

# Sientra, Inc.

## Thanks for the Mammaries

Derek C. Cheung  
Honne Capital  
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# Background and Business

# Background and Business

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- Sientra, Inc. is headquartered in Santa Barbara, California
- Sientra was founded in 2006 by aesthetics industry veterans with venture capital financing
- In April 2007 Sientra gained rights to silicone breast implant clinical trials through the acquisition of Silimed, Inc. (North America)

# Background and Business

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- Sientra received FDA approval for its silicone breast implant products in March 2012
- Since then, Sientra has hired a full sales team, developed a business with revenues tracking \$50 million and has begun working toward profitability
- Breast implants account for virtually all of Sientra's sales
- All of Sientra's products are supplied by Silimed Indústria de Implantes (Silimed), a Brazilian contract manufacturer

# Background and Business

- Sientra's breast implants are made of high-strength cohesive silicone gel

## HSC

(High-Strength Cohesive Silicone Gel)



**The round implant with the strongest cohesive gel on the market, yet soft to the touch.**

- The only round implant made with HSC Silicone Gel for the desired look and feel
- Offers a fuller, more dramatic appearance in the upper portion of the breast
- Available in both a smooth surface and a textured surface

## HSC+

(High-Strength Cohesive Silicone Gel)



**The first FDA-approved shaped breast implant. Not too hard, not too soft.**

- Our proprietary HSC+ Silicone Gel allows the implant to hold its shape without feeling too firm
- Designed to mimic the natural look and feel of a breast
- TRUE Texture® Surface designed to maintain the position of the implant in your body

Source: <http://feelgood.sientra.com/silicone-breast-implants>

# Background and Business

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- Sientra product technology video:



# Background and Business

Market Valuation		Valuation Multiples		
			\$	<i>Multiple</i>
Stock Price	\$4.80			
Diluted Shares Out.	<u>18.0</u>	Revenue 2014	44.7	—
Market Cap	\$86.4	Revenue 2015E <sup>(1)</sup>	53.3	—
Net Cash	<u>(123.0)</u>	EBIT 2014	(5.8)	—
Enterprise Value	(37.4)	EBIT 2015E	—	—
		EPS 2014	(2.28)	—
		EPS 2015E	—	—

1. Sientra FY 2015 revenue guidance reaffirmed on August 12, 2015

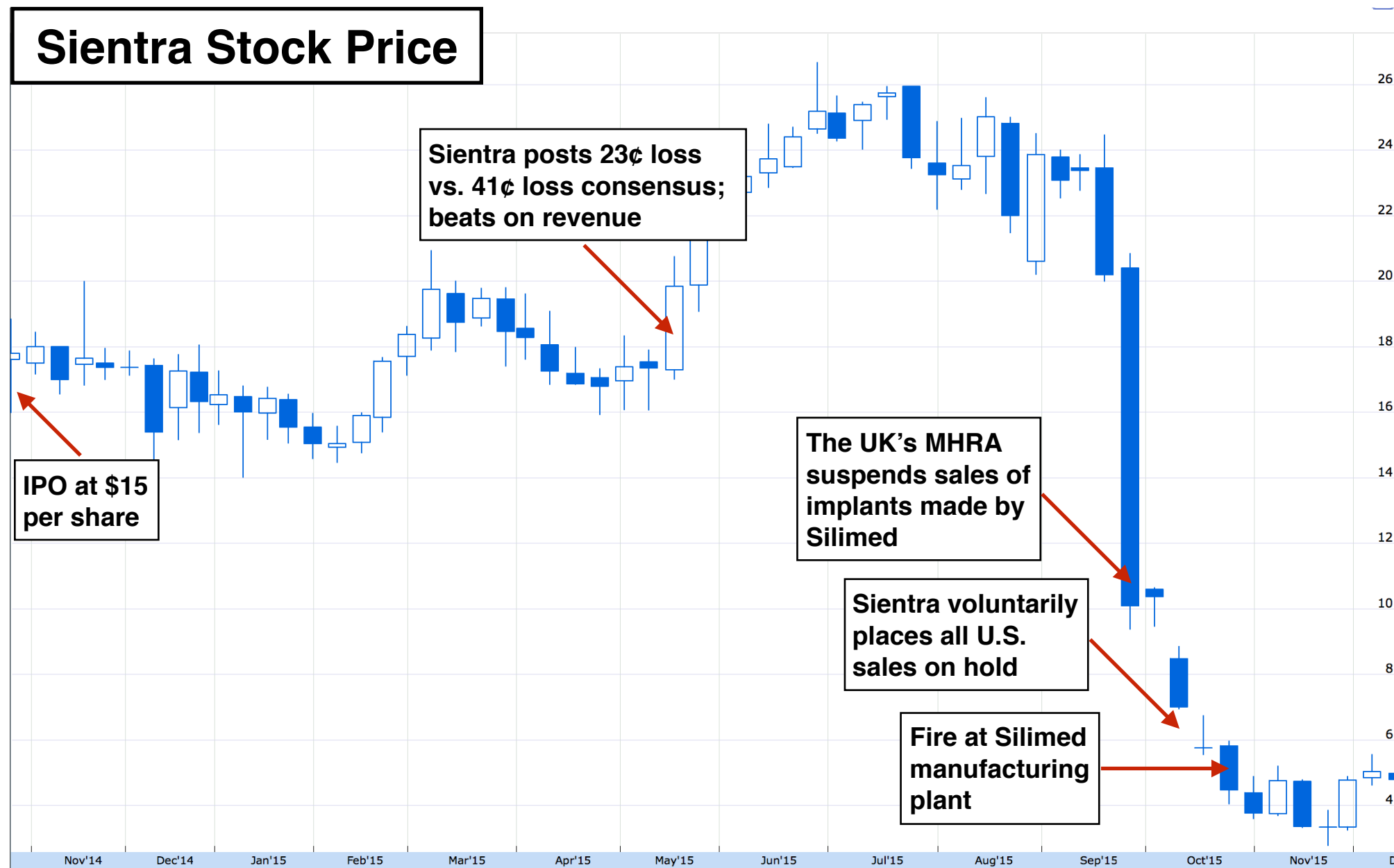


# Background and Business

<i>Fiscal Year Ending 12/31</i>			
<i>\$ (000s omitted)</i>	2012	2013	2014
Net Sales	10,447	35,171	44,733
<i>Growth y/y</i>	<i>n/a</i>	<i>236.7%</i>	<i>27.2%</i>
Operating Loss	(23,432)	(18,207)	(5,785)
<i>Operating Margin %</i>	<i>(124.3%)</i>	<i>(51.8%)</i>	<i>(12.9%)</i>
Other (Expense) Income	(1)	(918)	(26)
Pre-Tax Loss	(23,433)	(19,125)	(5,811)
Income Taxes	n/a	n/a	n/a
Net Loss	(23,433)	(19,125)	(5,811)

Source: Sientra 2014 Form 10-K

# Background and Business



Source: Reuters; Sientra SEC filings

# Silimed Manufacturing Issues

# Particulate-gate

- In September 2015 TÜV SÜD—a German certification organization—inspected Silimed’s manufacturing plant and “established that the surfaces of some devices were contaminated with particles.”
- TÜV SÜD suspended Silimed’s CE certificate, effectively barring Silimed from selling its products in Europe
- The CE marking on a product is a manufacturer’s declaration that the product complies with the essential requirements of European health and safety laws

# Particulate-gate

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- On September 23, 2015, the Medicines and Healthcare Products Regulatory Agency (MHRA), an agency of the United Kingdom, issued a press release announcing the suspension of sales and implanting in the U.K. of all medical devices manufactured by Silimed
- This announcement did not apply to Sientra's products, as Sientra's breast implants are regulated by the FDA only
- Sientra continued to make its breast implants available in the U.S.

# Particulate-gate

- Notably, the MHRA stated that “there has been no indication at this time that these issues would pose a threat to patient safety.”

# Particulate-gate

- On October 2, 2015, the Brazilian regulatory agency ANVISA announced that while it continues to review the technical compliance related to good manufacturing practices of Silimed's manufacturing facility, and due to the announced suspension of the CE certificate, it temporarily suspended the manufacturing and shipment of all medical devices made by Silimed, including products manufactured for Sientra
- ANVISA reiterated that no risks to patient health have been identified in connection with implanting Silimed products

# Particulate-gate - Doctors' Opinions

- “It has been known that particulate matter exists on implants, and these particles are sterilized along with the implant sterilization process. The presence of these sterile particles has not been shown to cause any adverse effects.”
- “The presence of sterile cotton and silica on the surface of silicone implants is common to all three companies’ [(Allergan, Mentor, Sientra)] manufacturing processes.”
- “Implants are routinely washed in betadine or antibiotic solution prior to implantation. Therefore, the particulates are cleansed from the surface of the implant and never make it into the patient’s body.”



# Particulate-gate - Doctors' Opinions

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- “Understand that the silicone particles are most likely from production of the implant shell, so there is nothing different about the material in comparison to the implant itself. Cotton lint is something that will occur with any surgery, due to use of the sterile cotton towels, gauze, and surgical sponges.”
- “There is no evidence of harm that would be caused by either of these, so the European decision is just precautionary until this issue is resolved.”

# Particulate-gate - Wall Street Analysts

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- “While Sientra’s products are manufactured at the same facility where Silimed manufactures the products in question, they follow separate protocols and thus we think it’s premature to extrapolate that the FDA will necessarily take similar action.”
- “Versus the products Silimed makes for the European market, the products Silimed manufactures for Sientra are manufactured in separate runs using different processes (guided by FDA compliance protocols). Therefore it may not be correct to make comparisons between MHRA’s observations and speculated FDA observations.”

# Particulate-gate - Wall Street Analysts

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- “We’d note that Silimed’s last inspection from the FDA—which looked at processes associated with Sientra products and compliance with good manufacturing practices—was in mid-2013. Additionally, the facility has undergone multiple FDA inspections over the last 10 years, and these inspections have never resulted in a Form-483 observation.”

# Particulate-gate - Voluntary Hold

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- On October 9, 2015 Sientra voluntarily placed a hold on the sale of all devices manufactured by Silimed and recommended that plastic surgeons discontinue implanting the devices until further notice
- The FDA has reiterated that no reports of adverse events and no risks to patient health have been identified in connection with implanting Silimed-manufactured products

# Silimed Manufacturing Issues - Fire

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- On October 22, 2015 a fire broke out at one of Silimed's two manufacturing buildings
- The fire occurred in the building where Sientra's breast implants are primarily manufactured (building F2)
- Silimed has indicated that a smaller production facility in building F1, which was not impacted by the fire, has the potential to be modified for breast implant manufacturing

# Sientra's Reaction

# Sientra's Reaction

- On November 12, 2015 Hani Zeini stepped down as CEO and was immediately replaced by Jeffrey Nugent, a Sientra board member since July 2014 <sup>(1)</sup>
- Mr. Nugent conducted successful turnarounds as CEO of four companies: Neutrogena (acquired by Johnson & Johnson), Revlon, Precision Dermatology (acquired by Valeant Pharmaceuticals) and Biolase <sup>(2)</sup>
- “Our immediate priority is to resolve the outstanding regulatory questions, maximize our existing inventory and ensure a stable manufacturing process moving forward.” <sup>(1)</sup>

1. Sientra press release dated November 12, 2015

2. Meet Sientra - Biography

# Sientra's Reaction

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- Sientra is dedicated to its ongoing review, conducted with the assistance of independent experts in quality management systems, to convince the FDA that its products are safe
- In addition, the company is testing its existing finished goods inventory and will continue to be in communication with the FDA prior to resuming shipments
- Current inventory supply is approximately 12 months
- “We expect to be in a position to present our findings to the FDA by the end of calendar year 2015.”



# Sientra's Reaction

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- There is a retention program in place to keep salespeople and other talented employees
- As of September 30, 2015 Sientra had \$148 million of unrestricted cash and only \$25 million of debt
- Sientra subsequently paid off all loans and is conserving its current net cash of over \$100 million

# Market Opportunity

# Reaching Profitability - Revenue

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- Prior to the Silimed manufacturing issues, we estimate that Sientra was on track to reach profitability by Q1 2016
- In March 2015 Sientra provided FY 2015 revenue guidance of between \$52.5 million and \$54 million, with the midpoint representing a YoY increase of 19% <sup>(1)</sup>
- Sientra reaffirmed FY 2015 revenue and gross margin guidance (73%) in August <sup>(2)</sup>

1. Sientra 8-K filed March 11, 2015

2. Sientra 8-K filed August 12, 2015

# Operating Leverage

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- Sientra achieved YoY sales growth in Q2 2015 of 21.2%, which was primarily driven by the increasing size and effectiveness of its sales force and greater familiarity with its products by surgeons
- Marketing dollars appeared to achieve a more efficient outcome after engaging on RealSelf—the world's largest online community for learning and sharing information about cosmetic procedures

# NOL Carryforwards

# NOL Carryforwards

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- As of December 31, 2014 Sientra had federal net operating loss carryforwards of approximately \$101.2 million, which expire in various years beginning in 2027
- Sientra assigns zero value to NOLs on its balance sheet, because existing NOLs may be subject to limitations arising from previous and future “ownership changes”
- Sientra has not completed a section 382 analysis to determine if an ownership change has occurred

# Section 382 Analysis

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- A section 382 “ownership change” occurs if immediately after an owner shift, there is a greater than 50% change in the value of the stock owned by five percent shareholders over a rolling three-year period <sup>(1)</sup>
- Abingworth’s \$65 million Series C funding round in 2012 <sup>(2)</sup> and Sientra’s subsequent IPO may have constituted an ownership change
- If so, Sientra’s NOLs will be limited to approximately \$3.5 million

1. Internal Revenue Code  
2. Sientra Crunchbase profile

# NOL Carryforwards

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- However, there is some probability that Sientra did not undergo an “ownership change”
- Assuming a corporate tax rate of 35%, Sientra’s NOLs would translate into approximately \$35 million of deferred tax assets, or 40% of the current market capitalization
- We expect Sientra to conduct a section 382 analysis upon reaching profitability



# Conclusion

# Conclusion

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- We expect Sientra shares to rerate higher in Q1 2016 once the company reverses the voluntary hold on U.S. sales
- The shares should rerate further higher once Silimed regains manufacturing ability lost from the fire at building F2
- With over \$100 million in cash, zero debt and a year's supply of finished goods inventory Sientra has time to wait for these developments to occur

# Conclusion

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- Sientra trades at a negative enterprise value, despite substantial industry recognition, intellectual property and future earning power
- Sientra has honest and able management in Mr. Jeffrey Nugent, who has led numerous companies through difficult times
- Once Sientra passes the current state of uncertainty, investors will apply a growth premium to the stock
- We expect Sientra shares to double in two years

# Disclaimer

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Funds advised by Honne Capital have purchased shares of Sientra, Inc. This analysis is based on publicly available information, interviews with Sientra's management, the Food & Drug Administration and numerous other industry sources. Honne presents this analysis "as is" and believes the information contained to be reliable. All information provided in this presentation is for informational purposes only and should not be deemed as investment advice or a recommendation to purchase or sell any specific security. Honne reserves the right to change its investment position at any time without further notice to any party.

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