Zacks Small-Cap Research

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Lombard Medical (EVAR-NASDAQ)

EVAR: Altura Acquisition, Not Cheap But Makes Sense

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	03/23/2015
Current Price (08/04/15)	$3.78
Target Price	**$8.50**

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 just launched in the U.S. and Japan, receiving warm receptions. We think Aorfix can take meaningful share from competing devices which have been used off-label for high neck angles and expect it to see meaningful demand across all patient anatomies (as it has in Europe). EVAR market growth looks attractive, catalyzed by ongoing shift from open surgery, AAA screening and increasing health/age-related issues.

SUMMARY DATA

52-Week High	**$9.99**
52-Week Low	**$3.55**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**20,744**
Shares Outstanding (mil)	**16**
Market Capitalization ($mil)	**$60**
Short Interest Ratio (days)	**0.32**
Institutional Ownership (%)	**76**
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 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**N/A,**
Type of Stock	**Small-Value**
Industry	**Med Instruments**

ZACKS ESTIMATES

Revenue
(in 000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	2.1 A	2.2 A	4.3 A	4.8 A	13.2 A
2015	3.4 A	4.5 A	4.6 E	5.6 E	18.1 E
2016					26.6 E
2017					43.7 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.62 A	-$0.86 A	-$0.52 A	-$0.51 A	-$2.39 A
2015	-$0.59 A	-$0.51 A	-$0.59 E	-$0.61 E	-$2.30 E
2016					-$2.24 E
2017					-$1.09 E

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

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WHAT's NEW…

Altura Acquisition

Last week (July 30), just days of reporting solid Q2 financial results, EVAR announced acquisition of Altura Medical, a privately-held Silicon Valley-based medical device company. Altura's *Agili-D* is a ultra-low profile (14f) AAA stent graft indicated for standard anatomies which received CE Mark in 2015. It is not yet approved in the U.S.

Terms of deal:

> Upfront:
- $15 million of Lombard common stock (3.75M shares @ $4)
- assumption of $5.5 million in bank debt and $2.5 million in liabilities and transaction costs

> Milestones (payable in cash or stock at Lombard's option):
- $15 million on achievement of $10 million in TTM sales
- $12.5 million on achievement of FDA approval of *Agili-D*

Rationale for the deal:

> Altura's product is one of the lowest profile stent grafts on the market. Only TriVascular's Ovation Prime and Cordis' InCraft have profiles as small as Altura's (14f). Ovation Prime is approved for sale in both Europe and the U.S. (FDA approval in Jan 2013). InCraft is marketed in Europe and Canada and undergoing a PMA study in the U.S.

> While EVAR's flagship device Aorfix is indicated for use in ~85% of AAA anatomies, the simplicity, ease-of-use and physician-familiarity of Altura's device lend it more to the ~70% of AAA patients with standard anatomies. Management indicated that they believe this will fill a sizeable gap in potential sales that they were losing when doctors would choose competitors' grafts instead of Aorfix in standard anatomy procedures

> Lombard will be the only company offering products for on-label use in both high neck angles and standard anatomies. They expect this to facilitate market share gains against competitors

> "Add-to-the-bag" product and leverage existing sales/marketing infrastructure. While EVAR anticipates incremental headcount additions to the direct sales forces in the U.K. and Germany, there should be minimal added OpEx related to detailing the product

> Lombard now has two technologies to choose from for new product development in areas such as fenestrated and thoracic stent grafts

> Will provide almost immediate bolt-on to revenue. Per management, revenue from Altura's device could account for up to 20% of 2016 sales. We model 2016 Aorfix revenue of $26.6 million (inline with consensus estimates) - which might imply Altura's device could do as much as $6 million in 2016

Launch Strategy:

Current activities will surround product branding and building of launch inventory. Initial introduction will happen in January 2016 in Germany and the U.K. EVAR expects to add ~4 and 3 new direct reps in the U.K. and Germany respectively. Launch into the broader European footprint aimed for 2H 2016. Plan is to increase distribution capability in Spain and the footprint in Italy.

U.S. Study:

EVAR expects to leverage their knowledge and contacts from Aorfix's pivotal PYTHAGORAS U.S. study in designing and executing a successful PMA study in support of FDA approval. Management noted that they expect enrollment of between 150 and 180 patients (for reference TriVascular's Ovation study enrolled 161 patients). Current expected timelines are;

- H2 2015: submit IDE
- 2016: IDE study approval
- 2017: first patient enrolled
- 2018 full enrollment
- 2019: final patient at 12-month follow-up
- 2019: modular submission with clinical follow-up results included in last module
- 2020: FDA approval
- 2020 / 2021: launch in U.S.

Japan:
Expect to use U.S. study data to support PMDA regulatory filing in Japan. Hope to file PMDA in 2021 and launch shortly afterwards.

Our Take:
The purchase price isn't cheap. The minimum (i.e. - no milestones) purchase price is $23 million. Assuming Altura's device can do $6 million in sales in 2016, the deal is valued at a minimum of 3.8x forward revenue. The revenue milestone of $15 million paid on the first $10 million in TTM sales means the purchase value does not fall below 3.8x revenue until Altura's device generates more than $10 million in sales. On the upside, this should be a seamless add-to-the-bag product, affording EVAR leverage of their current sales infrastructure which should speed improvement in operating income.

A U.S. PMA study is a significant commitment in time, personnel and money. Management made it clear that they fully intend to pursue this. We think the timelines laid out seem not unreasonable but probably have little to no wiggle room for unforeseen delays. We ballpark cost of the study at somewhere around $50k - $75k per patient or approximately between $8M - $14M. FDA approval triggers the $12.5M milestone. So all-in, cost of U.S. approval could conceivably be near $30M.

But FDA approval would significant expand the opportunity for the device. While Ovation Prime has been in the U.S. since early 2013 (and currently in a PEVAR study) and InCraft is ahead in FDA trials and could launch well ahead of Altura's stent graft, there are reasons to believe *Agili-D* can be highly competitive. For one, Ovation Prime may be more cumbersome to use as it utilizes polymer sealing rings - delivery and curing of which increases the procedure time. In addition, polymer leakage can be an issue. But, perhaps the most obvious competitive differentiation is one-stop shopping with Lombard reps which will have on label products for high neck angles (Aorfix) and an ultra-low profile, simple to use product for standard anatomies.

Product innovation in the AAA stent graft space has been rapid over the last several years as manufacturers seek to grab more of the ~$1.6B global (~$700M U.S.) EVAR market. Slimming down the catheter profile has been a significant area of focus as a lower profile allows for access to smaller vessels and / or percutaneous EVAR (PEVAR), eliminating the need for cutdown of the femoral wall. Studies have shown PEVAR is associated with shorter procedure time and lower risk of complications than traditional EVAR. So with PEVAR gaining more traction, this opens up another potentially receptive part of the AAA market to Lombard (albeit off-label) with the Altura graft.

So, despite the significant cost of PMA study, we think, given the outlined competitive positioning and potentially highly receptive U.S. market, FDA approval would almost certainly open up significant upside for Lombard. And while the deal isn't cheap at ~3.8x forward revenue, we see little risk that this will not provide substantial OpEx leverage opportunity at the get-go.

Model Update:
We have not yet updated our model for the transaction but will do so in a future report update.

FINANCIAL MODEL

Lombard Medical, Inc.: UNDER REVIEW FOR ALTURA ACQUISITION

	2014 A	Q1A	Q2A	Q3E	Q4E	2015 E	2016 E	2017 E	2018 E
Total Revenues	$13,277.0	$3,409.0	$4,535.0	$4,556.0	$5,615.0	$18,115.0	$26,552.7	$43,729.9	$63,703.5
YOY Growth	*90.8%*	*65.6%*	*106.8%*	*6.7%*	*18.0%*	*36.4%*	*46.6%*	*64.7%*	*45.7%*
Cost of Goods Sold	$7,541.0	$1,828.0	$2,191.0	$2,360.0	$2,886.1	$9,265.1	$11,922.1	$16,836.0	$20,130.3
Gross Income	$5,736.0	$1,581.0	$2,344.0	$2,196.0	$2,728.9	$8,849.9	$14,630.5	$26,893.9	$43,573.2
Gross Margin	*43.2%*	*46.4%*	*51.7%*	*48.2%*	*48.6%*	*48.9%*	*55.1%*	*61.5%*	*68.4%*
Sell, Mktg & Dist	$21,364.0	$6,268.0	$5,679.0	$6,344.0	$6,912.0	$25,203.0	$29,765.5	$35,464.9	$38,986.5
% SM&D	*160.9%*	*183.9%*	*125.2%*	*139.2%*	*123.1%*	*139.1%*	*112.1%*	*81.1%*	*61.2%*
R&D	$9,213.0	$2,442.0	$2,604.0	$2,680.0	$2,687.0	$10,413.0	$10,778.0	$10,981.0	$10,920.0
% R&D	*69.4%*	*71.6%*	*57.4%*	*58.8%*	*47.9%*	*57.5%*	*40.6%*	*25.1%*	*17.1%*
Admin	$9,799.0	$2,628.0	$2,297.0	$2,691.0	$2,884.0	$10,500.0	$12,338.0	$14,209.0	$15,888.0
% Admin	*73.8%*	*77.1%*	*50.7%*	*59.1%*	*51.4%*	*58.0%*	*46.5%*	*32.5%*	*24.9%*
Operating Income	($34,640.0)	($9,757.0)	($8,236.0)	($9,519.0)	($9,754.1)	($37,266.1)	($38,251.0)	($33,761.1)	($22,221.3)
Operating Margin	*-260.9%*	*-286.2%*	*-181.6%*	*-208.9%*	*-173.7%*	*-205.7%*	*-144.1%*	*-77.2%*	*-34.9%*
Total Other Income (Expense)	($1,339.0)	$25.0	($199.0)	($198.3)	($394.0)	($766.3)	($1,694.3)	($1,914.3)	($1,702.5)
Pre-Tax Income	($35,979.0)	($9,732.0)	($8,435.0)	($9,717.3)	($10,148.1)	($38,032.4)	($39,945.3)	($35,675.3)	($23,923.9)
Tax expense (benefit)	($1,227.0)	($189.0)	($239.0)	($194.3)	($203.0)	($825.3)	($798.9)	($713.5)	($478.5)
Tax Rate	*3.4%*	*1.9%*	*2.8%*	*2.0%*	*2.0%*	*2.2%*	*2.0%*	*2.0%*	*2.0%*
Net Income	($34,752.0)	($9,543.0)	($8,196.0)	($9,522.9)	($9,945.1)	($37,207.1)	($39,146.4)	($34,961.8)	($23,445.4)
YOY Growth	*224.7%*	*23.7%*	*-33.9%*	*12.6%*	*4.8%*	*7.1%*	*5.2%*	*-10.7%*	*-32.9%*
Net Margin	*-261.7%*	*-279.9%*	*-180.7%*	*-209.0%*	*-177.1%*	*-205.4%*	*-147.4%*	*-79.9%*	*-36.8%*
EPS	($2.39)	($0.59)	($0.51)	($0.59)	($0.61)	($2.30)	($2.24)	($1.09)	($0.62)
YOY Growth	*40.0%*	*-3.3%*	*-66.6%*	*12.5%*	*4.3%*	*-3.8%*	*-2.6%*	*-51.2%*	*-43.5%*
Diluted Shares O/S	14,556	16,186	16,186	16,202	16,205	16,195	17,500	32,000	38,000

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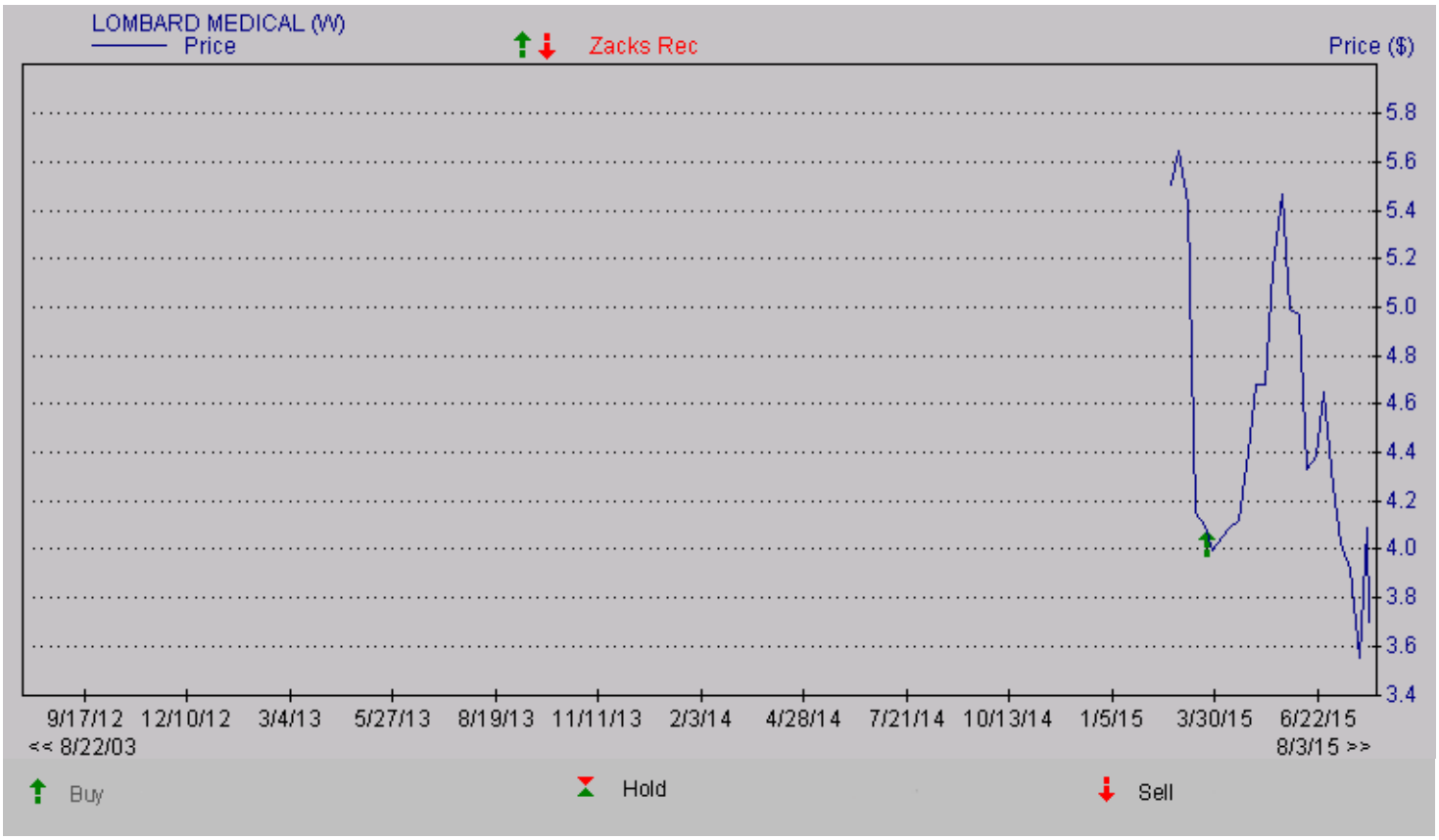

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