January 22, 2013

Emerging Healthcare Series

JenaValve Technology: Differentiated TAVI system

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GS hosts JenaValve Technology Inc. conference call

In the second edition of the 2013 Goldman Sachs Emerging Healthcare Conference Call Series, we hosted Helmut Staubinger (Chief Executive Officer) and Raymond Cohen (Chairman) of JenaValve Technology Inc. JenaValve Technology is the manufacturer and marketer of the JenaValve, a unique transcatheter-delivered aortic valve implementation system ("TAVI"). A replay of the call is available until February 1, 2013 at 800-332-6854, passcode: 650466.

JenaValve Technology Inc. snapshot

JenaValve Technology is a privately-held and venture-backed US developer, manufacturer and marketer of TAVI systems founded in 2006 and operates out of Munich, Germany. The company's transapical aortic valve system is CE marked since 4Q2011 and currently marketed primarily in Germany with over 250 valves sold in 2012, the first year of commercial sales (revenue totaled ~$6 million). In mid-2013, a clinical study will commence in Europe for the company's transfemoral aortic valve system, which is expected on the market in 2Q2014. The company plans to enter the US market in the future and is also exploring strategic partnerships.

Competitive advantage makes outlook favorable

The JenaValve has unique design features relating to positioning and anchoring during implantation that set the device apart from its larger competitors. The most important of these features are the valve's "feelers". These feelers give the physician tactile feedback, defining the correct anatomical alignment for the valve and guaranteeing accurate placement. Correct alignment significantly reduces paravalvular leakage, stroke, and the need for pacemaker implementation. Clinical results have corroborated JenaValve's claims, showing favorable mortality, no need for pacing during implantation, low rate of post procedure pacemakers and excellent paravalvular leakage data vs. other 2nd generation TAVI systems.

Background on the TAVI market

TAVI is, and should continue to be for several years, the fastest growing medical device market. We estimate the WW market to be $866 million in 2012, growing to $3.1 billion in 2016 (CAGR: 37%). Key public competitors are Edwards Lifesciences (EW; Buy), Medtronic (MDT; Neutral), St. Jude Medical (STJ; Neutral), and Boston Scientific (BSX; Sell). Only EW has a US approved device, while MDT is expected to enter the market in 2014.

David H. Roman
(212) 902-7839 david.roman@gs.com
Goldman, Sachs & Co.

Topher Orr
(212) 902-1017 topher.orr@gs.com
Goldman, Sachs & Co.

Chris Hammond
(212) 357-4031 chris.hammond@gs.com
Goldman, Sachs & Co.

Cameron Hansen
(801) 741-5443 cameron.hansen@gs.com
Goldman, Sachs & Co.

Key takeaways from JenaValve conference call

In the second edition of the 2013 Goldman Sachs Emerging Healthcare Conference Call Series, we hosted Helmut Staubinger and Raymond Cohen, the CEO and Chairman, respectively, of JenaValve Technology Inc.

Key takeaways from the call are as follows:

- **JenaValve presents a differentiated TAVI system**: The JenaValve is a self-expanding porcine pericardial valve with several key features that differentiate it from current valves. Most importantly, the self-expanding stent to which the valve is sewn has three "feelers". These feelers enable the implanting physician to accurately implant the new valve so that it aligns with the patient's native valve. This precise placement mitigates paravalvular leakage, which has been strongly linked to mortality and is a significant concern in other TAVI systems. Further, these feelers prevent the valve from being implanted too low in the ventricle and blocking the atrioventricular node (AV node; the part of the heart that controls electrical impulses in the top of the heart). By preventing the AV node from being blocked, there is no need for rapid pacing during implantation and there is a reduced chance of stroke, in addition to a reduced need for pacemaker implantation post-implant. Once the valve has been inserted, the JenaValve system uses a novel anchoring mechanism to resist migration and lock the valve in the correct anatomical position. The anchoring mechanism works by essentially clipping the patient's native valve between the feelers and the base of the valve, as opposed to primarily radial force in competitor valves. These features, in addition to a low-profile design that allows better blood flow within the heart, have resulted in positive clinical outcomes vs. other second generation devices even when the JenaValve is implanted in a sicker patient population as shown in Exhibit 1.

Exhibit 1: Major outcomes at 30 days in 2nd generation TAVI systems

	JenaValve (n=66)	Symetis (private) (n=90)	Engager (MDT) (n=61)
EuroScore	28.4	20.2	18.9
Mortality	7.6%	7.8%	9.9%
Stroke	3.0%	3.5%	1.8%
Myocardial infarction	0.0%	2.2%	1.8%
Pacemaker implantation	10.6%	11.1%	30.2%
PV leakage (>grade 2)	0.0%	0.0%	3.3%

Source: Company data.

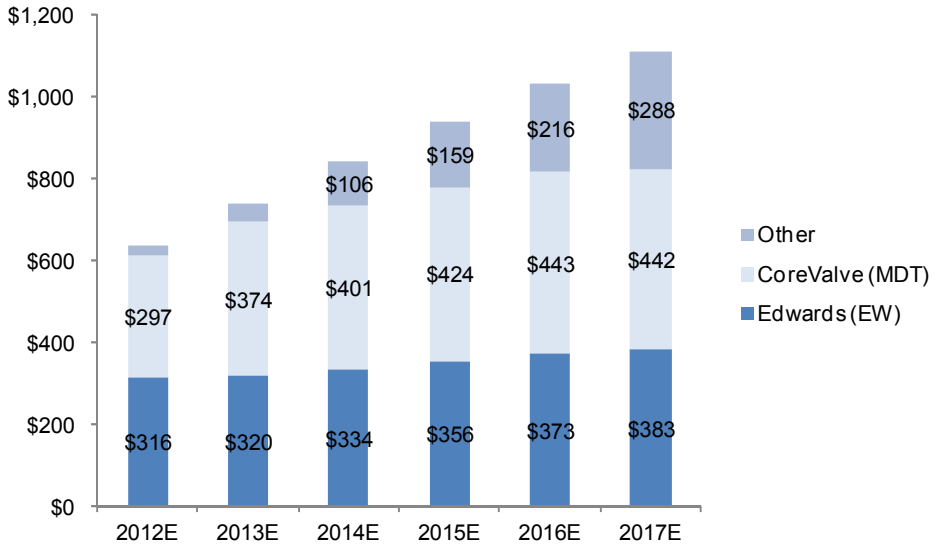
- **JenaValve is focused on developing a long-term commercially sustainable model:** The company was founded in 2006 and is a US corporation, though most operations are currently in Germany where the company also maintains a direct sales organization. In 2012 – its first year with a commercially available product – JenaValve had revenue of about $6 million and a gross margin of over 60%, despite low volumes. During the initial roll-out, JenaValve and its relatively small sales force has targeted high volume centers that are already familiar with TAVI technology. Management is confident it can take share at these centers given the novel, differentiated features of its product and expects to continue to gain share throughout 2013. Going forward, the company plans to increase its production capacity, expand to markets outside of Germany, and

develop new, smaller products, in addition to new surgical access and closure products. While continuing to focus on internal growth and development, the company is also exploring possible strategic partnerships, and we note that JenaValve is an attractive fundamental and strategic asset given its commercially ready product and strong IP portfolio.

- **We remain bullish on TAVI:** We view TAVI as the most significant new product cycle in MedTech, and sales should be sustained by implanting lower risk patients, new products in the US and EU, and further geographic expansion (Japan). Our estimates call for a WW CAGR of 37% from 2012-2016 that will bring the global market to $3.066 billion by 2016, composed approximately of a $1.9 billion US market (71% 2012-2016 CAGR), a $1.0 billion market in the EU (13% 2012-2016 CAGR), and the remainder coming from Japan. This compares with the JenaValve's internal estimates of $809mn and $908mn for the US and EU, respectively, by 2016. The primary reason for the large US delta is our more positive view on second generation devices and the total addressable market (to include younger patients) as the vast majority of the split occurs in 2015 and 2016. We do not estimate that JenaValve will be a major player in the market over the near-term, with Edwards Lifesciences and Medtronic dominating the market. However, we model smaller players to begin taking significant share from the incumbents beginning in 2014. JenaValve has already begun selling in EU (primarily in Germany; 43% of EU implants) and plans to expand once it is approved for both transapical (small incision between the ribs) and transfemoral (percutaneous implant through an artery in the groin) implantation. JenaValve is focused on taking share from Edwards Lifesciences over the near-term, given that Edwards is the only player in transapical market (about 30% of EU TAVI implants).

Exhibit 2: EU TAVI market estimates – 2012-2017

$ in millions



Source: Company data, Goldman Sachs Research estimates.

- **Management is confident the European TAVI market can continue to grow:** There are several short-term factors that are impacting quarter-to-quarter results for TAVI players (government austerity, increased competition, pricing

pressure, reimbursement delays/changes); however, JenaValve management sees a shift from the inoperable patient population to the operable patient population overshadowing any short-term concerns and providing sustainable market growth for several years. This shift will be driven by new products and improved technology, in addition to more clinical data demonstrating superior outcomes (particularly data regarding durability). Management believes that governments will not be able to ignore TAVI since it is likely to be a key element in the future of cardiac surgery, and while markets such as Spain and Italy may be struggling, these countries are relatively not that impactful to the overall health of the TAVI market.

- **Of the public players, we still favor EW:** We continue to see Buy-rated Edwards Lifesciences as the most attractive player in the TAVI market given the company's high-exposure TAVI (about 30% of 2012E sales growing to nearly 60% by 2016E). Additionally, JenaValve management pointed out that other hopeful players potentially have issues with their devices. For instance, Boston Scientific's valve system (Lotus; expected CE Mark approval in 1H2013) shortens significantly once it is released from its catheter, potentially causing implantation issues, and the device may be difficult to manufacture. With regard to St. Jude, the company's Portico device (received CE Mark approval in late 2012) may not be differentiated enough from Medtronic's CoreValve for physicians to truly consider it a viable alternative.

Ratings and pricing information

Boston Scientific Corp. (S/N, $6.70), Edwards Lifesciences Corp. (B/N, $94.56), Medtronic, Inc. (N/N, $45.67) and St. Jude Medical, Inc. (N/N, $39.45)

Disclosure Appendix

Reg AC

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