry Segment, comprised of its miraDry® system, is approved for sale in over 56 international markets and is the only non-surgical, FDA-cleared device indicated for the permanent reduction of underarm sweat and hair and may also reduce odor.

Sientra uses its investor relations website to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Sientra is routinely posted and is accessible on the Company's investor relations website at www.sientra.com.

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, based on management's current assumptions and expectations of future events and trends, which affect or may affect the Company's business, strategy, operations or financial performance, and actual results may differ materially from those expressed or implied in such statements due to numerous risks and uncertainties. Forward-looking statements are made only as of the date of this release. The words "believe," "may," "might," "could," "will," "aim," "estimate," "continue," "anticipate," "intend," "expect," "plan," "position," 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. Forward-looking statements may include information concerning the Company's sales of its OPUS breast implant products in Japan. Such statements are subject to risks and uncertainties, including positive reaction from plastic surgeons and their patients to Sientra's Breast Products and the ability to meet consumer demand. Additional factors that could cause actual results to differ materially from those contemplated in this press release can be found in the "Risk Factors" section of Sientra's public filings with the Securities and Exchange Commission. All statements other than statements of historical fact are forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, and such estimates, projections and other forward-looking statements speak only as of the date they were made, and, except to the extent required by law, the Company undertakes no obligation to update or review any estimate, projection or forward-looking statement. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in the Company's business.

() Data on file*

Contact

Investor Relations
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