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): March 20, 2019

SIENTRA, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-36709	20-5551000
(State or other jurisdiction of incorporation)	(Commission File Number)	(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 March 20, 2019, the Company issued a press release regarding its initial response to the U.S. Food and Drug Administration's (the "FDA") Warning Letter, dated March 19, 2019, relating to the Company's failure to meet the FDA-approved minimum retention rate for a post-approval study.

The full text of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated March 20, 2019.

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: March 21, 2019

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

Exhibit 99.1

Sientra ® Issues Statement in Response to FDA Post-Approval Study Warning Letter

Provides Initial Response to FDA

SANTA BARBARA, Calif., March 20, 2019 — Sientra, Inc. (NASDAQ: SIEN), a medical aesthetics company ("Sientra or the "Company"), today announced it has provided an initial response to the U.S. Food and Drug Administration ("FDA") related to a post-approval study Warning Letter issued on March 19, 2019 and will provide a comprehensive plan for compliance to FDA within 15 days. The Company also issued the following statement:

> Sientra takes this matter seriously and will take all necessary steps to address the topic of the Warning Letter issued by the FDA for one of the Company's post-approval studies. We are working to fully address the points noted with our study's participant retention, including patient questionnaire completion and additional follow-up office visits. We have employed numerous methods to encourage patient participation and look forward to continuing to work collaboratively with the FDA for a prompt resolution.
>
> Our primary focus has always been, and continues to be, upholding the highest levels of patient safety. Importantly, the totality of our clinical and real-world data, including our 10-year Post-Approval Cohort Study (PACS) which included almost 1,800 participants and fully met FDA's compliance requirements, has confirmed the long-term safety and effectiveness of our products. Our peer-reviewed, open-label PACS study is the largest silicone gel breast implant pivotal trial that has occurred in our industry to date.

Sientra looks forward to discussing its plans to achieve compliance at the FDA's General and Plastic Surgery Devices Panel meeting scheduled for March 25-26, 2019.

As a clinically-driven company, Sientra continues to be a leading contributor of physician education and awareness around breast implant safety, and the Company's mission is to provide board-certified plastic surgeons, patients and regulatory officials with balanced, evidence-based information.

The Company noted it believes this matter will not have an adverse impact on its ongoing business or operations.

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, comprises its miraDry ® system, which is approved for sale in over 40 international markets, and is the only non-invasive FDA-cleared device for the permanent reduction of underarm sweat, odor and hair of all colors.

(*) Data on file

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 include, but are not limited to, statements regarding the Company's ability to fully address the topics raised in the FDA's Warning Letter, the Company's plans to achieve compliance with the topics raised in the FDA's Warning Letter, and the impact of the FDA's Warning Letter on the Company's ongoing business or operations. Such statements are subject to risks and uncertainties, including the dependence on conclusion of the audit procedures for the year ended December 31, 2018 by the Company's independent auditors, positive reaction from plastic surgeons and their patients to Sientra's Breast Products, the ability to meet consumer demand, the acceptance and growth of its miraDry segment. 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. 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. 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.

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