

Sientra, Inc.
Form 8-K
September 03, 2015

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): September 3, 2015

SIENTRA, INC.

(Exact Name of Registrant as Specified in Its Charter)

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(State or Other Jurisdiction
of Incorporation)

(Commission
File Number)

(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.

In connection with Sientra, Inc.'s (the *Company*, *Sientra*, *we* or *us*) filing of a Registration Statement on Form S-1 relating to a proposed offering of the Company's common stock, the Company is providing the following information:

Launch of new style and configuration of Silicone Gel Breast Implants. In late August 2015, we introduced a new round breast implant featuring our unique high-strength HSC+ silicone gel which was previously available only in our anatomically shaped breast implants. We believe our new HSC+ round breast implants allow surgeons and patients to benefit from the highly cohesive gel in the form of a more traditional round implant. We believe that prior to this introduction by us, such benefits were only accessible to surgeons in the form of shaped implants. In addition, in the fourth quarter of 2014, we launched a line extension to our line of smooth round silicone gel breast implants that provides a higher fill ratio that we believe is desired by some surgeons. We also recently added 16 additional sizes and configurations of our moderate-plus and high projection round implants. This makes a total of over 195 available shapes, sizes and configurations of our silicone gel breast implants.

Direct-to-Consumer Marketing through Exclusive Campaign with Realself.com. We have expanded our exclusive relationship with Realself.com, or Realself. Realself is one of the world's largest online communities for learning and sharing information about cosmetic procedures with nearly 1.5 million unique users a month specifically interested in breast augmentation. For the first six months of 2015, we saw a strong engagement with the Sientra brand and its value proposition where the Sientra brand held a commanding 56% share of all branded breast implant traffic on Realself. We have also experienced substantial growth in the number of Sientra pages viewed on Realself, which we primarily attribute to the launch of our branded Sientra webpages on Realself in May 2014. From 2013 to 2014, the number of Sientra pages viewed on Realself increased by over 50-fold to over 1.2 million in 2014, approximately 1.0 million of which occurred in the last six months of the year. More recently, as our exclusive relationship with Realself has deepened, the number of Sientra pages viewed on Realself has increased. During the first six months of 2015, the number of Sientra pages viewed on Realself increased to approximately 2.9 million views an approximately 20-fold increase when compared to the first six months of 2014.

In August 2015, we launched our Orange Dot campaign with Realself in which all plastic surgeons who are Sientra customers are identified with an orange dot on their profile. Simultaneously, Sientra has advertisements on Realself that explain that the easiest way to identify a board-certified or board-admissible plastic surgeon is by looking for the orange dot because Sientra sells only to board-certified and board-admissible plastic surgeons.

In addition, we achieved a very high 97% worth it approval rating, a metric that is highly relevant to the site and its members as it indicates their approval, the relevance of the material and their decision making. We believe that such targeted efforts utilizing online communities are important elements of our brand expansion and that further targeting such direct-to-consumer marketing will help build consumer engagement with the Sientra brand and create value for our surgeons for the long-term.

Increased Sales Organization to a total of 46 Plastic Surgery Consultants. During the first half of 2015, we increased the number of plastic surgery consultants, or PSCs, by 7 from 39 to 46, and we plan to continue adding more PSCs in order to obtain broader coverage and deeper account penetration in certain geographic markets.

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Our Eight-Year Follow-Up Data from the pivotal trial that was the basis of PMA Approval in the United States. In May 2015, an update on the eight-year follow-up data from Sientra's ongoing PMA Study of our gel breast implant, authored by Stevens, Harrington, Alizadeh, et al, was published in the peer-reviewed Aesthetic Surgery Journal. Among the significant statistics reported were data on key complications measured among the 1,116 women in the primary-augmentation cohort of Sientra's Core Study, an ongoing 10-year open label, prospective, multicenter clinical study, including:

| | Sientra 8-Year |
|-------------------------------|---------------------------|
| Rupture (overall) | 4.9% |
| (MRI cohort) | 7.2% |
| (non-MRI cohort) | 1.5% |
| Capsular Contracture (III/IV) | 11.2% |
| Reoperation | 20.7% |

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This newly released 8-year follow-up data allows the following summary of Sientra's key clinical data over various follow-up periods:

| | 3-Year | 5-Year | 6-Year | 8-Year |
|--------------------------|----------------------|---------------|---------------|---------------|
| | Kaplan-Meier % (KM%) | | | |
| Rupture (overall) | 0.7 | 2.0 | 3.2 | 4.9 |
| Rupture (MRI cohort) | 2.5 | 4.2 | 5.4 | 7.2 |
| Rupture (non-MRI cohort) | 0.0 | 0.6 | 1.7 | 1.5 |
| Capsular Contracture | 6.0 | 8.8 | 10.0 | 11.2 |
| Reoperation | 12.6 | 16.6 | 18.7 | 20.7 |

Our clinical study was not designed to facilitate head-to-head comparisons with our competitors. However, our clinical data and our competitors' clinical data are publicly available to both surgeons and patients who are able to use such data to compare and contrast competing implants. For example, comparisons of the eight-year follow-up data from our pivotal study to the eight-year follow-up data from our competitors' pivotal studies are shown below:

| | Sientra Pivotal Study | Mentor Pivotal Study | Allergan Pivotal Study |
|----------------------|------------------------------|-----------------------------|-------------------------------|
| Augmentation | (N=1,116) | (N=552) | (N=455) |
| Rupture (overall) | 4.9% | NR | 5.8% |
| Rupture (MRI) | 7.2% | 10.6% (24.2% at 10 years) | 7.7% (8.8% at 10 years) |
| Capsular Contracture | 11.2% | 10.9% | 16.8% |
| Reoperation | 20.7% | 20.1% | 32.1% |

N = Number of patients

NR = Not reported

Key complications by Kaplan-Meier rate (KM%)

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As shown above, Sientra's clinical rupture data at 8 years of follow-up compares favorably to both of our competitors' rupture data at eight years. In addition, in 2015, a rupture trending analysis of data from Sientra's Core Study was published. This study evaluated 1,792 implants (approximately 52% of which were smooth and 48% of which were textured) in 935 patients (implanted at 31 sites with an average follow-up of 6.6 years - range 147 days to 10.6 years) of which 43 implants were ruptured. The study showed that, in each of the first two years following implantation there were 2 or fewer ruptures and, following that, in each of years 3-10, there was a single-digit number of ruptures each year, with no real pattern from year-to-year. The most significant finding of the study was the observation that approximately half of the ruptures originated from three particular surgeons which suggests that surgical technique is a significant factor in rupture rates.

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: September 3, 2015

By: /s/ Joel Smith
Joel Smith
*General Counsel, Secretary and Chief Compliance
Officer*
