Zacks Small-Cap Research

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Brian Marckx, CFA
bmarckx@zacks.com
Ph (312) 265-9474

scr.zacks.com

10 S. Riverside Plaza, Chicago, IL 60606

Lombard Medical (EVAR-NASDAQ)

EVAR: Altura / IntelliFlex LP Will Add Fuel to 2016

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	03/23/2015
Current Price (02/23/16)	$.0.89
Target Price	**$4.00**

OUTLOOK

Aorfix, Lombard's flagship device, is the only AAA stent-graft approved for neck angles greater than 60 degrees – which represents ~20% - 30% of the AAA population. Aorfix has been available in Europe and more recently launched in the U.S. and Japan.

While Aorfix appears to have had meaningful success in the high neck angle indication, it looks to have underperformed expectations in standard anatomy segment. This has resulted in downward revisions to estimates.

EVAR recently acquired Altura, an ultra-low profile AAA stent graft in order to more fully penetrate the low neck angle segment. EVAR is now only company with products on-label for all AAA patient anatomies. Altura just launched and feedback is very positive. IntelliFlex LP to launch in 2016. Both products should help fuel additional revenue growth. EVAR beefed up Europe sales teams to support launches. U.S. strategy is now one of wringing out efficiencies of sales force instead of expansion.

SUMMARY DATA

52-Week High	**$5.92**
52-Week Low	**$0.55**
One-Year Return (%)	**-84.09**
Beta	**N/A**
Average Daily Volume (sh)	**75,967**
Shares Outstanding (mil)	**16**
Market Capitalization ($mil)	**$18**
Short Interest Ratio (days)	**0.38**
Institutional Ownership (%)	**80**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Value**
Industry	**Med Instruments**

ZACKS ESTIMATES

Revenue
(in 000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	3.4 A	4.5 A	4.2 A	2.9 A	15.1 A
2016	3.4 E	3.9 E	4.6 E	5.1 E	17.0 E
2017					23.9 E
2018					30.2 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.59 A	-$0.51 A	-$0.45 A	-$0.58 A	-$2.13 A
2016	-$0.49 E	-$0.46 E	-$0.46 E	-$0.40 E	-$1.80 E
2017					-$0.92 E
2018					-$0.77 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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Q4 Financial Results: *Q4 Less Than Exciting, But Continue To Look For Altura and IntelliFlex LP To Power 2016 …*

Lombard announced financial results for the fourth quarter ending December 31st. Revenue, as expected following the company's preannouncement in January, came in at $2.9M in Q4. Revenue for the full year was $15.1M – while up almost 14% (+18% on constant currency) from 2014, this is at the low end of management's revised guidance (provided with Q3 earnings release) and well below the $18M - $20M the company was shooting for earlier in 2015. The Q4 number represents contractions of 31% and 39% sequentially (from $4.2M in Q3 2015) and yoy (from $4.8M in Q4 2014), respectively.

Other than a relatively strong showing from sales in the U.K. there were few highlights in the Q4 revenue numbers. Every other itemized territory experienced a yoy revenue contraction and Germany, Japan (revenue contraction in Japan due to stocking order in prior year) and ROW also saw sales fall on a sequential basis. Germany has been a particular disappointment given that this was an area which looked to hold more promise given its large size and reliable reimbursement. Sales in that country fell each of the four quarters in 2015 and similarly missed our respective estimates. Lombard expects Europe to return to growth in 2016, buoyed by introduction of IntelliFlex LP and Altura.

However, the full year numbers were much more palatable in the U.S. and Japan, both of which turned in 42% growth. And while Japan benefitted from significant inventory stocking earlier in the year, fundamentals there appear strong. And to be fair, the 75% yoy contraction in Japan sales in Q4 relates to inventory stocking in the year-earlier period, not to lack of demand or procedural volume. In fact management noted on the call that Aorfix has already garnered 6% share of the Japanese market with procedural volume growing from 112 cases in 2014 to 436 in 2015. And while U.S. sales also fell in Q4, they were down less than 2% and would have shown positive growth if not for adverse effects of currency exchange rates.

While anecdotally, Aorfix uptake in high neck angulations (>60 degrees) has been meaningful, we think adoption among less challenging anatomies (i.e. 0 to 60 degrees) is likely falling short of what had been expected given the number of competing stent grafts on the market, including ultra-low diameter (i.e. 14f) devices. We think this reflects the relative weakness in sales, downward revenue guidance during 2015 and the impetus in acquiring Altura.

As the company's previous indicated intentions, they added 2 to 3 reps to their direct sales forces in both Germany and the U.K. to support the launch of IntelliFlex LP (lower profile delivery system) as well as Altura (recently acquired ultra-low profile, 14f, AAA stent graft). But, in a recent change in strategy, instead of increasing the size of the direct sales force in the U.S., Lombard has instead reduced it and is concentrating their efforts in the most productive territories of the country. While the about-face in the U.S., from one of expansion to now one of contraction/concentration, is revealing of lower adoption of Aorfix (likely in the standard anatomy segment), it should increase efficiency of the sales force and provide some expense containment. The U.S. sales force, which averaged about 32 reps throughout 2015 and ended the year at around 25, has been trimmed to just 10.

Lombard is guiding for revenue to grow approximately 20% in 2016. While the guidance was not product-specific, clearly much of the anticipated growth is related to Altura, which just launched in Europe in late January, as well as IntelliFlex which is expected to enter Germany and the U.K. around mid-year and, possibly, the U.S. later in 2016. We note that our model assumes a more conservative revenue growth rate for 2016 as compared to company guidance as we assume IntelliFlex LP does not reach the U.S. market until 1H 2017 and we assume contraction of Aorfix sales in some territories.

While Lombard still expects IntelliFlex to launch in Europe in late Q2/early Q3 (following requisite CE Marking), the anticipated U.S. introduction has been pushed back. Submission seeking FDA clearance was made in December 2015 and management had been guiding for regulatory approval and launch to happen by Q1 (i.e. current quarter). However, FDA responded (~mid-February) to the filing asking for supporting clinical data. While study protocol has yet to be confirmed with the agency (EVAR expects to submit this in the coming days), Lombard believes a small (~20-30 patients), short (30-day follow-up) study will be deemed sufficient. If that is the case management thinks they can complete the study, compile and submit the supplemental information and have FDA clearance and launch prior to current year-end.
We continue to model contribution from IntelliFlex LP in Europe starting in 2H 2016 but have pushed back anticipated initial introduction in the U.S. until 1H 2017 (from Q2 2016) as we think the delay caused by the requisite clinical trial may mean the device does not make it to the U.S. market until sometime next year. And as launch in

Japan is expected to follow that of the U.S., initial contribution in that country has similarly been pushed back in our model. And while the U.S. delay is a disappointment, in a big-picture view, it should be relatively meaningless as once on the market, we expect IntelliFlex to provide a meaningful and long-term additional revenue opportunity.

Altura should be an even more significant driver of revenue. A significant factor that played into Lombard's decision to pull the trigger on Altura was that the device gave them the sole position as a provider of products for on-label use in both high neck angles and standard anatomies – the benefit to providers is that EVAR is now a one-stop shop for all anatomies. That benefit could be significant in terms of facilitating uptake of both products. And this being an add-to-the-bag product targeting the exact same call-points as Aorfix means this should be a seamless fit to, and leverage off of, EVAR's existing sales/marketing infrastructure.

The device, which is already CE Marked and began rolling out in late January in Germany and the U.K., provides the opportunity to take more significant share of the standard anatomy market. We think Altura should be very well received given its ultra-low 14f profile (only TRIV's Ovation Prime and Cordis' InCraft have 14f profiles), simplicity and ease of use. In addition, the standard anatomy segment is 3x – 5x larger than that of the high neck angle segment.

With Altura, Lombard expects to target about 20 reference centers (10 Germany,10 U.K.) for the initial introduction. Management noted on the call that they are already in five of these and have done multiple cases in most. Feedback has been very positive. The recent addition to the German and U.K. sales forces along with case presentations (such as the live case at LINC Germany in January) will facilitate the launch and broader roll-out, the latter which EVAR expects to begin in Q2. Meanwhile, the gameplan continues to be to roll out Altura to other European countries, such as Spain and Italy (via existing 3rd-party distribution), later in 2016.

Q4 Numbers…

Total revenue fell 38% yoy and was down 30% sequentially. As noted, every itemized territory except U.K., where revenue grew 31% from the year-earlier period, experienced a yoy revenue contraction. Germany has been very weak and saw sales fall 35% for the full year. But while Japan was down almost 74% in Q4, the prior year period revenue of ~$2M was all stocking, making the comparison unfair. And as we noted, demand in Japan is very robust and appears to be growing steadily with Aorfix already claiming ~6% market share after only five quarters following launch and procedural volume growing from 112 cases in 2014 to 436 in 2015. And while U.S. revenue was just slightly less than flat in Q4, it was up almost 42% for the year – and this is in the face of a strong FX headwind – which understates the domestic revenue growth.

Q4 gross margin was a relatively paltry 28.2% (GM had averaged ~49% in first 3 qtrs of 2016) which management attributed to lower fixed cost absorption (from lower sales), initiating the transition of manufacturing of IntelliFlex LP to the U.K. and some launch preparation of Altura. EVAR expects GM to come back to around historical levels once the manufacturing transition of IntelliFlex LP and Altura to the U.K. has been completed. We ballpark this to be done mid-year which is reflected in our modeled step-up in GM throughout 2016.

Q4 operating expenses were also less than exciting. S&M was up from Q3 and about flat from the prior year period but this was on sales that were down by 38% over the same time. R&D and Admin expenses were also up meaningfully from Q4 2014 but also from Q3 2015. But, the good news is that headcount reductions to the U.S. sales force and some operational and manufacturing streamlining are expected to result in OpEx falling in 2016 as compared to 2015. And while we had been anticipating a step-up in R&D expense in 2016 related to a U.S. IDE study for Altura, this is now not expected to begin until early 2017 (following receipt of FDA approval of IDE).

Q4 EPS was ($0.58) compared to our ($0.52) estimate. EVAR exited the year with $32.3M in cash and equivalents, which they believe is sufficient to fund operations at least until Q3 2016 and as long as Q1 2017. EVAR also has $5M yet to draw on the Oxford term loan, which is available if they hit certain revenue targets by 12/31/2016.

VALUATION / RECOMMENDATION

We value EVAR using 10-year DCF. While our model assumes a rate of continued innovation of Aorfix commensurate with the pace of the industry, we do not currently include any contribution from introduction of new products (other than Altura and IntelliFlex LP) such as a TEVAR stent-graft which the company has talked in the past about potentially pursuing. As such new product introductions, unrelated specifically to Aorfix or Altura, could provide upside to our model and related valuation.

We model 10-year revenue CAGR of 21%, gross margin widening from 45% to 71% over that period. We look for OpEx to eventually scale but now (following the Altura acquisition) forecast more elongated significant operating losses related to development of Altura for the U.S. and Japanese markets. Our 10-year DCF model, which uses an 11% discount rate and 2% terminal growth rate, values EVAR at approximately $4/share.

FINANCIAL MODEL

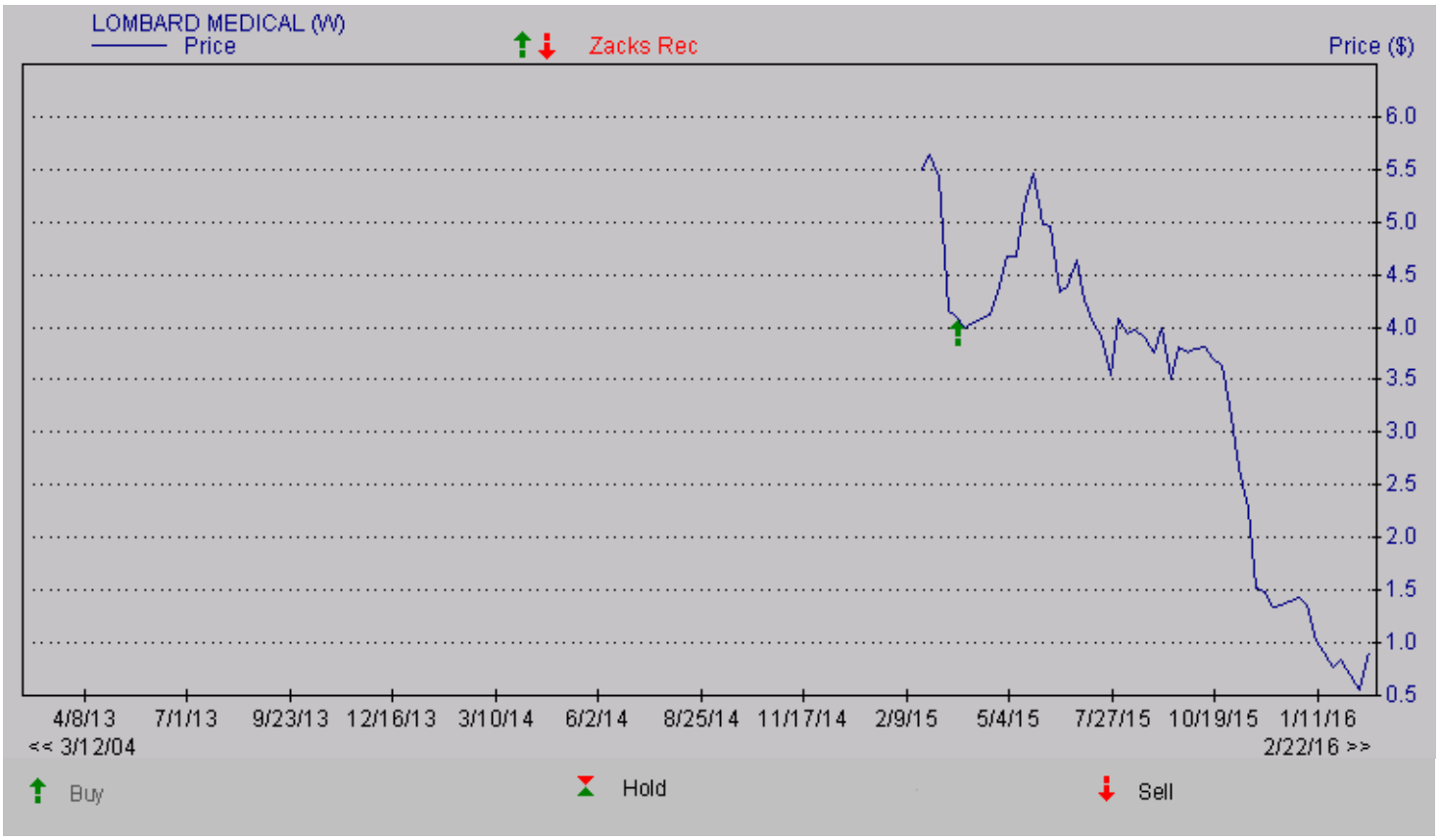
Lombard Medical, Inc.

	2015 A	Q1E	Q2E	Q3E	Q4E	2016 E	2017 E	2018 E	2019 E
Total Revenues	$15,114.0	$3,361.0	$3,892.0	$4,597.0	$5,128.0	$16,978.0	$23,896.0	$30,229.4	$36,742.3
YOY Growth	*13.8%*	*-1.4%*	*-14.2%*	*8.8%*	*74.2%*	*12.3%*	*40.7%*	*26.5%*	*21.5%*
Cost of Goods Sold	$8,296.0	$2,184.7	$2,432.5	$2,666.3	$2,871.7	$10,155.1	$12,425.9	$12,847.5	$14,109.0
Gross Income	$6,818.0	$1,176.4	$1,459.5	$1,930.7	$2,256.3	$6,822.9	$11,470.1	$17,381.9	$22,633.2
Gross Margin	*45.1%*	*35.0%*	*37.5%*	*42.0%*	*44.0%*	*40.2%*	*48.0%*	*57.5%*	*61.6%*
Sell, Mktg & Dist	$23,125.0	$5,194.0	$5,431.0	$5,621.0	$6,001.0	$22,247.0	$24,174.8	$25,380.3	$28,948.2
% SM&D	*153.0%*	*154.5%*	*139.5%*	*122.3%*	*117.0%*	*131.0%*	*101.2%*	*84.0%*	*76.7%*
R&D	$11,279.0	$3,116.0	$3,024.0	$2,844.0	$2,947.0	$11,931.0	$15,481.0	$30,420.0	$13,562.0
% R&D	*74.6%*	*92.7%*	*77.7%*	*61.9%*	*57.5%*	*70.3%*	*64.8%*	*100.6%*	*28.2%*
Admin	$11,707.0	$2,651.0	$2,359.0	$2,961.0	$3,282.0	$11,253.0	$12,142.0	$12,644.0	$12,933.3
% Admin	*77.5%*	*78.9%*	*60.6%*	*64.4%*	*64.0%*	*66.3%*	*50.8%*	*41.8%*	*35.2%*
Operating Income	($39,293.0)	($9,784.7)	($9,354.5)	($9,495.3)	($9,973.7)	($38,608.1)	($40,327.7)	($51,062.4)	($32,810.3)
Operating Margin	*-260.0%*	*-291.1%*	*-240.4%*	*-206.6%*	*-194.5%*	*-227.4%*	*-168.8%*	*-168.9%*	*-89.3%*
Total Other Income (Expense)	($726.0)	($379.0)	($385.8)	($485.3)	($482.3)	($1,732.3)	($1,872.3)	($1,678.5)	($750.2)
Pre-Tax Income	($40,019.0)	($10,163.7)	($9,740.3)	($9,980.5)	($10,455.9)	($40,340.3)	($42,200.0)	($52,740.9)	($33,560.5)
Tax expense (benefit)	($2,215.0)	($508.2)	($487.0)	($499.0)	($522.8)	($2,017.0)	($844.0)	($1,054.8)	($671.2)
Tax Rate	*5.5%*	*5.0%*	*5.0%*	*5.0%*	*5.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*
Net Income	($37,804.0)	($9,655.5)	($9,253.2)	($9,481.5)	($9,933.1)	($38,323.3)	($41,356.0)	($51,686.1)	($32,889.3)
YOY Growth	*8.8%*	*1.4%*	*12.5%*	*8.8%*	*-4.4%*	*1.4%*	*7.9%*	*25.0%*	*-36.4%*
Net Margin	*-250.1%*	*-287.3%*	*-237.8%*	*-206.3%*	*-193.7%*	*-225.7%*	*-173.1%*	*-171.0%*	*-89.5%*
EPS	($2.13)	($0.49)	($0.46)	($0.46)	($0.40)	($1.80)	($0.92)	($0.77)	($0.44)
YOY Growth	*-10.8%*	*-20.6%*	*-9.7%*	*1.8%*	*-8.7%*	*-15.7%*	*-48.8%*	*-16.1%*	*-43.2%*
Diluted Shares O/S	17,745	19,900	20,000	20,500	25,000	21,350	45,000	67,000	75,000

Brian Marckx, CFA

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