Single-Minded: Lombard Medical Aims For Double Top In Triple A

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Executive Summary

Vascular surgery device specialist Lombard Medical has seen a large uptick in revenues in both the US and OUS markets just as it has made a pivotal acquisition. With new funding secured and pipeline developments ahead, is the Bay Area listed company now on a platform of sustainable growth?

- Lombard pins it colors to the mast with a – surprising to some – vascular surgery acquisition that deepens its expertise and reach in Class III implantables.
- The safe, intuitive Altura stent for abdominal aortic aneurysms brings Lombard a unique combination of offerings and gives it a patient-focused approach that will help it take share from larger rivals in a market set to reach $1.9 billion.
- With shorter procedure times and lower inventory, the new stent will help providers save time and take money out of overall procedure costs in a segment where 200,000 new US AAA patients are identified every year.
- Its new strength in the Japanese market, plans for new EU and US launches and a major uptick in allocation to R&D are further tangible evidence or strong indications that Lombard sees itself as a new force to be reckoned with in triple A.

A "one product company no more," or words to that effect, was how **Lombard Medical Inc.**'s CEO Simon Hubbert described the significance to his company of the June 2015 purchase of fellow abdominal aortic aneurysm (AAA) stent graft manufacturer **Altura Medical Inc.** But in a tricky investment climate and with a review of ongoing funding needs not too distant in memory, was this the right time to invest more deeply in an area where the company already has a unique market reach claim?

"What we aimed to do across a number of months was look across a range of opportunities, focused on the core vascular surgeon. I had no interest in Lombard moving out of vascular surgery or into the commodity space," Hubbert told *IN VIVO*. The next M&A move was always going to be an implantable Class III device targeted at the vascular surgeon customer, he adds.

And the AAA space is a market in growth – worth $1.6 billion now and set to top $1.9 billion in 2018-2020, as morbidity rises in the aging population.

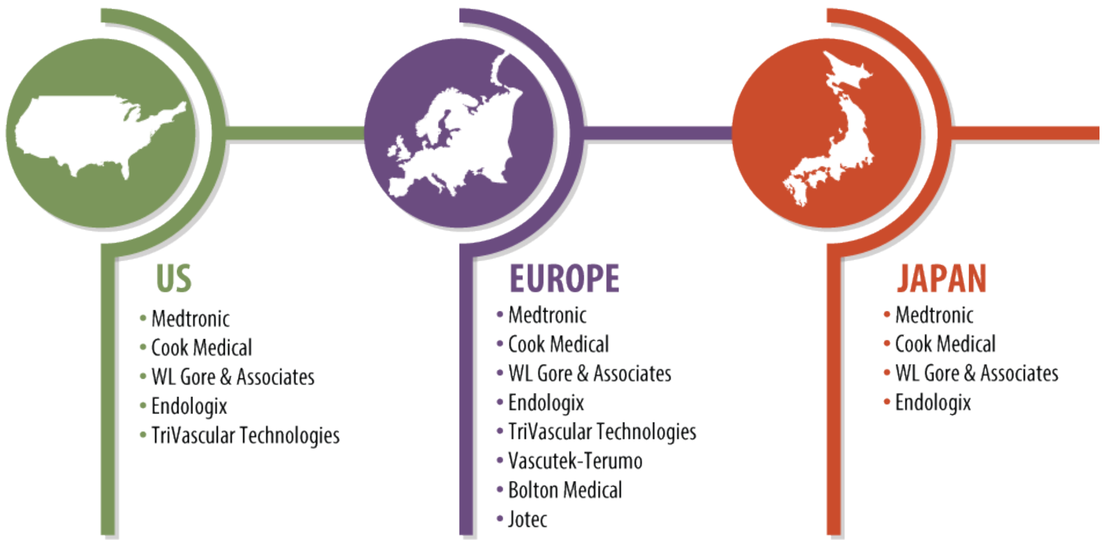
Altura has given Lombard the opportunity to become a broad-based player with a patient-focused portfolio, in that it now has two products that offer two distinct options to surgeons treating a triple A. The company had in fact been reviewing M&A options to broaden its portfolio since its IPO in April 2014, and found that the Menlo Park, CA, next-generation endograft manufacturer made good sense in terms of a fit with Lombard's *Aorfix* stent graft.

Aorfix is Lombard's flagship endovascular aneurysm repair (EVAR) solution. It has a broader label than any approved EVAR product in the US and Japan, but being an on-label solution for patients with aortic neck angulation up to 90 degrees, it is specifically targeted to treat patients with tortuous anatomy. The *Altura* device targets 70% of the target population, that is, the mainstream patients, who need a "simple, safe, intuitive device" that helps move them through the system very quickly. "It gives us a patient-focused approach that none of our competitors have," says Hubbert.

The big three in the global AAA market are **Medtronic PLC**, **WL Gore & Associates Inc.** and **Cook Medical Inc.**, which between them have an 80% to 85% share combined. It is market share from these three majors that Lombard is targeting principally as it begins to ramp up its business, though there are several other larger rivals and smaller players in or on the fringes of the AAA market. (*See Exhibit 1*.)

Exhibit 1

Lombard Medical's Key Competitors



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Company reports

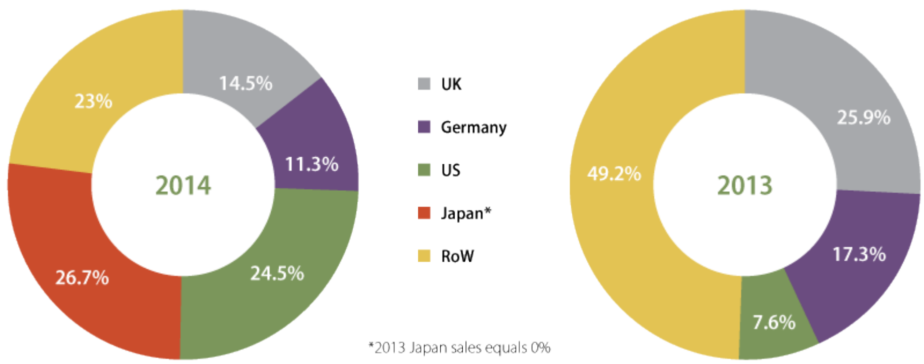
Lombard Medical's business expansion was clearly evident in fiscal 2014, when a 500%+ rise in US revenues and first-time Japanese business were behind a 91% rise in the company's sales of $13.3 million for that year. (*See Exhibit 2*.)

Sales in the second quarter and first half of fiscal 2015 were similarly strong, more than doubling to $4.5 million, and just short of doubling at $7.9 million, respectively. "We had a very solid quarter, and we have a great story going in Japan, where in less than three financial quarters, we've taken a 5% market share with a very capable and experienced distribution partner, Medico's Hirata," says Hubbert.

However, Lombard remains a loss-maker – although the deficit narrowed in second-quarter 2015 compared with a year earlier – and a move into profit is some time away. Hubbert declines to speculate on when that would be, but he clearly sees Lombard's near- and mid-term development plans as helping to bring that moment closer. "It's almost unprecedented in the Class III device world to generate cash at less than $80 to $100 million of revenues," he notes.

Exhibit 2

Lombard Medical's Evolving Sales Spread, 2013- 2014



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Lombard Medical

The key for Hubbert is that Lombard is very focused on strong growth and is making investments. "At some point later, we'll decide whether to push forward to generate cash or make other investments to grow the business faster."

The Acquisition Package

In Altura, Lombard has bought the company's assets and all the IP. Altura employs about a dozen staff in the Bay Area of San Francisco, including three in R&D, and the remaining being manufacturing engineers and support staff, as well as the product experts who are on hand when the surgeon implants the stent graft.

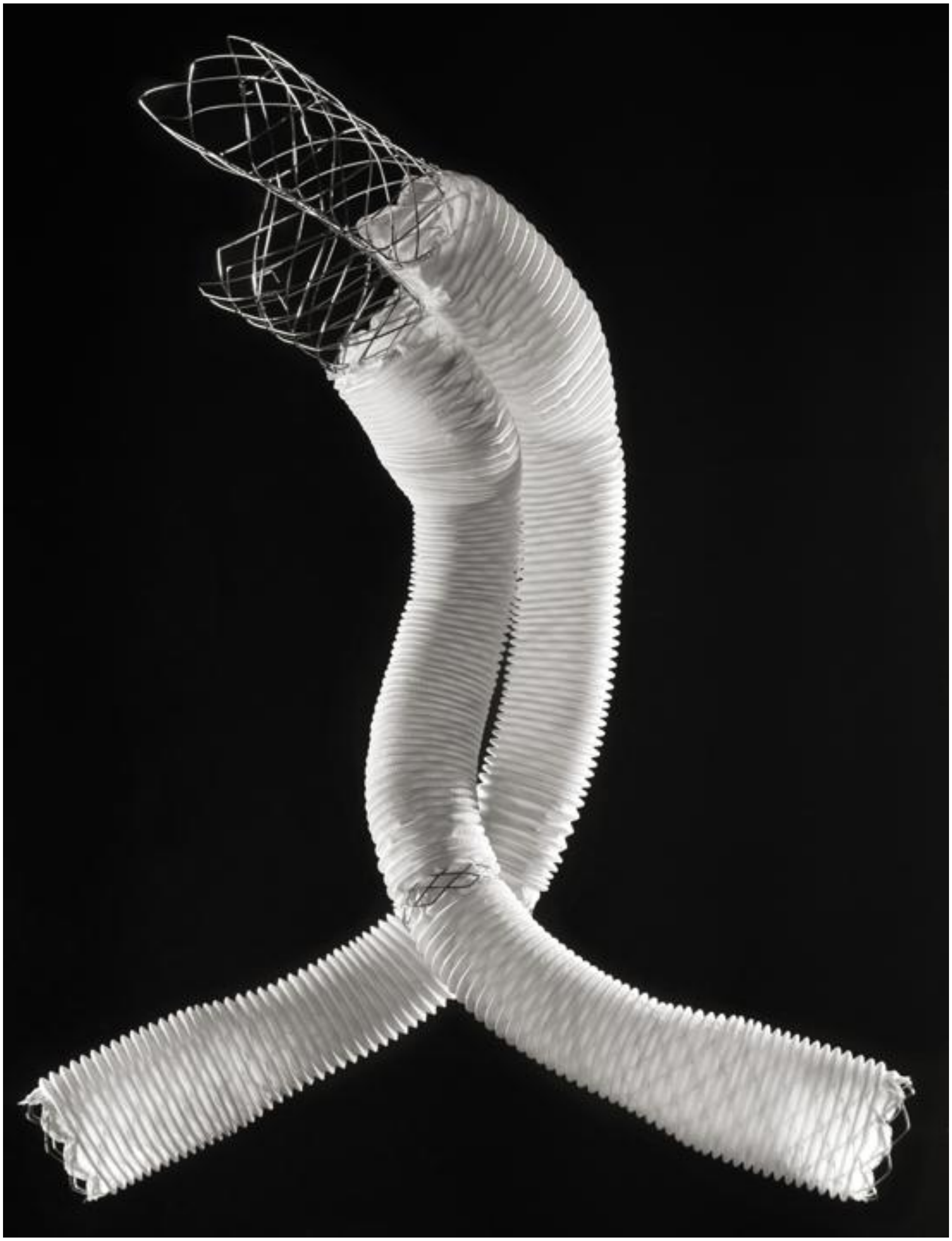
The total consideration could reach $50.5 million, including the issuance of $15 million in Lombard common stock units, assumption of $5.5 million in debt, $2.5 million in liabilities and costs and potential regulatory and performance milestones totaling $27.5 million. [See Deal]

About 100 Altura stent grafts have been implanted in the last two to three years, although the device is not yet commercially available. The Altura stent graft will become the second key brand at Lombard alongside Aorfix. Lombard is now working on plans for global launches of Altura.

In Europe, Lombard will scale up and launch the already CE-marked product in early 2016. In the US, Lombard intends to file for a US IDE with the FDA in early 2016 and recruit for a US clinical study later in 2016 as it moves through the PMA process. Japanese market planning will also begin.

Manufacturing of the Altura stent is currently outsourced to a third party in the Bay Area, but in time, it will be transferred to the production facility in Didcot, UK, which will remain Lombard's global production center.

Hubbert reiterates that Altura is a very simple, intuitive and accurate stent graft system that allows quick treatment of patients with simple anatomy. Its ultra-low "best-in-class" delivery profile is 14 French (14F). Along with a very small diameter, there is no cannulation involved – a process that can take time; Altura has two "kissing stents" that sit side by side, helping to produce a shorter and more predictable procedure time. Additionally, there is no polymer in the graft, and therefore no risk of polymer leakage, which may be a concern to physicians using one or two other stent grafts on the market.



Lombard's Altura

"A great feature is that the stent is completely recapturable into the delivery system for redeployment," says the Lombard CEO. "Altura is also very accurate at the distal end: the surgeon picks the landing zone for the stent at the bottom end, and deploys it back up into the aortic segment, which gives exact deployment. It's a fantastic feature, which physicians will love."

The device also has “market-leading” inventory requirements. The best-selling stents currently have at least 140 separate product codes to treat all patients, meaning that the provider must keep a “huge amount” of inventory. The modular Altura solution has just six product codes to treat all patients. Lombard plans to add a larger-diameter Altura stent graft to the range, but this will still only necessitate two more (for a total of eight) product codes.

This makes Altura an attractive option for health care systems looking to manage their costs. “Coupled with predictable and shorter procedure times, the lower inventory needs mean you’re taking money out of overall procedure costs, and that’s a great goal,” says Hubbert.

Market Demand Changing

iData Research data quoted by Lombard claim that in the US alone some 200,000 patients are diagnosed every year with AAA. And the market has fragmented slightly, in that a percentage of those aneurysm patients have difficult-to-treat angles and comorbidities and will need longer hospital stays along with the appropriate device to treat their complex anatomy. That is where Aorfix comes in.

Then there are the mainstream patients, many of whom are diagnosed with an aneurysm as the result of a screening program. This is where Altura comes in, helping to speed these patients through the health care system with very simple treatments. “That’s why having Altura sit side by side with Aorfix seemed very attractive for us,” says Hubbert. “Nobody else has that portfolio,” he stresses, adding that it would have been difficult for any other company to have made the acquisition without admitting a lack of faith in its own technology.

“Aorfix can treat more patients on-label than any other device, but Altura gives us a more attractive device for treating a portion of those patients,” he adds. “We can specifically target those patients with Altura by sitting down with physicians and talking about the specific anatomy of a patient.” It will change the way Lombard engages with its customers.

Building The US Infrastructure And Growing The Teams

Following its NASDAQ IPO in April 2014, Lombard Medical has been building a new leadership infrastructure at its Irvine, CA, headquarters. The company’s sales, marketing and global management teams now sit in the US, while all manufacturing responsibilities, a product development function and other support functions remain in the UK.

In preparation for setting up its HQ in the US and ahead of its IPO, the company hired Ray Cohen as chairman, a specialist in running US medical device companies, including latterly Vessix Vascular Inc.. That appointment was made in mid-2013. In December 2014, William Kullback was appointed as chief financial officer, in succession to Ian Ardill, and in February 2015, AtriCure Inc. president and CEO Mike Carrel joined the Lombard board.

These senior management changes were a factor of becoming a US listed company. Lombard has also extended its physical US infrastructure with a new innovation and development center in Irvine. A VP of product development with experience in Class III catheters has been hired, and he has been busy bringing on local specialists who will work on the next generation of Aorfix and Altura products.

Exhibit 3

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Lombard Medical

At year-end 2014, Lombard had a head count of 192 globally and, post-Altura, it continues to grow as it builds for the European Altura launch. The company now plans to increase its German and UK direct sales staff by seven, to 20 combined.

The German and UK markets are very much the focus for Lombard in Europe. AAA is well reimbursed in Germany and in the UK, and there are strong UK National Institute for Health and Care Excellence (NICE) recommendations on treating aneurysms with endovascular methods rather than open repair. The main challenge in the UK is that there has been a strong consolidation of treatment centers, with the number doing AAA surgery having reduced from about 110 to115, to some 75. But this consolidation is viewed by Lombard as the right thing to do as it means more patients are treated by those centers – even if the transition has made business somewhat "bumpy" in the short term.

The caveats in the EU market are the developments surrounding the proposed EU Medical Device Regulation (MDR) discussions, which resumed this fall after a short summer break. The new, harsher "scrutiny" procedures for high-risk devices may result in longer or more burdensome assessment of new products. This will be a factor across the industry, not just for Lombard Medical.

It is very early in the game for Lombard Medical in the US, where the company believes to have around 1% of the market. US prospects for growth are good, however, and Lombard has a team of over 30 people locally and appears to be building up to a cruising speed on the back of an impressive rise in second-quarter revenues.

Current Funding Secured

The somewhat brighter outlook for the company was underpinned recently when it was granted a $26 million secured loan facility by Oxford Finance LLC. Lombard notes that the recent economic instability has made it difficult for some companies to obtain funding or debt financing. But Hubbert sees it in fairly black and white terms, "It's very clear that funds will be available in the US capital markets and in the UK if we have a strong growth trajectory."

The additional funding extends the company's runway of debt financing into late 2016 and is an illustration of the CEO's point. Lombard Medical received $11 million in cash in April 2015 and an additional $5.5 million at the end of July used to retire term debt on the books of Altura. The firm can draw down another $4.5 million (between July 1 and December 31, 2015) after achieving $8.5 million in trailing six-month revenues, and a final $5 million after reaching $25 million in trailing 12-month revenues. That can be drawn prior to December 31, 2016.

Very little cash – just $2.5 million up front – was used in the Altura deal, Hubbert notes. The rest was stock and the $5.5 million debt assumption noted above, which was covered through Lombard's debt facility with Oxford Finance. The CEO says that when the time is right, the company will consider how to refinance. "For now, the cash reserves are strong, with over $40 million cash at hand, plus access to debt capital." That puts Lombard in really strong financial shape, he says.

R&D Momentum Continues

Lombard allocated $9.2 million to R&D in 2014 (32% more than the $7 million in 2013), and is set to up the allocation further as it works on more new projects.

These include a new Aorfix delivery system, Intelliflex, due to be launched late this year or early 2016 in the US. This is a lower-profile delivery system than the current offering, and presents “very accurate delivery characteristics,” according to test results so far.

Intelliflex will be launched in Europe in first-quarter 2016. Hubbert says that it will considerably increase both Lombard’s position and interest in the product. A further improved delivery system is expected to follow some 18 to 24 months after the Intelliflex launch.

Lombard is also working on plans to enter the fast-growing thoracic EVAR (TEVAR) market. Its R&D teams are reviewing which of its two AAA platforms would be best for developing a new thoracic aortic aneurysm (TAA) stent graft system for patients requiring dissections and partial transections or treatment for rupture.

TAAs are treated either by highly invasive open surgical repair or by TEVAR, which is currently a $400 million market and is set to grow to more than $480 million by 2018.

Elsewhere, the company is looking to develop a platform for the fenestrated stent market, for use in patients whose aneurysms are too close to the arteries that feed the kidneys and for whom endovascular graft placement has not been an option because the stent graft itself would block blood flow to the kidneys. Hubbert says, “You can anticipate that we’ll make some moves in one or both of those platforms – thoracic and/or fenestrated stents.”

Next Steps, Next Targets

The Lombard CEO says the acquisition and second-quarter growth send a strong message about the firm’s ambition and its pursuit of a top position – or even “double top” now that Altura is part of the company.

“It’s our objective to be a major player in the broader AAA market going forward,” he says, ruling out any notion that Lombard is being shaped into an M&A target. “To be acquired should not be a strategy – for any company. If that happens, the endgame is out of your hands. It’s my belief that companies should build toward becoming successful, solid, stand-alone companies.”

It would be a different matter, however, if someone came along and made an attractive offer along the way. “As a public company, you have to consider that,” says Hubbert.

Lombard has worked with the strategics before: around nine to 10 years ago, **Boston Scientific Corp.** took a large minority stake in the company, but the partnership ended in August 2006 when Boston declined the option to be the exclusive Aorfix distributor outside the US.

Hubbert’s view is that “anyone who is interested in becoming a shareholder in the company is welcomed.” Lombard’s major shareholders at present are Invesco Asset Management Ltd. (39%) and Abingworth LLP (20.7%).

The CEO also thinks that there needs to be some consolidation in the AAA space. “We’ve started that process, and maybe we surprised a few people.” The company may well look at other opportunities in the implantable space. “We’ve signaled our intent that we’re ambitious and we’re being aggressive,” he says, adding, “All is aimed at producing a successful cash-generative company over the next few years.”