Zacks Small-Cap Research

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Lombard Medical (EVAR-NASDAQ)

EVAR: Altura Feedback Positive, Resources Shifted to EU To Support Launch

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.

Current Price (05/16/16)	$1.39
Valuation	**$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	**$5.67**
52-Week Low	**$0.55**
One-Year Return (%)	**-72.55**
Beta	**1.39**
Average Daily Volume (sh)	**70,716**
Shares Outstanding (mil)	**20**
Market Capitalization ($mil)	**$28**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**65**
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	2.9 A	3.6 E	4.5 E	5.0 E	16.0 E
2017					23.6 E
2018					29.8 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	-$0.38 A	-$0.40 E	-$0.40 E	-$0.41 E	-$1.60 E
2017					-$0.92 E
2018					-$0.77 E

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

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Q1 Financial Results / Operational Update: *Altura Feedback Positive, Resources Shifted to EU in Support of Launch..*

Lombard reported financial results for the first quarter ending March 31. While revenue remained tempered, falling 14% yoy and missing our numbers fairly sizably in three of the five itemized territories and beating only slightly in one (with the other inline), management reiterated guidance of 20% revenue growth for the full year.

With what EVAR describes as an extraordinary response to the controlled launch of Altura and encouraging physician feedback to its performance and ease of use, Lombard expects demand to blossom for their recently acquired ultra-low profile AAA stent graft. Altura began rolling out in a select number of reference centers in the U.K. and Germany in February and with 57 procedures already performed, appears to be off to a strong start. Management noted on the call that 19 of their initial targeted 20 reference centers have done at least one Altura procedure and 17 have done more than one. Additional centers are expected to come online in the very near term and coupled with headcount additions to the European sales force, impending entry into other international territories and budding awareness of the benefits of Altura, a much more substantial revenue contribution from the device is expected to begin later this year.

We think awareness-building will be a key focus to help drive demand. While the ground campaign should benefit from incremental rep additions, the heavy lifting will rely on case data and positive patient outcomes. Initial data, through 30 days post-procedure, from an ongoing 5-year follow up study in 57 patients was announced today (May 17th) showing no instances of rupture or need to abandon the AAA procedure and convert to open surgery. Other endpoints, including device delivery success, freedom from Type I/III endoleaks and freedom from graft occlusion were also positive. The data is expected to be published later this year.

•Device delivery success	98%
•Freedom from Type I/III endoleaks	98%
•Freedom from rupture	100%
•Freedom from conversion to open procedure	100%
•Freedom from graft occlusion	98%

Lombard will also push the unique benefits of Altura as compared to the other (2) 14f AAA stent grafts currently on the market – those benefits being greater ease of use (including non-polymer sealing and no cannulation) and greatly reduced inventory requirements as compared to competing systems. Lombard noted on the Q1 call that they expect to publish on these unique benefits in the near future. In addition, Lombard is initiating a patient registry which will document case data on 1k patients, collecting information on both the performance of Altura as well as the ease-of-use and cost benefits.

Relative to IntelliFlex, EVAR's lower profile delivery system for Aorfix, management is still guiding for launch in Germany and the U.K. around the middle of this year. This is contingent on receipt of CE Marking – which EVAR expects in Q2. Similar to the Altura introduction, IntelliFlex is also projected to receive a warm welcome.

In Japan Aorfix procedural volume continues to rapidly grow with 147 Aorfix cases performed in Q1, up from just 85 and 128 in Q1 and Q4 of last year, respectively. But this growth has not been reflected in the flattish sales (at ~$500k) the last two quarters due to inventory-burn of the legacy Aorflex delivery system in anticipation of the IntelliFlex introduction. This could reverse, however, as PMDA (Japan regulatory) approval of IntelliFlex may happen prior to current year-end and result in potentially significant initial inventory stocking orders. As a reminder, in Q3 2014 EVAR booked $1.6M of revenue related to an initial inventory stocking order of Aorfix from its Japanese distributor following the August 2014 PMDA approval of the device.

Lombard is now shifting some resources from the U.S., where uptake of Aorfix in less challenging anatomies (i.e. 0 to 60 degrees) has clearly fallen short of earlier expectations, to their European direct sales territories to support the (ongoing) Altura and (impending) IntelliFlex roll-outs. The U.S. sales force was slashed from ~27 at 2015 year-end to just 10 currently. The initial effect was obvious in the Q1 numbers which showed a dramatic drop in SG&A. And while U.S. sales were down 24% yoy and 27% from Q4 2015, sales and marketing expenses fell by an even greater 34% and 29%, respectively, reflecting significant sales rep productivity gains. In addition, Lombard cut administration expenses by 28% and 48% as compared to the same periods.

U.S. sales should return to growth following the domestic launch of IntelliFlex, expected timing of which was recently pushed back but which could possibly still materialize before current year-end. As a reminder, EVAR filed for FDA clearance in December 2015 – at that time management was guiding for U.S. launch in Q1 2016. However, FDA responded (~mid-February) asking for supporting clinical data. Lombard expects to conduct a small (~30 patients), short (30-day follow-up) study. Management noted on the call that if they have IDE approval and initiate enrollment by August, that they believe they can file and have FDA clearance by the end of this year. We think this may be a somewhat aggressive timeline and continue to model initial launch in the U.S. in 1H 2017. And as launch in Japan is expected to follow that of the U.S., initial contribution in our model from that country also begins next year.

Update on Altura U.S. Regulatory Program…
Lombard expects to submit an IDE to FDA this summer for approval to begin a U.S. PMA study for Altura. The company anticipates total enrollment of approximately 150 patients and 12 month follow-up. They currently anticipate IDE approval and initiation of enrollment sometime in 1H 2017.

Q1 Numbers…
Total revenue fell 14% yoy and was flat on a sequential basis. While the U.K. and Germany both posted high single-digit gains compared to Q1 2015 which were likely aided by contribution from Altura (launched in those areas in February), that growth along with a 16% increase in ROW sales were more than offset by 24% and 43% declines in the U.S. and Japan, respectively. As noted, U.S. sales were impacted by a ~60% reduction in the sales force (although rep productivity gains offset some of the impact from headcount reduction). And while fundamentals remain strong in Japan with procedural volume and market share gains continuing to grow (EVAR estimates Aorfix now has 7.5% market share), revenue contribution continues to be impacted by the distributor burning through remaining Aorflex inventory in anticipation of the launch of IntelliFlex.

Q1 gross margin was 34% - while up significantly from the 28% posted in Q4 2015, it was well below the 46% of Q1 2015. Management attributed the recent contraction in GM 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 on revenue growth and following completion of the manufacturing transition of IntelliFlex LP and Altura to the U.K.

Operating expenses were a particular highlight in Q1. At $8.3M, they were at the lowest level since Q1 2014 (when revenue was just $2.1M) and down 27% and 35% as compared to Q1 ($11.3M) and Q4 ($12.8M) of last year. Headcount reductions to the U.S. sales force had a significant positive impact and, along with some operational and manufacturing streamlining, should continue to benefit the remainder of 2016. 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).

Q1 EPS was ($0.38), well ahead of our ($0.49) estimate. While revenue came in 32% lower than our forecast ($3.4M E vs. $2.9M A), this was more than offset by the beat on OpEx ($11.0M E vs. $8.3M A). EVAR exited Q1 with $22M in cash and equivalents, which they believe is sufficient to fund operations through the end of 2016.

VALUATION

While management is guiding for revenue growth of 20% in 2016, we look for 6% growth. The difference is mostly related to our assumption that initial IntelliFlex sales begin next year (we model 48% revenue growth from 2016 to 2017). 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.

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FINANCIAL MODEL

Lombard Medical, Inc.

	2015 A	Q1A	Q2E	Q3E	Q4E	2016 E	2017 E	2018 E	2019 E
Total Revenues	$15,114.0	$2,922.0	$3,642.0	$4,472.0	$4,956.0	$15,992.0	$23,580.7	$29,783.7	$36,189.5
YOY Growth	*13.8%*	*-14.3%*	*-19.7%*	*5.8%*	*68.4%*	*5.8%*	*47.5%*	*26.3%*	*21.5%*
Cost of Goods Sold	$8,296.0	$1,938.0	$2,323.6	$2,651.9	$2,839.8	$9,753.3	$12,497.8	$12,955.9	$14,258.7
Gross Income	$6,818.0	$984.0	$1,318.4	$1,820.1	$2,116.2	$6,238.7	$11,082.9	$16,827.8	$21,930.8
Gross Margin	*45.1%*	*33.7%*	*36.2%*	*40.7%*	*42.7%*	*39.0%*	*47.0%*	*56.5%*	*60.6%*
Sell, Mktg & Dist	$23,125.0	$4,110.0	$4,605.0	$4,818.0	$5,612.0	$19,145.0	$23,864.1	$25,022.6	$28,532.6
% SM&D	*153.0%*	*140.7%*	*126.4%*	*107.7%*	*113.2%*	*119.7%*	*101.2%*	*84.0%*	*76.7%*
R&D	$11,279.0	$2,306.0	$2,581.0	$2,644.0	$2,956.0	$10,487.0	$15,481.0	$30,420.0	$13,562.0
% R&D	*74.6%*	*78.9%*	*70.9%*	*59.1%*	*59.6%*	*65.6%*	*65.7%*	*102.1%*	*28.2%*
Admin	$11,707.0	$1,888.0	$2,057.0	$2,216.0	$2,453.0	$8,614.0	$11,008.0	$12,644.0	$12,738.7
% Admin	*77.5%*	*64.6%*	*56.5%*	*49.6%*	*49.5%*	*53.9%*	*46.7%*	*42.5%*	*35.2%*
Operating Income	($39,293.0)	($7,320.0)	($7,924.6)	($7,857.9)	($8,904.8)	($32,007.3)	($39,270.2)	($51,258.8)	($32,902.5)
Operating Margin	*-260.0%*	*-250.5%*	*-217.6%*	*-175.7%*	*-179.7%*	*-200.1%*	*-166.5%*	*-172.1%*	*-90.9%*
Total Other Income (Expense)	($726.0)	($491.0)	($504.0)	($606.0)	($606.0)	($2,207.0)	($1,872.3)	($1,678.5)	($750.2)
Pre-Tax Income	($40,019.0)	($7,811.0)	($8,428.6)	($8,463.9)	($9,510.8)	($34,214.3)	($41,142.4)	($52,937.3)	($33,652.7)
Tax expense (benefit)	($2,215.0)	($205.0)	($421.4)	($423.2)	($475.5)	($1,525.2)	($822.8)	($1,058.7)	($673.1)
Tax Rate	*5.5%*	*2.6%*	*5.0%*	*5.0%*	*5.0%*	*4.5%*	*2.0%*	*2.0%*	*2.0%*
Net Income	($37,804.0)	($7,606.0)	($8,007.2)	($8,040.7)	($9,035.2)	($32,689.1)	($40,319.6)	($51,878.6)	($32,979.6)
YOY Growth	*8.8%*	*-23.6%*	*-2.2%*	*-3.6%*	*-6.8%*	*-13.5%*	*23.3%*	*28.7%*	*-36.4%*
Net Margin	*-250.1%*	*-260.3%*	*-219.9%*	*-179.8%*	*-182.3%*	*-204.4%*	*-171.0%*	*-174.2%*	*-91.1%*
EPS	($2.13)	($0.38)	($0.40)	($0.40)	($0.41)	($1.60)	($0.90)	($0.77)	($0.44)
YOY Growth	*-10.8%*	*-40.9%*	*-23.0%*	*-8.5%*	*-8.1%*	*-25.0%*	*-44.0%*	*-13.6%*	*-43.2%*
Diluted Shares O/S	17,745	19,886	19,900	20,000	22,000	20,447	45,000	67,000	75,000

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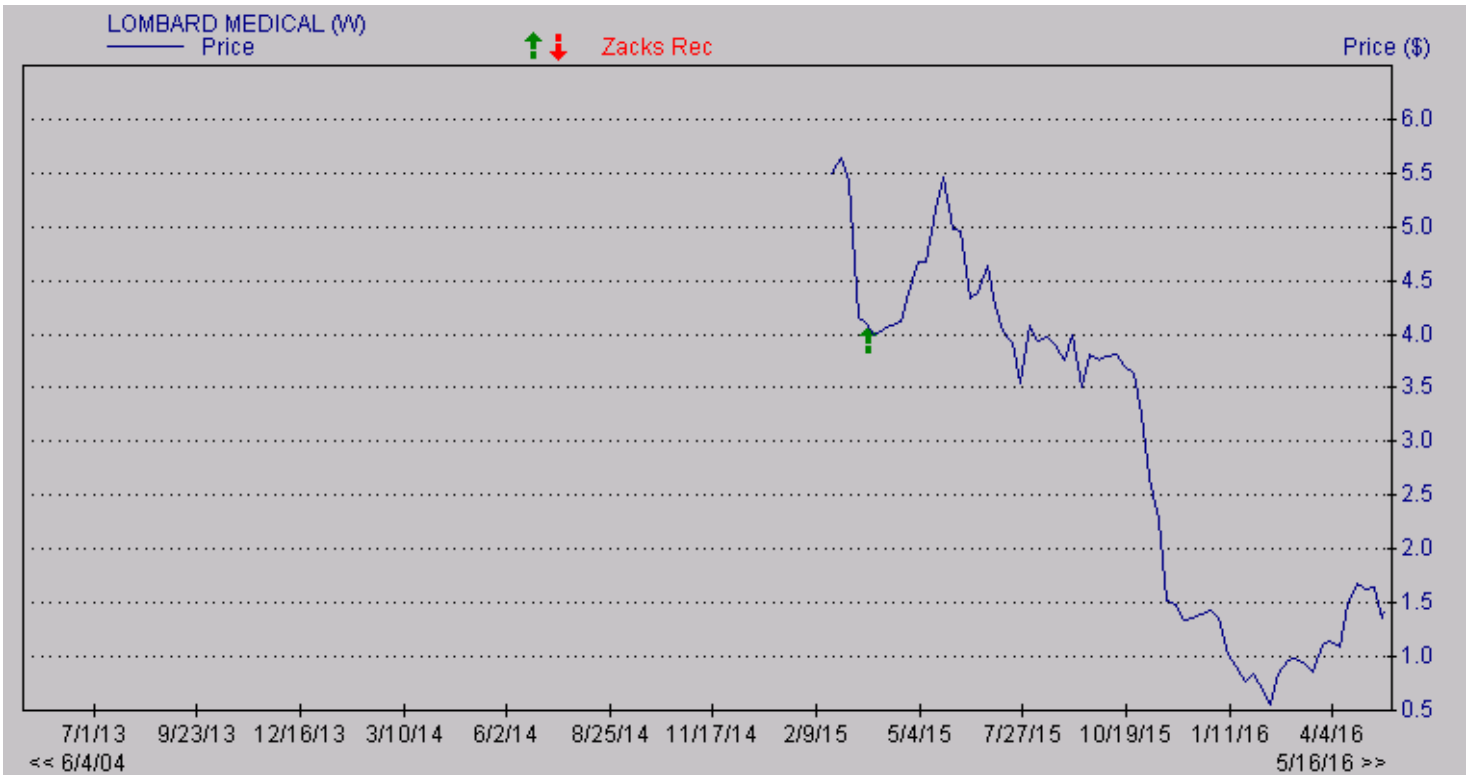

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