

## Lombard Medical (EVAR-NASDAQ)

**EVAR: Exploiting High Neck Angle Stent-Graft Market. Initiating Coverage at Outperform**

<b>Current Recommendation</b>	<b>Outperform</b>
Prior Recommendation	N/A
Date of Last Change	03/23/2015
Current Price (03/23/15)	\$4.10
<b>Target Price</b>	<b>\$9.50</b>

### 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. We are initiating coverage of Lombard Medical with an Outperform rating and \$9.50/share price target.

### SUMMARY DATA

52-Week High	\$11.34
52-Week Low	\$3.80
One-Year Return (%)	N/A
Beta	N/A
Average Daily Volume (sh)	12,206

Shares Outstanding (mil)	16
Market Capitalization (\$mil)	\$66
Short Interest Ratio (days)	N/A
Institutional Ownership (%)	77
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	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2014	2.1 A	2.2 A	4.3 A	4.8 A	13.2 A
2015	3.1 E	4.2 E	5.0 E	6.4 E	18.7 E
2016					27.7 E
2017					43.7 E

#### Earnings per Share

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2014	-\$0.62 A	-\$0.86 A	-\$0.52 A	-\$0.51 A	-\$2.39 A
2015	-\$0.61 E	-\$0.61 E	-\$0.61 E	-\$0.44 E	-\$2.22 E
2016					-\$1.47 E
2017					-\$1.07 E

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

## SNAPSHOT

Lombard Medical, Inc. (NASDAQ ticker: EVAR) is a med-tech company engaged in the development, manufacturing and commercialization of endovascular stent-grafts. The company's focus is on abdominal aortic aneurysm (AAA) repair and, more specifically, AAAs with severely angulated anatomy. Lombard's flagship product, Aorfix Endovascular Stent Graft ("Aorfix"), is the only endovascular stent-graft with global approval for treatment of AAAs with neck angulation of up to 90 degrees.

Abdominal aortic aneurysms are a result of weakening of blood vessel walls of the aorta, the largest artery in the human body which extends from the heart to the abdomen, where it then splits into two smaller arteries (i.e. - iliac arteries). The blood vessel walls balloon (or dilate) as they lose the ability to sustain the force of blood flow and can rupture, often resulting in death. Risk of rupture is greater with larger diameter aneurysms. The majority of AAA cases occur in people 65 – 75 years of age and are more common in men and those that smoke. In addition to age and smoking, other potential contributing factors include genetics, high blood pressure and heart disease, among others. Approximately 200k Americans and ~500k people worldwide are diagnosed with AAA each year, although cumulative incidence is much higher than this. Risk of ruptured AAA, which causes ~15k deaths each year in the U.S.<sup>1</sup>, may be able to be reduced with increased screening and earlier intervention.

The two options for AAA treatment are either Endovascular Aneurysm Repair ("EVAR" – which is also Lombard's ticker symbol) or open surgical repair. While open surgical repair was at one time the only option, EVAR (introduced in the 1990's) now accounts for approximately 75% of all AAA repair procedures in the U.S. due largely to its lower mortality rate, fewer complications and shorter recovery time. EVAR treatment is currently estimated at a ~\$1.5 billion market and growing at about 6%/year. EVAR growth is being driven by an ageing population, increased screening and the continued shift from open surgery.

Lombard's Aorfix incorporates a proprietary design allowing for maximum flexibility. And while there are several other types of stent-grafts used in EVAR procedures including those from well-known medical device companies such as Medtronic, Endologix and Cook Medical, Aorfix is the only one approved by the FDA for aortic neck angles greater than 60 degrees (i.e. – high neck angles). The ~20% - 30% of AAA patients with high neck angles or tortuous iliacs represents the low-hanging fruit for Lombard, although their device has experienced significant demand across all patient anatomies.

Aorfix was evaluated in a multi-site pivotal IDE clinical trial with over 200 patients, ~70% of which had neck angles >60 degrees. The study, which demonstrated strong performance of Aorfix in these difficult to treat patients, formed the basis for FDA's approval of an indication for use of Aorfix in neck up to 90 degrees. Positive two-year follow-up data from an ongoing post-marketing study was recently presented. To-date, over 4k patients have been treated with Aorfix. The device received FDA (PMA) approval in February 2013 and formally launched in the U.S. in November 2013. It is also approved and being marketed in Japan and Europe.

Lombard's major focus is on the U.S., Germany, U.K. and Japan which represent the top four EVAR markets and are worth approximately \$1 billion annually. The company has rapidly grown a direct U.S. sales force, resulting in U.S. revenue ramping immediately following the late-2013 launch. The recent launches in the U.S. and Japan (September 2014), coupled with strong growth in procedural volume throughout the commercial footprint fueled 116% Aorfix revenue growth in 2014. Lombard expects this momentum to continue and is guiding for 2015 revenue of \$18M to \$20M (+35% to +50%) with anticipation that procedural volumes will more than double in their four key markets and pricing will remain stable.

In April 2014 Lombard completed an IPO on NASDAQ, raising \$48M (net). Some of the proceeds have been reinvested in build-out of the company's sales/marketing infrastructure as well as for development of next-gen products. And while the recent growth in the expense base has had the effect of increasing operating loss, despite the rapid revenue growth, we model earnings to quickly improve with relative stabilization of operating expenses and continued strong growth on the top line. The IPO also further strengthened the company's balance sheet. As of 12/31/2014 cash balance stood at \$53M.

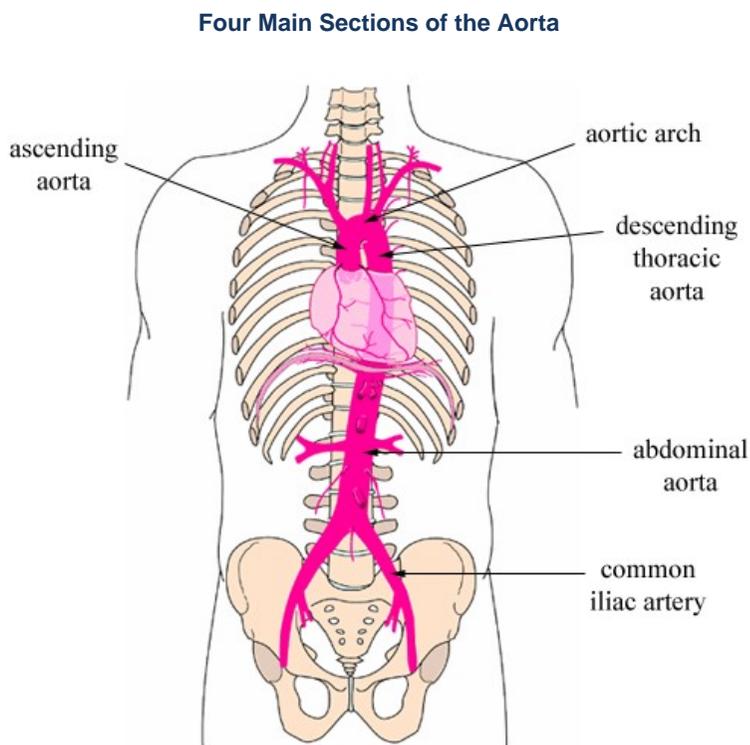
<sup>1</sup> [Emedicine.medscape.com](http://Emedicine.medscape.com) *Abdominal Aortic Aneurysm*

## BACKGROUND

### Abdominal Aortic Aneurysms

The aorta is the largest artery in the human body and responsible for distributing blood throughout the entire body. It is about 12 inches long and runs from the left ventricle (i.e. – where blood is pumped from) to the abdomen. The aorta is divided into four main sections;

- **ascending aorta** extends upwards from the heart. Arteries from the ascending aorta feed blood to the heart
- **aortic arch** is after the ascending aorta. Arteries from the aortic arch send blood to the head, neck and arms
- **descending thoracic aorta** is after the aortic arch. It extends through the chest and supplies blood to areas of the ribs and the diaphragm
- **abdominal aorta** is after the descending thoracic aorta. It begins at the diaphragm, extending downward and then splits into the iliac arteries in the lower abdomen. It supplies blood to the major organs and the lower part of the body (blood to the legs are fed by the iliac arteries)



SOURCE: [www.cts.usc.edu](http://www.cts.usc.edu)

Aortic aneurysms are caused by a weakening of the blood vessel walls of the aorta. They typically occur at the abdominal aorta and approximately 85% of abdominal aortic aneurysms occur below the kidneys. The blood vessel walls balloon (or dilate) as they lose the ability to sustain the force of blood flow. The specific causes of AAAs are unknown although contributing factors are thought to include older age, smoking, genetics, obesity, high blood pressure and heart disease, among others. The majority of cases occur in people 65 – 75 years of age and are more common in men. Women are afflicted with AAA at only about 25% as the rate of men.

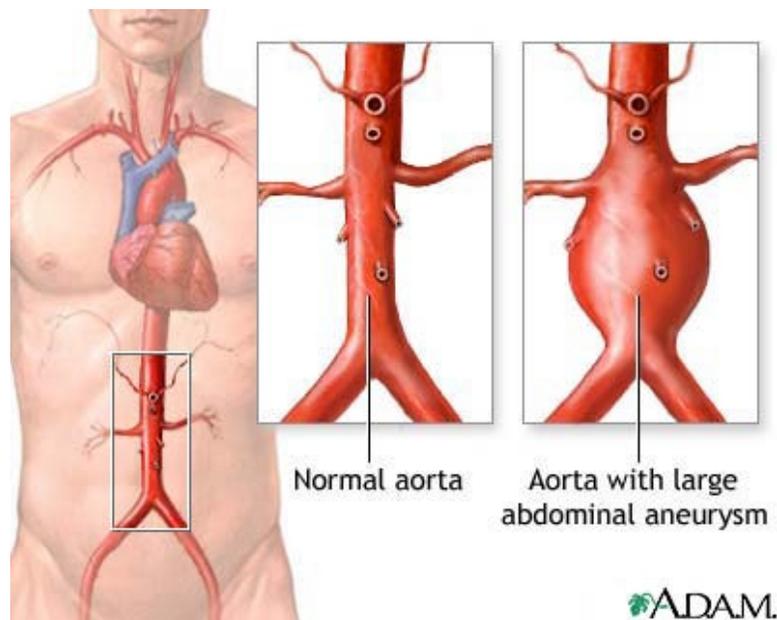
### **Prevalence of AAA...**

While we have not found a definitive source that can provide concrete figures for incidence or prevalence rates, most (including those from CDC) estimate prevalence of AAA in the U.S. ranges between 1.0 million – 2.0 million people and incidence between 500k – 600k. Of the U.S. population afflicted with AAA, approximately 200k are diagnosed each year and ~65k were treated with either open surgery or EVAR last year. Estimates of annual deaths in the U.S. from AAA range from ~10k – 15k.

Prevalence in the U.K. is estimated at 1 in every 70 men over the age of 65. With approximately 11 million people over the age of 65 living in the U.K., assuming half are men, and further assuming 1 in 280 (~25% the rate of men) of women over the age of 65 has AAA, this puts prevalence there at about 100k people. We were unable to find reliable prevalence rates for AAA in Germany or Japan, which are the other two markets that Lombard has major focus on. But if we assume similar rates as those in the U.K., AAA prevalence in Germany (~17M over age of 65) and Japan (~32M over age of 65) is approximately 150k and 300k, respectively. Using the same methodology for Italy and Spain, the other two markets where Aorfix is being commercialized, adds another ~200k.

This aggregates to a total AAA population in Lombard's currently commercialized territories of about 2.3 million people. Diagnosis rate in the U.S. is approximately 15% of all cases – applying that rate to the calculated AAA population in the company's commercialized territories results in an estimated diagnosed population of ~350k people. While this is a substantial market, with improvement in diagnosis (only ~15% of all AAA cases are currently being identified), Lombard's target market may grow even further.

### Abdominal Aortic Aneurysm



SOURCE: A.D.A.M. Medical Illustrated Encyclopedia

And while Aorfix can be used for all AAA cases, it is the only stent-graft approved by the FDA for AAAs with neck angulation of up to 90 degrees. “Neck” refers to portion of the abdominal aorta just below where the renal arteries connect to the aorta. The neck can become more angulated as the disease progresses. In about 20%<sup>2</sup> of AAA cases the neck is angled at 60 degrees or more. Aorfix's proprietary design provides it with exceptional flexibility, making it less prone to kinking and endoleaks (i.e. - leaking of blood around or through the stent-graft) in areas of severe angles as compared to other stent-grafts. It also looks to have similar advantages when used in tortuous iliac arteries. Data from the pivotal PYHTAGORAS study indicates ~10% of people with AAA with neck angles <60 degrees have moderate to severe tortuosity of the iliac arteries. This 20% - 30% of the AAA market with complex anatomies is where Aorfix's sweet-spot lies and where we think the device has potential to dominate.

### **Symptoms and Consequences of AAA...**

Initial symptoms can include sudden and severe pain in the back or abdomen which may spread to the lower portion of the body, clammy skin, rapid heart rate, nausea / dizziness and even passing out. Diagnosis usually begins by a doctor feeling the abdomen for rigidity or to determine if there is a mass. A more definitive diagnosis is done with ultrasound or CT scan of the abdomen.

Consequences of AAAs can vary from mild to severe. Smaller, slower growing AAAs may result in only mild and non-life threatening symptoms. However, with larger aneurysms the force of blood flow is more likely to cause a

<sup>2</sup> Per Medtech Ventures

dissection, whereby blood leaks between the arterial walls, or an outright rupture. Since aneurysms that are small and appear to be growing slowly have a lower risk of rupture, doctors will often decide against surgery (which carries its own risks) and instead recommend monitoring the patient with bi-annual scans of the aneurysm. For aneurysms that are larger than two inches or are growing rapidly surgery is usually recommended as the bigger then aneurysms, the greater the risk of rupture (up to 90% of AAA ruptures result in death). These treatment guidelines are just recommendations, however, as studies have shown that 10% or more of aneurysms that rupture are smaller (< 2") and 50% or more of larger aneurysms do not rupture.

### **Greater Awareness of Benefits of AAA Screening...**

Over the last several years the importance of screening for AAA has gained more attention following certain measures by U.S. government health agencies as well as several studies which have concluded that not only is AAA screening effective in reducing mortality but that it is also cost-effective. The U.S. Preventative Task Force recommends one-time screening for AAA with ultrasound in men ages 65 – 75 years who have ever smoked. The SAAAVE (Screening AAA Very Effectively) Act, enacted in 2006, provides male smokers and men and women with a family history of AAA who are entering Medicare a free, one-time AAA screening as part of the Welcome to Medicare Physical Exam.

While these measures appear to have had a positive effect with increasing the number of people screened for the condition, some AAA experts recommend screening of an even greater proportion of the population. Authors of a comprehensive study<sup>3</sup> of the effectiveness of AAA screening, which was published in the journal Baylor University Medical Center Proceedings, recommend one-time screening for all men (regardless of smoking history) possibly as early as age 55. And the Society for Vascular Surgery (SVS), a non-profit organization composed mostly of vascular surgeons, recommends screening for all men (regardless of smoking history) 60 – 85 and 50 and older who have a family history of AAA. SVS also recommends AAA screening for women over 60 with a history of heart disease and those over 50 with a family history of AAA.

In the U.K., men over the age of 65 are eligible to be screened (via ultrasound) for AAA. This program was first implemented during 2009 and has rolled out incrementally over the subsequent years throughout England and Wales. U.K.'s National Screening Committee, whose mission is to improve the nation's health, has a goal to reduce deaths from AAA by 50% through this screening program. And while there currently is no national AAA screening program in Germany (another of Lombard's major target markets), there has recently been more significant efforts towards the study and potential implementation of such. These efforts included a full symposium dedicated to the discussion of a AAA-screening program in Germany during the 2014 Munich Aortic & Carotid (MAC) Conference. Most, if not all of the German health organizations with an interest in vascular health, including the German Society of Angiology, German Vascular Society and Federal Joint Committee appear to support a AAA-screening program in some fashion.

There is substantial evidence that indicates AAA screening programs are effective in reducing AAA-related deaths which was a topic during the MAC conference. An oft-cited Cochrane review<sup>4</sup> (Cosford PA, Leng GC, Thomas J) which examined data from four large AAA screening studies (two U.K., one Denmark, one Australia) concluded that the data proves AAA screening programs do reduce AAA-related mortality. However, not all data suggests that current screening guidelines are appropriate. More current data from national screening programs in the U.K., Sweden and Australia were shared at a Charing Cross International Symposium in 2012 which indicated reduced rates of growth and rupture of AAAs among 65 year-olds. It was opined that this may be a result of lower rates of smoking and cholesterol levels. But despite the question of whether screening programs should focus on men over the age of 65, data still suggests that these screening programs are cost effective.

We think the broad-based evidence supporting the effectiveness of screening programs and recent measures by various organizations focused on improving AAA outcomes could bode well for the likelihood that Germany, as well as other nation-states where Lombard is already active or may be so in the future, adopt screening programs. This, coupled with an ageing population in the U.S. and elsewhere, may in-turn increase the number of people diagnosed with the condition (although lower smoking rates seem to have helped reduced AAA incidence in most of the developed world, which may offset some of the benefit of increased screening) and further expand the potential patient-market sizes for Aorfix. We think the U.S., in particular, will remain a very important and attractive market for Aorfix given the less-than ideal lifestyle choices and health conditions (~2/3 of Americans are overweight or

<sup>3</sup> Silverstein MD, Pitts S, Chaikof EL, Ballard DJ. *Abdominal aortic aneurysm (AAA): cost-effectiveness of screening, surveillance of intermediate-sized AAA, and management of symptomatic AAA*. Proc (Bayl Univ Med Cent). Oct 2005; 18(4): 345-367

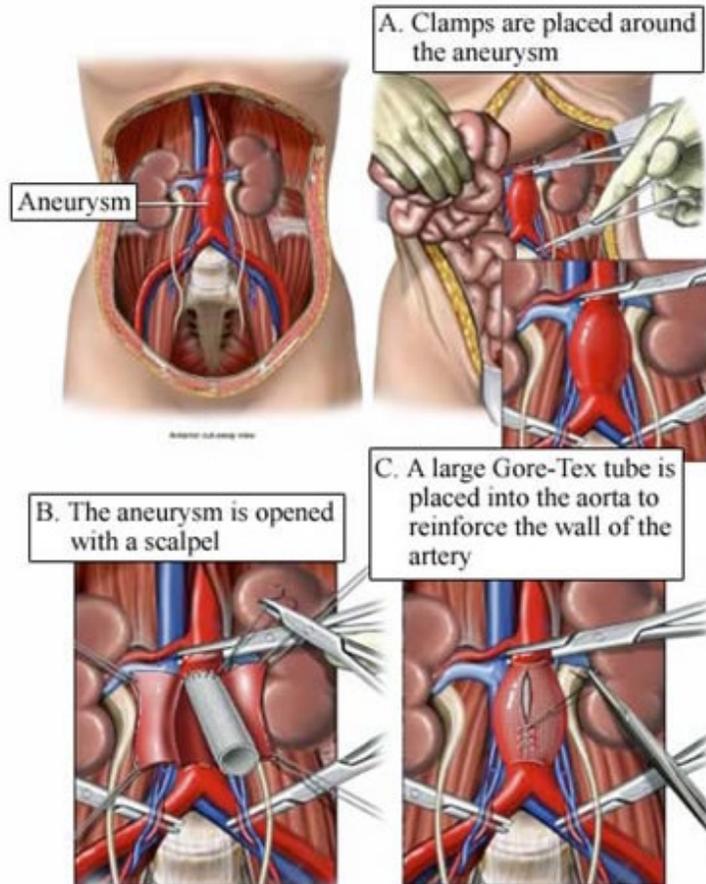
<sup>4</sup> Cosford PA, Leng GC, Thomas J. Screening for abdominal aortic aneurysm. Cochrane Database of Systematic Reviews 2007, Issue 2. Art. No.: CD002945. DOI: 10.1002/14651858.CD002945.pub2

obese) and the potential that the already robust AAA screening program in this country is expanded to include an even broader demographic.

### AAA Repair Options

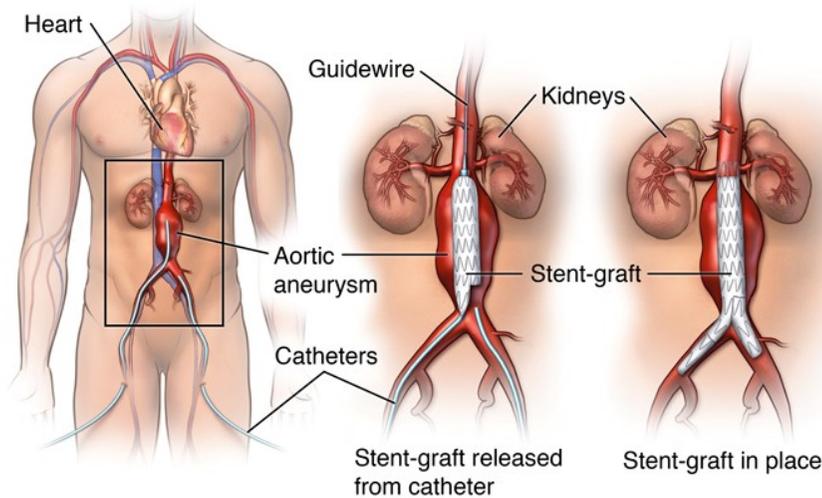
While a watchful waiting approach is typically recommended for smaller AAAs, repair of the aneurysm is usually prescribed with larger AAAs. Repair options are either open surgery or EVAR. Surgery had been the only option for decades until the early 1990's when the first EVAR procedure was performed. The popularity of EVAR has grown since, surpassing open surgery as the method of choice in 2003 and currently accounting for approximately 75% of AAA repairs in the U.S.

#### AAA Open Surgery



The growth in EVAR is the result of improvements in stent-graft technology and more product options as well as certain important benefits of EVAR over surgery. Among these benefits is the less-invasive nature of EVAR and longer recovery time required with open surgery. Open surgery is a major procedure and involves opening up the abdomen via an incision from the lower breastbone to below the navel in order to access the aneurysm, clamping the aorta above and below the aneurysm and then suturing in a synthetic tube at the aneurysm site. By contrast, EVAR is relatively non-invasive and is typically done under regional anesthesia. Small incisions are made in the groin and a stent-graft is threaded through the femoral artery with a catheter and guidewires. The stent-graft is pushed up into the aneurysm and then expanded to the sides of the aorta wall. The catheter is then threaded back out, expanding the entirety of the stent-graft as it is removed.

## EVAR Procedure



SOURCE: [www.hopkinsmedicine.org](http://www.hopkinsmedicine.org)

Open surgery exposes the patient to certain inherent risks absent with EVAR including dangers of general anesthesia and greater risk blood loss and associated complications. Recovery and pain exposure is also less patient-friendly compared with EVAR.

In addition to these advantages, data from large landmark studies (EVAR1, DREAM) comparing open surgery to EVAR in regards to patient outcomes have demonstrated EVAR is associated with significantly lower aneurysm-related mortality up to six months following the repair. And while these same studies showed this mortality benefit did not persist over the long term, with EVAR patients experiencing similar or higher (depending on the particular study) rates of aneurysm-related death at six years after the procedure, a more recent clinical trial (OVER study) showed the EVAR-mortality benefit was sustained for three years.

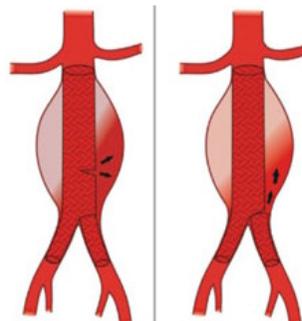
One drawback of EVAR is the risk of endoleaks, which is when blood leaks either around or through the stent-graft and into the aneurysm sac – which can make the aneurysm larger and more prone to dissection or rupture. Type I and III endoleaks have been the most problematic. The risk of endoleaks means EVAR patients must have regular scans to ensure the graft-stent is working properly. And if an endoleak is discovered, reintervention is often required.

Type I is where blood leaks around the top or bottom of the stent-graft due to lack of a sufficient seal with the aorta while Type III is when joints in the graft fail to seal adequately or a break in the fabric of the graft results in blood flowing into the aneurysm sac. Type I and III endoleaks were included as effectiveness endpoints in Aorfix's pivotal PYTHAGORAS clinical study which supported the FDA approval application.

### Type I Endoleak



### Type III Endoleak



SOURCE: [www.scielo.br](http://www.scielo.br)

A retrospective study<sup>5</sup> led by Dr. Andres Schanzer from the Division of Vascular and Endovascular Surgery, University of Massachusetts Medical Center looked at a database of over 10k EVAR patients (treated with various stent-grafts). Over 3k patients (32%) were found to have an endoleak during follow up with 76% of these endoleaks occurring in the first year. And five years following EVAR procedure, 41% of patients were found to have sac enlargement. Perhaps, interestingly (in the context of how Aorfix may address the endoleak risk) is that one of the independent predictors of sac enlargement were aortic neck angles of >60 degrees.

But despite not all of the clinical data favoring EVAR, the continued growth in popularity of this procedure in place of open surgery clearly indicates the benefits of EVAR are outshining any perceived weaknesses. And with Aorfix specifically addressing the issue of complex anatomies (which are often repaired with open surgery) and related endoleaks, the popularity of EVAR should blossom even further. In addition, other stent manufacturers are developing next-gen and improved products (although none that are likely to compete anytime soon with Aorfix's unique U.S. indication) that may also drive even greater adoption of EVAR. According to Endologix, another stent-graft manufacturer, of the 63k AAA repairs performed in the U.S. in 2012, about 75% were done using EVAR and the remainder via open surgery. And while open surgery was considered the only viable option for the repair of ruptured AAAs, EVAR has increasingly become a popular option for treatment of these patients. In fact a non-scientific survey<sup>6</sup> taken at the 2013 International Congress of Endovascular Specialists showed almost 70% of respondents favor EVAR over open surgery for ruptured AAAs.

### **Complex Anatomies Present Repair Challenges...**

Approximately 20% - 30% of AAA patients present with tortuous anatomies wherein the neck of the abdominal artery and/or the iliac arteries are at severe angles. This can present significant challenges with conventional stent-grafts which have limited flexibility. Access can be problematic due to difficulty in threading the stent-graft through the severe angles. But even if accessible, there is risk that conventional stent-grafts will kink in the angle-bends and not sufficiently conform to the walls of the aorta.

This increases the likelihood of endoleaks. And the risk of endoleaks has been shown to increase over time, particularly with changing anatomies where the neck angles increase. As such, with complex anatomies the physician's treatment of choice is often open surgery (open surgery and Aorfix are the only approved treatments for AAA neck angles greater than 60 degrees) where access is typically a non-issue and the stent-graft is sutured in place, reducing risk of kinking or non-conformability. We note, however, that while Aorfix is the only stent-graft approved by FDA for neck angulations over 60 degrees, traditional stent-grafts are sometimes used off-label in patients with AAAs with highly (>60°) angulated necks. But, as noted, there is real risk of these traditional stent-grafts kinking or generally not conforming to the arterial wall and resulting in endoleaks.

### **Aorfix: Only Stent-Graft Approved for Neck Angles Up to 90°, Addresses Issues of Complex Anatomies**

Aorfix Endovascular Stent Graft received FDA (via PMA) approval in February 2013 and formally launched in the U.S. in November 2013. Aorfix is the only stent-graft approved by FDA for repair of AAAs with neck angulation of up to 90 degrees. Data from the company's PYTHAGORAS pivotal study (discussed below) was used as support for FDA approval. Aorfix was approved in Japan, also for neck angles up to 90 degrees, in August 2014 and launched there shortly afterwards. And while Aorfix had already been approved for sale in Europe, it received high angle (60 – 90 degrees) approval there in 2010. To-date, over 4k patients have been treated with Aorfix.

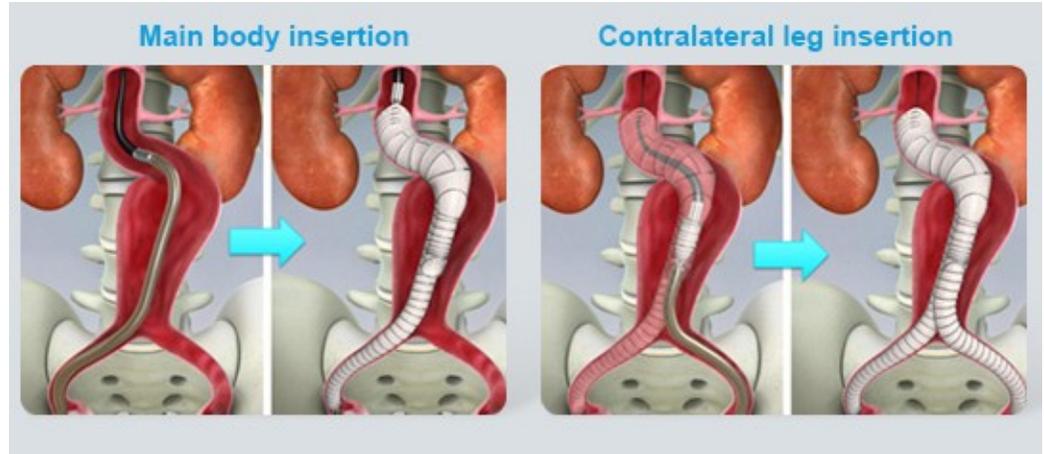
Aorfix is comprised of a main body and a "plug-in leg". Aorflex, which is Lombard's proprietary stent-graft delivery system is used to insert the main body of Aorfix into the aorta and one of the iliac arteries. The plug-in leg is then placed into the other iliac artery and connected to the main body. Once Aorfix is secured in the aneurysm it allows blood to flow through it, relieving pressure against the compromised aortic wall and significantly reducing risk of rupture.

---

<sup>5</sup> Schanzer A. et al. *Predictors of Abdominal Aortic Aneurysm Sac Enlargement After Endovascular Repair*. *Circulation*. 2011;123-2855 April 2011

<sup>6</sup> Mary Thompson. *EVAR Update: Competitors Stake Their Ground In A High-Growth Space*. Medtech insight. April 2013

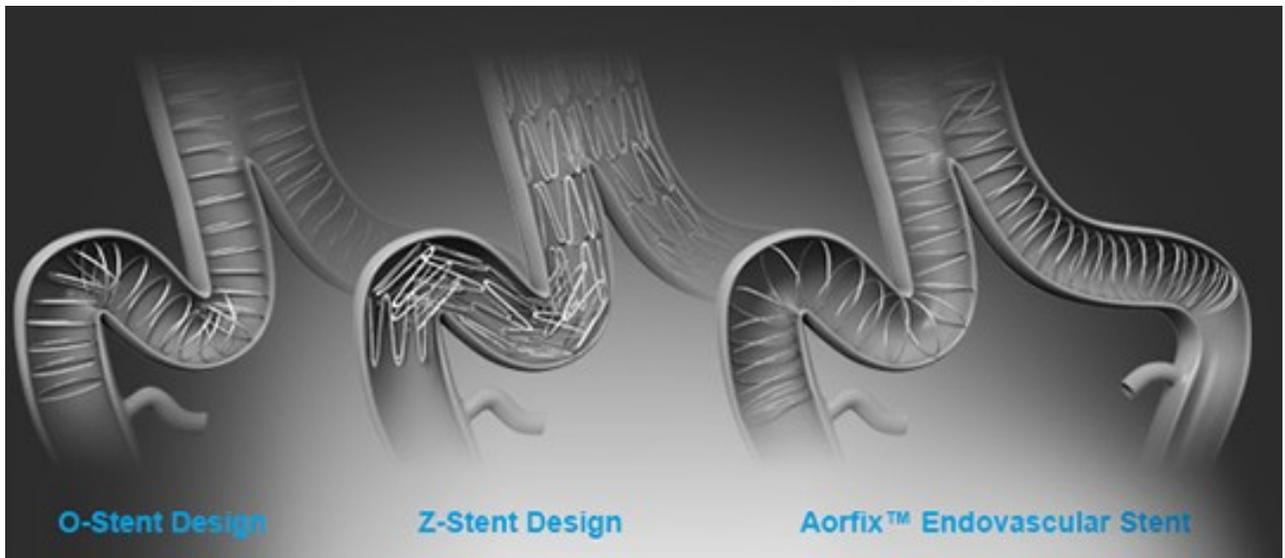
## Aorfix Stent Graft



SOURCE: Lombard Medical

Certain proprietary attributes of Aorfix set it apart from other graft-stents on the market. The main structure is nitinol (nickel and titanium) wire constructed in an interlocking helical (i.e. – spiral) design which provides superior flexibility and high durability. The top of the stent has (what Lombard calls) a fishmouth design which is supported with four closely spaced nitinol wires. At the ends of the fishmouth are eight hooks which are secured onto the aorta to keep the stent in place (migration was an effectiveness endpoint in PYTHAGORAS). The fishmouth and helical structure provides for superior flexibility and a better seal than traditional stents, allowing Aorfix to be threaded through high angles and minimizing risk of endoleaks. The nitinol wire is covered by a woven polyester fabric.

### Aorfix's Helical Design Provides Greater Flexibility / Less Kinking Compared to Competitors' "O" and "Z" Stents



SOURCE: Lombard Medical

Lombard owns 155 patents, 17 of which are U.S. patents. In addition, 28 patents are pending worldwide, including six in the U.S. Lombard's reinforced graft patents, which relate only to Aorfix expire in January 2019. However, the company owns other patents related to Aorfix, the most recent of which doesn't expire until October 2022. We expect this will provide ample protection until a next-gen device is commercialized, which presumably would have novel patents and extend the patent life even further.

Medtronic filed a lawsuit against Lombard claiming infringement of a patent (# 6,306,141, also known as the “Jervis patent”) owned by that company related to medical devices using shape memory alloys. In late 2013 the parties agreed to a settlement which, in exchange for a one-time payment (~\$2.0 million) from Lombard to Medtronic (paid in 2013) and royalties on U.S. sales of stent-grafts, provides Lombard with non-exclusive use of the patent until it expires (2021) or is found unenforceable.

**FDA Approval Supported by Pivotal PYTHAGORAS Study...**

PYTHAGORAS was a controlled, prospective, non-randomized clinical study conducted at 41 sites in the U.S., three in Canada and one in Poland. Results of the study were the main support for Lombard’s U.S. premarket approval (PMA) filing and what FDA based their approval decision upon.

218 patients were enrolled in the investigational arm and 210 ultimately treated. Of the 210 treated with Aorfix, 67 had neck angles less than 60 degrees, 109 with 60 degrees to 90 degrees, and 42 greater than 90 degrees. The Aorfix-treated group was compared to an open surgical group which consisted of 76 patients. Open surgery was chosen as the control as it was (i.e. – prior to Aorfix gaining FDA approval for this indication) the only approved therapy for AAA neck angles over 90 degrees.

**Effectiveness Endpoints Met...**

Effectiveness was measured at 12 months following implantation using an analysis group of only those patients with neck angles between 60 and 90 degrees. The primary composite endpoint consisted of the following components (with a threshold of at least 80%);

- free of type I and type III endoleaks
- free of migration of the end of Aorfix by more than 10mm
- free of graft fracture in the fixation zone (i.e. – where the top of the graft attaches to the aorta)

Follow-up timepoints were at months one, six and twelve following the procedure and annually for five years following the procedure.

The composite endpoint was met not only by the predefined analysis group (i.e. – neck angles 60 – 90 degrees) but also with patients with all neck angles. 89% (67 of 75) of patients in the predefined analysis group and 90.7% (127 of 140) of all neck angles met the composite endpoint. In addition 90% (90 of 100) with neck angles greater than 60 degrees and 92.5% (37 of 40) also met the composite endpoint.

There were no Type I or III endoleaks in the below 60 degree cohort (which is noteworthy given data from competitive graft-stents which have shown endoleaks as high as 2.5% in this group) and only two (1.9%) endoleaks in the greater than 60 degree cohort. There were also no patients in this below 60 degree cohort which experienced sac expansion (a secondary endpoint) or migration of the stent – these are also noteworthy statistics given that data from competitive stent-graft studies have shown sac expansion and stent migration at 12 months in as many as 7% and 2.8% of patients, respectively.

**Composite Efficacy Endpoint at 12 Months Post-Procedure**

<b>% (n/N) [95% CI]<sup>2</sup> Primary Effectiveness</b>	<b>Aorfix™ &lt;60° As Treated N=67</b>	<b>Aorfix™ ≥60° As Treated N=143</b>	<b>Aorfix™ As Treated N=210</b>
<b>Composite endpoint success</b>	92.5% (37/40) [79.6%, 98.4%]	90.0% (90/100) [82.4%, 95.1%]	90.7% (127/140) [84.6%, 95.0%]
<b>Endoleak Type I or III</b>	0	1.9% (2/105)	1.3% (2/150)
<b>Fracture in fixation zone (Hooks)</b>	6.4% (3/47)	6.1% (7/114)	6.2% (10/161)
<b>Migration (&gt;10mm)</b>	0	1.7% (2/119)	1.2% (2/172)

SOURCE: <http://www.accessdata.fda.gov/>

### Safety Endpoints Met...

Safety was measured by major adverse event (MAE) rates of Aorfix patients compared to open surgery patients within 30 days and 12 months post-implantation / operation. Safety was further assessed by comparing Aorfix event rates with those of historical open surgery data from the Society for Vascular Surgery Lifeline registry.

Similar to efficacy, safety endpoints were met not only in the predefined analysis group but also in patients of all neck angles. Safety was better with Aorfix at both 30 days and 12 months. Among the predefined analysis group, 75% were free of MAEs within 30 days as were 76% of all neck angles. This compares to just 59% of open surgery subjects. Blood loss was the safety component that was the most improved by Aorfix as compared to open surgery with 36% of open surgery patients requiring transfusions as a result of excessive bleeding compared to only 12% in the Aorfix all neck angles cohort.

% (n/N) [95% CI]	Aorfix™ <60° N=67	Aorfix™ ≥60° N=151	Aorfix™ ITT N=218	COS ITT N=76
Freedom from any MAE within 30 days	82.1% (55/67) [72.9%- 91.3%]	72.8% (110/151) [65.8%- 79.9%]	75.7% (165/218) [70.0%- 81.4%]	59.2% (45/76) [48.2%-70.3%]

Through 12 months 67% of Aorfix patients (all neck angles) were free of MAEs compared to 54% of open surgery subjects.

% (n/N)	Aorfix™ <60° N=67	Aorfix™ ≥60° N=151	Aorfix™ ITT N=218	COS ITT N=76
Freedom from any MAE within 12 months	74.6% (50/67)	64.2% (97/151)	67.4% (147/218)	53.9% (41/76)

SOURCE: <http://www.accessdata.fda.gov/>

The SVS registry, initially expected to also be used as a primary safety endpoint, was relegated to a secondary endpoint due to certain limitations of the registry, most notably lack of defined neck angle measurements as well as differences in defined MAE characteristics. Notwithstanding the limitations, safety of Aorfix was also superior to the SVS registry data.

Among the Aorfix patients 93% of those with less than 60 degree neck angles, 82% of greater than 60 degree neck angles and 85% of all neck angles were free from MAEs at 30 days compared to 56% of the SVS registry. Through 12 months, 88% of Aorfix patients with 60 degree neck angles were free from MAEs as were 76% of those with greater than 60 degree neck angles and 80% of all neck angles compared to only 55% of the SVS registry.

% (n/N) [95% CI]	Aorfix™ <60° N=67	Aorfix™ ≥60° N=151	Aorfix™ ITT N=218	SVS N=323
Freedom from any SVS-MAE within 30 days	92.5% (62/67) [83.4% - 97.5%]	81.5% (123/151) [74.3% - 87.3%]	84.9% (185/218) [79.4%-89.4%]	56.3% (182/323) [50.8% - 61.8%]
Freedom from any MAE within 12 months	88.1% (59/67) [77.8% - 94.7%]	76.2% (115/151) [68.6% - 82.7%]	79.8% (174/218) [73.9% -84.9%]	54.5% (176/323) [48.9% - 60.0%]

SOURCE: <http://www.accessdata.fda.gov/>

### FDA Approved in 2013, Post-Approval Data Continues to Demonstrate Strong Efficacy / Safety Profile...

Aorfix received FDA approval on February 14, 2013. It is indicated for the treatment of patients with abdominal aortic and aorto-iliac aneurysms having vascular morphology suitable for endovascular repair, including:<sup>7</sup>

<sup>7</sup> [http://www.accessdata.fda.gov/cdrh\\_docs/pdf11/P110032A.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf11/P110032A.pdf)

- Adequate iliac or femoral access that is compatible with vascular access techniques, implants, and accessories
- Aortic neck landing zone diameters with a range of 19mm to 29mm
- Non aneurysmal proximal neck center-line length of  $\geq 15$ mm
- Infrarenal aortic neck angulations including those up to and including 90°
- Common iliac landing zone diameters with a range of 9mm to 19mm
- Distal fixation length of  $\geq 15$ mm

FDA required Lombard (as they have other manufacturers) to perform a long-term post-approval study to demonstrate continued safety. The five-year post-approval study consists of the follow-up of all available patients from the PYTHAGORAS trial plus additional patients treated with Aorfix which will aggregate to at least 455 patients, at least 282 of which must be evaluable at the five-year anniversary of implantation. Lombard will report data on pre-specified criteria at least annually.

Primary safety endpoint is freedom from aneurysm-related death at five years following the Aorfix procedure with a performance comparator of 94%. Secondary endpoints are MAEs and serious adverse events through five years post-implantation.

In November 2014 at VEITHsymposium Lombard presented positive two-year follow-up data from the post-approval study. Among the patients with AAA neck angles of 60 to 90 degrees, the data showed zero aneurysm ruptures, 98% freedom from Type I and III endoleaks, 99% freedom from device migration, 98.2% freedom from AAA-related death (superior to the 94% performance criteria) and 97.2% from graft occlusion.

---

## EVAR Market / Competition

According to GlobalData MediPoint research, the aortic stent markets of ten major countries are worth approximately \$1.3 billion today and are expected to increase by a CAGR of 9.5% to 2018 and 6.7% to \$1.9 billion in 2020. The firm further predicts the U.S. market, which currently holds approximately 44% of total global share, to grow at a CAGR of 5.9% through 2020 and remain the largest single market with 42% share.<sup>8</sup> The authors note that global growth will be facilitated by an increasing prevalence of AAA as well as aging populations. Specifically to the U.S. and the lower forecasted growth in America compared to the global market, the authors indicate that dearth of availability of devices to address difficult to treat conditions is a factor – which we think may benefit Lombard.

The rapid growth of the AAA market has spurred manufacturers to accelerate development of next-generation products which have improved longer-term safety profiles, can be more effectively and safely used with complex anatomies and are appropriate for a greater proportion of the AAA population. Companies such as Medtronic, Endologix, Cook Medical, TriVascular, Cook Medical and W.L. Gore and Associates are all vying for a bigger piece of the growing AAA stent-graft pie.

In addition to safety and efficacy, important characteristics of stent-grafts that can enhance their competitiveness are certain attributes that allow them to be used on a larger portion of the AAA population. These characteristics are spelled out in the labeling of FDA-approved stent-grafts and include:

- Aortic neck landing zone diameters: the landing zone refers to the area below the renal arteries. The greater the range of landing zone diameters that a stent-graft is indicated for, the greater proportion of the population that it is appropriate for
- Proximal neck length: refers to how much healthy aorta at the top of the aneurysm that is required for a specific stent-graft to attach to. The shorter the required proximal neck length, the greater proportion of the population that it is appropriate for
- Distal fixation length: refers to how much healthy artery there must be where the bottom of the stent-graft attaches. The shorter the required distal fixation length, the greater proportion of the population that it is appropriate for
- Infrarenal neck angulation: refers to angle of the aorta between the renal arteries and the top of the aneurysm. The greater the range of neck angles that a stent-graft is indicated for, the greater proportion of the population that it is appropriate for

---

<sup>8</sup> GlobalData MediPoint: Aortic Stent Grafts – Global Analysis and Market Forecasts. Oct 2014

In addition to these labeled indications, another unique attribute is the profile (i.e. – diameter) of the catheter of the delivery system of each stent-graft. A lower profile may allow 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.

	<b>Aorfix Plus</b> (Lombard)	<b>Endurant II/IIIs</b> (Medtronic)	<b>AFX</b> (Endologix)	<b>Excluder</b> (Gore)	<b>Zenith Flex</b> (Cook)	<b>Ovation Prime</b> TriVascular
Aortic landing zone (mm)	19 - 33	19 - 32	18 - 32	19 - 29	18 - 32	16 - 30
Proximal neck length (mm)	≥ 15	≥ 10	≥ 15	≥ 15	≥ 15	≥ 10
Distal fix length	≥ 15	≥ 15	≥ 15	≥ 10	≥ 10	≥ 10
Neck angulation	≤ 90°	≤ 60°	≤ 60°	≤ 60°	≤ 60°	≤ 60°
Catheter profile	22f	18f	17f	18f - 20f	18f - 22f	14f - 15f
PEVAR Indicated	No	No	Yes	No	No	Yes

Aside from a larger catheter profile, Aorfix's attributes are competitive with the other FDA-approved graft stents. Noteworthy is that in early February of this year Lombard received FDA approval of Aorfix Plus, which increased the indicated aortic landing zone range of their AAA stent graft from 19mm – 29mm to 19mm – 32mm. This supplement provides an upper-bound landing range greater than any of the competing graft stents approved for sale in the U.S. and, per Lombard's estimates, increases the potential target market for their device by approximately 10%.

But, the most significant competitive attribute of Aorfix remains its indicated use for neck angles up to 90 degrees as no other stent graft is approved for neck angles greater than 60 degrees. And while we think the low-hanging fruit for Aorfix is this higher neck angle population, the device is used across various patient anatomies with about 30% - 50% of Aorfix patients having neck angles less than 60 degrees. Also, despite Aorfix having a catheter profile larger than any of its competitors and not indicated for PEVAR, this has not precluded its use in these less-invasive procedures. In fact Aorfix is used in PEVAR more often than in traditional EVAR. Lombard is developing a next-gen delivery system with a lower profile which could facilitate even greater use of Aorfix with PEVAR.

Product innovation remains furious, however, with current EVAR participants working on enhancements to existing products and other companies looking to newly enter the market. This includes novel products from Endologix and Cook and a new entrant from Johnson & Johnson. Product enhancements and new entrants could make the EVAR market even more competitive as participants look to capture a greater portion of the ever-growing EVAR procedure pie, although we do not foresee any other product being approved in the U.S. for neck angles greater than 60 degrees in the near-term.

Endologix, which trails Medtronic, Cook and Gore in EVAR market share, is looking to gain ground with introduction of Nellix, its next-gen stent graft. Nellix incorporates a unique polymer sealing technology to fix the stent graft in place, which in clinical trials to-date looks to reduce the potential for reinterventions, even in difficult to treat anatomies. Nellix, which received CE Mark in Q1 2013 is undergoing a pivotal study in support of an FDA filing – which could happen in 2016.

Another under-development product candidate from Endologix, this one dubbed Ventana, is also being positioned to increase the potential AAA target population that can be treated with the company's devices, particularly with difficult to treat anatomies. Ventana Fenestrated System is an off-the-shelf device for the treatment of juxtarenal AAs (i.e. – when the top of the stent graft is fixed just above the renal arteries). Ventana is based on the AFX system and would allow use with proximal neck lengths shorter than 10mm. Ventana is undergoing clinical studies in the U.S.

Cook also has an off-the-shelf fenestrated device under development. Zenith p-Branch is also undergoing U.S. clinical trials. Medtronic and Gore are also moving towards development of fenestrated devices, although in earlier stages than either Endologix or Cook.

Johnson & Johnson is also aiming to be more competitive in the EVAR space. J&J's InCraft stent graft, which launched in Canada and Europe in late 2014 and is currently in a pivotal U.S. study, is ultra-low profile (12f -14f) which could make it very formidable in the PEVAR space in particular.

### Aorfix Outcomes Data Also Competitive...

Lombard compiled outcomes data from clinical trials of competing stent graft products. And while potential differences of each study including those related to design, protocol, and patient populations, among others, preclude the ability to make direct comparisons or form concrete conclusions, when compared to data from Lombard's PYTHAGORAS study, Aorfix's outcomes data looks to be competitive. In fact, up to 50% of patients treated with Aorfix to-date had neck angles less than 60 degrees. The summarized data below is from patients with neck angles less than 60 degrees from various studies.

	DEVICE							COOK ZENITH (HIGH RISK)
	AORFIX NECK ANGLES LESS THAN 60 DEGREES	TRIVASCULAR OVATION	MEDTRONIC TALENT	MEDTRONIC ENDURANT	ENDOLOGIX POWERLINK	GORE EXCLUDER	COOK ZENITH	
PMA Application Number	P110032	P120006	P070027	P100021	P040002	P020004	P020018	P020018
Date of FDA Notice of Approval	2/14/13	10/5/12	4/15/08	12/16/10	10/29/04	11/6/02	5/23/03	5/23/03
Freedom from SVS MAE (30 days)	92.5%	97.5%	89%	96%	N/A	N/A	N/A	N/A
Mortality (30 days)	1.5%	0.6%	1.8%	0%	1%	1.3%	0.5%	2%
Mortality (1 year)	4.5%	2.5%	6.5%	4%	6.8%	7.2%	3.5%	9%
Sac shrinkage (5 mm./ 1 year)	36.7%	32.0%	33.6%	49.6%	35.7%	14.3%	67.5%	62.9%
Sac expansion (5 mm./ 1 year)	0%	0.7%	2.3%	0%	2%	7.1%	1.3%	1.6%
Type I/III leak (1 year)	0%	0%	2.5%	0%	0%	1.3%	1.4%	1.8%
Migration (10 mm./ 1 year)	0%	0%	0.8%	0%	0.7%	2.3%	2.5%	2.8%

SOURCE: Lombard Medical. <http://www.nasdaq.com/markets/ipos/filing.ashx?filingid=9407825SEC>

### Aorfix is a Small, Unique Fish in a Big Pond...

Medtronic's Endurant / Endurant II is the market leading stent graft in the U.S. Cook Medical (Zenith) and W.L. Gore (Excluder), while not nearly as dominant as Medtronic, also hold formidable share of the market. Endologix (AFX) is estimated to hold the fourth spot with less than 10% share<sup>9</sup>.

Aorfix commands low-single digit share in the U.S. but that does not reflect its competitiveness. Aorfix is a relative newcomer to the AAA market, having launched in the U.S. in late 2013. And Lombard, at a market capitalization of ~100M with ~150 employees is miniscule compared to the likes of Medtronic (\$72B market cap, ~49k employees) and certainly does not have the distribution or marketing resources of its much larger brethren.

The U.S. market for EVAR is estimated at \$500M - \$700M. Approximately 20% - 30%, or \$100M - \$200M, of this market is estimated to be comprised of procedures involving patient anatomies with highly angulated necks and / or iliac artery tortuosity. As Aorfix is the only stent graft indicated for use by FDA with highly angulated necks, we think Lombard will be very competitive in this market.

In Europe EVAR popularity has not blossomed as quickly as it has in the U.S. with open surgery still accounting for approximately one-half of all AAA repairs. The aggregate European market for EVAR is about 65% as large as the U.S., or approximately \$400M. Medtronic is even more dominant in Europe, commanding approximately 50% market share. The remaining pie is more diversified among the other manufacturers – which we estimate at about 20% - 25% for both Cook and Gore, and ~10% for Endologix. Aorfix has been fairly competitive in Europe since its launch in 2006. Aorfix received CE Mark for high angle procedures in 2009 and, per Lombard estimates, currently holds approximately 7% share of the U.K. market. And while we think Europe also represents an attractive market for Aorfix, it has more direct on-label competition in higher neck angulations as Endurant II as well as Bolton Medical's Treovance are CE Marked for neck angles up to 75 degrees.

Aorfix received regulatory approval in Japan in August 2014 and launched there in Q3 2014 through the company's Japanese distributor, Medico's Hirata. Japan is the second largest standalone EVAR market, which is estimated at ~\$100M - \$150M annually. While Japan was loathe to quickly accept EVAR with the first procedure not being performed until 2006, since then EVAR has grown rapidly making Japan one of the fastest and most attractive

<sup>9</sup> Tony Semedo, VP / GM Medtronic Endovascular Innovations business. *FDA Approves Medtronic's Endurant AAA Stent Graft*. Amanda Pedersen

markets for the procedure. One of the hindrances to earlier acceptance is Japan's stringent regulatory policies for approval of stent grafts. Another is Japan's "high risk" restriction which only allows for insurance reimbursement for EVAR in AAA cases which are deemed too risky to be repaired via open surgery. The high regulatory hurdle affords current participants some level of protection from new potential entrants to the Japanese market. And while the "high risk" restriction hindered EVAR uptake initially (EVAR accounted for only ~10% of AAA repairs in 2008), this appears to be less of a headwind today with EVAR now accounting for over 50% of AAA repairs in Japan. According to MedTech Ventures, EVAR has increased at a CAGR of 18% over the last five years. Similar to the U.S., Lombard has the only stent graft approved for neck angles greater than 60 degrees, which, coupled with the large size and rapid growth of the Japanese market, offers very attractive fundamentals and provides the potential that revenue can ramp relatively quickly.

---

## **Commercialization**

Aorfix has been commercially available in parts of Europe since 2005 and in 2009 received an indication there for high neck angles between 75 and 90 degrees. It received FDA approval and regulatory approval in Japan in February 2013 and August 2014, respectively and launched with high neck angle indications in those countries in Q3 2013 and Q3 2014.

Sales in Europe are handled by a direct sales force in the U.K. and Germany (total of 11 reps) and through third-party distribution in Italy and Spain. Medico's Hirata acts as Lombard's distributor in Japan. The company quickly assembled a direct sales force in the U.S. which it expects to continue to grow from the 35 at 2014 year-end to approximately 50 by mid-2015.

### ***Europe Will Remain Significant Contributor But May Lag Japan / U.S. in Long-Term Growth...***

While Europe has been an important market for Lombard and Aorfix, and will likely continue to contribute a significant portion of revenue in the coming years, we think the company's main focus for long-term growth of the Aorfix franchise will be in Japan and the U.S.

Germany likely holds the most promise for growth of Lombard's European territories given its large size, relatively healthy economy, reliable reimbursement and it being a major medical device market. The company has noted that they will look to opportunistically expand their sales force in Germany, although we do not expect this to be a massive ramp like what they are doing in the U.S. We think Germany holds opportunity for reasonable near-to-mid term growth but Lombard's other European territories may be somewhat more challenging given the recent move in the U.K. to relegate EVAR procedures to just a select number of high-volume centers and lingering economic weakness and related austerity measures in Italy and Spain. Another potential hindrance to wider uptake of EVAR in certain parts of Europe is less-standardized and / or potentially less attractive reimbursement. While this does not appear to be an issue in Germany, it can be in other countries.

So while we think Europe, which generated \$6.5 million in Aorfix sales in 2014, up 15% from \$2.6M in 2013, remains an attractive market and one where we think Aorfix can continue to take market share, we see the fundamentals of Japan and the U.S. as holding even greater opportunity, particularly over the long-term.

### ***Japan: Big, Dense and Rapidly Growing EVAR Market With Competitive Benefits...***

Japan has a number of attractive attributes including market size, density, relative EVAR immaturity, uniform reimbursement and regulatory barriers to competition. Japan, with a population of just 127 million is estimated to be a \$100 million - \$200 million market for EVAR, compared to Europe which is estimated at \$400 million - \$500 million annually but Europe encompasses 750 million people over a much larger and widespread geography. And Japan is relatively new to EVAR but procedural volume is growing fairly rapidly despite high-risk restrictions. Aorfix is the only stent-graft approved in Japan for high neck angles, offering another relative advantage to Europe, where both Bolton Medical and Medtronic have products indicated for neck angles up to 75 degrees. Reimbursement in Japan is also conducive to increasing EVAR procedural volumes given uniform and relatively high (~\$18k) reimbursement rates. And finally, high regulatory hurdles offer Aorfix more competitive insulation in Japan than in most other countries.

Lombard wasted no time in exploiting the opportunities in Japan. Medico's Hirata is one of the most prominent vascular product suppliers in Japan and, having previously provided distribution for Cook Medical, has extensive experience and contacts within the stent-graft space. Medico placed large stocking orders immediately following Aorfix regulatory approval in Japan, generating \$3.6 million of revenue for Lombard in the second half of 2014. And

while we expect soft sales in Q1 2015 (and perhaps through the first half) as Medico burns through certain of the inventory, management noted on the Q4 2014 call that they think for the full-year, 2015 revenue from Japan should be higher than the \$3.6 million in 2014. We think Japan offers significant upside for Lombard over the long-term.

**U.S.: Largest & Most Established Market w/ Favorable Demographics, Policies Fueling Growth...**

The fundamentals of the U.S. market including size, increasing shift from open surgery to EVAR, premium pricing, age and health of the population and screening measures provide fertile ground for Aorfix. And similar to Japan, Aorfix is the only stent-graft approved for neck angles higher than 60 degrees.

The U.S. is the largest EVAR market, estimated at \$500 million - \$700 million, including ~\$100 million - \$200 million related to high neck angles. Demand for devices to treat difficult anatomies is particularly strong. EVAR is also well established in the U.S. and continues to account for a greater proportion of AAA repairs (75% currently), driven by literature demonstrating lower mortality, fewer complications and shorter recovery time with EVAR as compared to open surgery. Pricing in the U.S., at approximately \$13.8k per device is also substantially better than other areas of the world including the U.K. where selling price is ~\$9k. Screening recommendations and programs, which are already much more established in the U.S. as compared to other parts of the world, particularly in areas of Europe, may broaden even further as advocates push for an even greater proportion of the U.S. population to be screened for AAA. Age and health of the U.S. population also work in favor of increasing demand for EVAR. Growth in the over-65 population is expected to almost double over the next 40 years, from 43 million in 2012 to approximately 84 million in 2050<sup>10</sup>. And, finally the relatively poor health of the American population including increasing incidence of AAA risk factors such as obesity (69% over age 20 are overweight, up from 55% in 1994), high blood pressure (33% over age 20 have hypertension, up from 24% in 1994) and heart disease (~70% over age 60 have heart disease) provides further fuel for continued growth of EVAR procedural volume in the U.S.<sup>11</sup>

Lombard has been aggressive in exploiting the U.S. opportunity and Aorfix appears to already be well-received in America. While the formal launch was in November 2013 sales initiated in Q3 of that year. As illustrated in the chart below the ramp in the U.S. has been impressive and has been the main catalyst to driving total Aorfix revenue growth since its introduction here.

	Q3 2013	Q4 2013	Q1 2014	Q2 2014	Q3 2014	Q4 2014
U.S. Aorfix revenue	\$199k	\$293k	\$509k	\$568k	\$993k	\$1,188k
Sequential growth	-	47%	70%	12%	75%	20%
U.S. as % total Aorfix revenue	14%	14%	24%	26%	38%*	42%*
Total Aorfix Sales	\$1,460k	\$2,083k	\$2,048k	\$2,193k	\$2,638k*	\$2,838k*
Sequential growth	-8%	43%	-2%	7%	20%	8%

\*Excludes Japan stocking order

Lombard's initial U.S. strategy entails marketing to the top 300 EVAR centers (of ~1,500 total) where currently approximately 50% of the procedures are performed. Physician training programs, which are critical to help accelerate uptake, are at the heart of Lombard's marketing program. And while Lombard's marketing efforts will have a distinct focus on the roughly 30% of the EVAR population that presents with high neck angles and tortuosity of the iliac arteries and which have previously often been treated off-label with competing devices, there is already meaningful demand across various patient anatomies with ~ 30% - 50% of Aorfix patients to-date with neck angles less than 60 degrees. And, perhaps unexpectedly, despite the relatively large delivery profile (and lack of indication for PEVAR) a significant portion of the Aorfix procedures are being done via PEVAR instead of EVAR. So while Aorfix may initially be viewed as somewhat of niche product for high angle EVAR procedures, there is clear and significant demand for it in the broader AAA market.

Lombard has been selective in hiring their sales force, bringing on reps already experienced with EVAR and vascular products. The sales force includes technical personnel who handle physician training which encompasses highlights of the PYTHAGORAS study, review of Aorfix indications, computerized demonstration on performing an

<sup>10</sup> Ortman JM, Velkoff VA, Hogan H. *An Aging Nation: The Older Population in the United States*. United States Census Bureau. May 2014

<sup>11</sup> *Health, United States, 2013*. U.S. Centers for Disease Control and Prevention, National Center for Health Statistics

Aorfix procedure and a case review of correct placement of the device. While these training sessions, which are mandated by FDA, are key to facilitating adoption of Aorfix, it means the sales process can be somewhat lengthy. In order to quickly broaden their geographic footprint, the company expects to grow their sales force from approximately 35 today to 50 by mid-year 2015.

---

## Investment Considerations

### ✦ **EVAR Growing With Demand Particularly Strong in Complex Anatomies and Emerging Areas**

EVAR represents an annual global market worth approximately \$1.5B, including about \$1.3B in the ten largest countries. Worldwide growth is expected to pace at almost 10% per year through 2018 and about 7% through 2020. While almost one-half of the current global EVAR market resides in the U.S., growth in certain international markets where EVAR is at an earlier stage of adoption but gaining accelerated acceptance and driven by favorable attributes (i.e. – reimbursement, large population, etc), such as Japan, could be particularly robust and outpace the rate of the global stage.

We think long-term growth in the U.S. will continue to be driven by the shift from open surgery to EVAR / PEVAR as well as, potentially, from additional screening initiatives. Both of these, as well as the ageing population and relatively poor health of Americans means that the EVAR market here could meaningfully expand. Certainly more robust screening measures could have a dramatic effect of increasing the overall EVAR market, given that only ~15% of cases are currently being diagnosed.

But over the more near-term we see much of the domestic growth being fueled by demand for devices to address complex and difficult anatomies. The development frenzy by stent-graft manufacturers has a clear focus on this market. We view Lombard as sitting in the catbird's seat relative to the 20% - 30% of AAA cases with high neck angles and tortuous iliacs given that Aorfix is the only stent-graft approved in any and all of its commercialized territories for neck angles up to 90 degrees. We think Aorfix can be very competitive in this segment and take share from off-label use of competing devices.

### ✦ **Aorfix Demand Coming from Diversified Patient Anatomies, EVAR and PEVAR**

While the sweet-spot for Aorfix is in the 20% - 30% of the AAA market with high neck angles and tortuous iliacs, demand has been strong across patient anatomies with up to 50% of patients treated with Aorfix to-date having neck angles less than 60 degrees. This is perhaps being driven by the PYTHAGORAS data which suggested Aorfix is very competitive with other stent-grafts in this low-angle segment and offers the potential that Lombard's device can take meaningful share of this 70% - 80% of the market.

Aorfix is also seeing meaningful demand in PEVAR, despite having a relatively large catheter profile and not specifically indicated for the procedure. While PEVAR adoption among all AAA repair remains somewhat limited, it may gain in popularity if future clinical evidence can demonstrate cost effectiveness. Per Lombard, Aorfix is being used in PEVAR at least as much as it is in EVAR, which indicates that increased adoption of PEVAR may not curb demand for Aorfix.

### ✦ **Pipeline Offers Potential To Expand Target Markets, More Fuel To Revenue Growth**

Lombard is working on broadening Aorfix's size range, developing a lower-profile delivery system and also looking to tap the thoracic EVAR (TEVAR) market with introduction of a thoracic stent-graft. Successful development of these will expand Lombard's overall target markets, increase their shots on goal and offer additional catalysts to revenue growth.

FDA approval of Aorfix Plus, which increased the indicated aortic landing zone range of their AAA stent graft from 19mm – 29mm to 19mm – 32mm, came in early February and, per Lombard, expands the potential target market for their device by approximately 10%. Future enhancements should further expand their indicated patient population.

Development of a lower profile delivery system is also underway, introduction of which would also broaden Lombard's AAA repair target market, particularly for patients with smaller vessels and in PEVAR procedures. The company hopes to launch this next-gen delivery system later in 2015.

Development of a TEVAR device, for treatment of thoracic aortic aneurysms (TAA), would bolt on a new market segment for Lombard. TAAs occur in the upper portion of the aorta including the 180 degree bend where the aorta comes off of the heart. TAAs represented a worldwide market estimated (per Medtech Ventures) at ~\$380 million in 2013 and expected to grow to over \$480 million by 2018. As open surgery is even more invasive with TAAs (involves opening the rib cage) than with AAAs, TEVAR is often considered a more palatable option. Lombard believes their ultra-flexibility technology could be ideal for TEVAR, particularly TAAs located at the hairpin bend off of the heart. And while introduction of a TEVAR device will not be a near-term event (Lombard hopes to have a TEVAR device ready to enter clinical trials by 2017), successful launch of this could provide another significant long-term revenue opportunity.

#### ✦ **While Small Relative to Peers, Lombard is Highly Competitive**

Lombard is one of the smallest stent-graft manufacturers and commands relatively little market share compared to the likes of Medtronic, Endologix, Cook Medical and others. The fast pace of the AAA market and growing demand for safer, more effective stent-grafts has stimulated development of novel and next-gen devices from established participants as well as new entrants. Competition for market share is fierce and being waged with device enhancements such as lower profile delivery systems, improved fixation technologies and greater flexibility. Complex anatomies look to be developing as a particularly competitive area. And while we do not foresee a competing product being approved in the U.S. for neck angles greater than 60 degrees in the near-term, the high neck-angle segment is in the crosshairs of the major manufacturers and is already being partially addressed off-label with non-indicated stent-grafts. So while Lombard has had real success in tapping the greater AAA space (low and high neck angles) and continues to innovate in order to appeal to an even greater portion of the AAA market, its peers are not sitting idle and can be expected to continue to provide stiff competition.

#### ✦ **Long-Term Growth Story**

While we think the competitive advantages of Aorfix and Lombard's commercialization strategy bode well for long-term success of the organization as well as for investors in the company, this will not be an overnight success story. Lombard is still at a relatively early stage with commercialization of Aorfix given that the device just very recently entered the two largest EVAR markets.

We expect the recent introductions in the U.S. and Japan and widening of the sales / distribution footprint in legacy territories will provide near-term catalysts to revenue growth. Mid-to-long term growth is sustainable with share gains from competing devices as well as an overall expansion of the EVAR market. Share gains could be particularly meaningful in the high neck angle segment, although as noted, Aorfix is seeing demand across patient anatomies. Meanwhile, it seems a given that the worldwide EVAR market will grow – partly due to the ongoing shift from open surgery, but also greater awareness, improved screening and growing populations of people with risk factors.

Despite what we model to be fairly robust revenue growth, profitability is, in our opinion, unlikely to materialize within the next few years. Lombard will be investing in operating infrastructure, including beefing up the direct sales force and be maintaining a sizeable R&D budget. We recommend patience as the newly hired sales force will need time to become fully productive and, longer-term, meaningful share gains are often more marathon than sprint. Gross margin levels are production-volume related and should expand over time. Revenue growth should outpace that of expenses in the short-term and believe profitability is attainable in the coming years.

---

## VALUATION / RECOMMENDATION

Management has guided to 2015 revenue of \$18 million - \$20 million, implying yoy growth of 35% - 50%. We think the growth rate steepens into 2016 as the newly hired U.S. sales reps reach a more productive level. Japan revenue may be somewhat tepid in early 2015 as Medico Hirata burns through certain inventory from the recent large stocking orders. We look for revenue from Japan to pick up again in the back half of the current year and think this territory will be a very strong contributor in 2016 and beyond as Lombard and their highly experienced distributor exploit the attractive growth fundamentals of that market. Meanwhile, we think the European markets where Lombard is selling direct, Germany in particular, will be a solid double-digit revenue growth territory for at least the next several years.

We look for gross margin expansion on higher production volumes and benefitting from direct sales growing faster than those via third-party distribution. We have GM at about 47% in 2015 but, based on industry comps and

Lombard's focus on markets with favorable reimbursement, we think this can eventually reach 70% or better. We think operating expenses increase more than revenue in 2015 as Lombard continues to build out its direct sales force and incurs certain additional overhead costs (such as those related to relocating its global headquarters) but for leverage in OpEx to materialize in 2016 and improve thereafter on revenue growth and a more productive sales force, despite fairly continued heavy-spend on R&D in support of new and enhanced products.

We value EVAR using a combination of 10-year DCF and EV/revenue comps. 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 such as a TEVAR stent-graft which the company does expect to pursue. As such new product introductions, unrelated specifically to Aorfix, could provide upside to our model and related valuation.

We model 10-year revenue CAGR of 24%, gross margin widening from 47% to 71% over that period and scalability in OpEx. Our 10-year DCF model, which uses an 11% discount rate and 2% terminal growth rate, values EVAR at approximately \$9.00/share.

We also look at valuation using comparable 2015 and 2016 EV/revenue multiples of Endologix (2015: 6.7x, 2016: 5.7x) and TriVascular (2015: 3.9x, 2016: 2.7x). Average 2015 and 2016 EV/revenue multiples values EVAR at \$9.20/share (2015 comp) and \$10.20/share (2016 comp). Average of the two is \$9.70/share.

Average of DCF and EV/revenue is approximately \$9.50/share. We are initiating coverage of EVAR with an Outperform rating and \$9.50/share price target.

## FINANCIAL MODEL

### Lombard Medical, Inc.

	2014 A	Q1E	Q2E	Q3E	Q4E	2015 E	2016 E	2017 E	2018 E
<b>Total Revenues</b>	\$13,277.0	\$3,113.0	\$4,166.0	\$5,006.0	\$6,386.0	\$18,671.0	\$27,696.5	\$43,706.5	\$62,210.2
<i>YOY Growth</i>	90.8%	51.3%	90.0%	17.3%	34.2%	40.6%	48.3%	57.8%	42.3%
Cost of Goods Sold	\$7,541.0	\$1,677.9	\$2,216.3	\$2,633.2	\$3,320.7	\$9,848.1	\$12,435.7	\$16,827.0	\$19,658.4
<b>Gross Income</b>	\$5,736.0	\$1,435.1	\$1,949.7	\$2,372.8	\$3,065.3	\$8,822.9	\$15,260.8	\$26,879.5	\$42,551.8
<i>Gross Margin</i>	43.2%	46.1%	46.8%	47.4%	48.0%	47.3%	55.1%	61.5%	68.4%
Sell, Mktg & Dist	\$21,364.0	\$6,312.0	\$6,641.0	\$6,814.0	\$7,102.0	\$26,869.0	\$30,521.6	\$35,096.3	\$38,072.7
<i>% SM&amp;D</i>	160.9%	202.8%	159.4%	24.3%	24.0%	143.9%	110.2%	80.3%	61.2%
R&D	\$9,213.0	\$2,414.0	\$2,557.0	\$2,620.0	\$2,687.0	\$10,278.0	\$10,774.0	\$10,851.0	\$10,920.0
<i>% R&amp;D</i>	69.4%	77.5%	61.4%	52.3%	42.1%	55.0%	38.9%	24.8%	17.6%
Admin	\$9,799.0	\$2,654.0	\$2,771.0	\$2,988.0	\$3,075.0	\$11,488.0	\$12,881.0	\$14,544.0	\$16,177.0
<i>% Admin</i>	73.8%	85.3%	66.5%	59.7%	48.2%	61.5%	46.5%	33.3%	26.0%
<b>Operating Income</b>	(\$34,640.0)	(\$9,944.9)	(\$10,019.3)	(\$10,049.2)	(\$9,798.7)	(\$39,812.1)	(\$38,915.8)	(\$33,611.8)	(\$22,617.9)
<i>Operating Margin</i>	-260.9%	-319.5%	-240.5%	-200.7%	-153.4%	-213.2%	-140.5%	-76.9%	-36.4%
Total Other Income (Expense)	(\$1,339.0)	\$15.0	\$5.0	\$0.0	\$0.0	\$20.0	\$0.0	\$0.0	\$0.0
<b>Pre-Tax Income</b>	(\$35,979.0)	(\$9,929.9)	(\$10,014.3)	(\$10,049.2)	(\$9,798.7)	(\$39,792.1)	(\$38,915.8)	(\$33,611.8)	(\$22,617.9)
Tax expense (benefit)	(\$1,227.0)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>Tax Rate</i>	3.4%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
<b>Net Income</b>	(\$34,752.0)	(\$9,929.9)	(\$10,014.3)	(\$10,049.2)	(\$9,798.7)	(\$39,792.1)	(\$38,915.8)	(\$33,611.8)	(\$22,617.9)
<i>YOY Growth</i>	224.7%	27.2%	-12.5%	19.0%	4.4%	14.5%	-2.2%	-13.6%	-32.7%
<i>Net Margin</i>	-261.7%	-319.0%	-240.4%	-200.7%	-153.4%	-213.1%	-140.5%	-76.9%	-36.4%
<b>EPS</b>	(\$2.39)	(\$0.61)	(\$0.61)	(\$0.61)	(\$0.44)	(\$2.22)	(\$1.47)	(\$1.07)	(\$0.62)
<i>YOY Growth</i>	40.0%	-1.0%	-46.7%	16.7%	-3.2%	-7.0%	-33.8%	-27.3%	-41.9%
Diluted Shares O/S	14,556	16,300	16,400	16,500	22,500	17,925	26,500	31,500	36,500

Brian Marcks, CFA

## LEADERSHIP

### Management

**Simon Hubbert**  
**Chief Executive Officer**

Simon Hubbert joined Lombard Medical in June 2010 as VP Sales and Marketing, International. He has held various sales and marketing roles for Johnson & Johnson and Medtronic, including the role of European Business and Marketing Manager for Medtronic. During his time as Vice President of Sales and Marketing International for LMA, a publicly traded company focused on innovative medical devices for the anesthesia markets, he was responsible for growing revenue through a hybrid distribution mode. This included a direct sales organization in several major markets, and support of third party distribution partners in other markets. Mr. Hubbert started his career in patient care, working in an operating theatre at a renowned neurosurgical unit in the UK. Mr. Hubbert was appointed Chief Executive Officer on January 1 2011.

**Bill Kullback**  
**Chief Financial Officer**

Bill Kullback brings more than 30 years of broad corporate finance and accounting experience to Lombard Medical, including more than 20 years in chief financial officer roles ranging from large, publicly traded to privately held growth companies. His deep industry experience includes CFO positions at medical technology companies ActivStyle, Inc., Angeion Corporation, IntriCon Corporation and MedSource Technologies, Inc. Most recently, he served as partner, chief financial officer and chief compliance officer of Integris, LLC, a SEC-registered wealth management firm with more than \$300 million in assets under management. Mr. Kullback received a B.A. in economics and English, as well as an MBA with a concentration in accounting, from the State University of New York at Buffalo.

**Peter Phillips**  
**Chief Technology Officer**

Peter Phillips has a PhD from Guy's Hospital London. Dr. Phillips co-developed the Aorfix stent-graft and led the development and commercialization of Aorfix from 1995. He is the Company's leading expert on the technology and its clinical application. In 2006, Dr. Phillips moved to the United States to become President of Lombard's U.S. subsidiary, which was set up to support the Aorfix U.S. clinical trial. Upon returning to the United Kingdom in 2009, he took up the position of Chief Technology Officer. Dr. Phillips was a director of Surgicraft Ltd, a UK orthopedics company.

**Michael Gioffredi**  
**President, LMT Inc. North America**

Michael Gioffredi has held that position since May 2013. Before joining Lombard, he was Chief Commercial Officer of Vessix Vascular, acquired by Boston Scientific in late 2012. Mr. Gioffredi worked at Angioscore in the position of SVP Global Sales and Marketing for seven years, and prior to that was Chief Sales and Marketing Officer for Cardiac Science, a NASDAQ listed company.

### Board of Directors

**Raymond Cohen**  
**Non-Executive Chairman**

Raymond Cohen joined Lombard Medical on July 9 2013 as Non-Executive Chairman. Mr Cohen has extensive international medical device experience having held several Chairman and CEO positions on the boards of both publicly listed and private life sciences companies in the US and Europe. Mr Cohen currently serves as the Chief Executive Officer and member of the board of directors of Irvine, CA based Axonics Modulation Technologies, Inc., a venture backed developer of neuromodulation devices. Mr Cohen also currently serves as the Non-executive Chairman of Jenavalve Technology, Inc., a private Munich-based developer, manufacturer and marketer of transcatheter aortic valve systems; Non-executive Chairman of BioLife Solutions, Inc. (OTC:BLFS), a manufacturer and marketer of biopreservation media for human cells; Non-executive Chairman of Synchroness, Inc., a contract engineering firm and also serves as a Non-executive Director of Spectrum Pharmaceuticals, Inc. (NASDAQ:SPPI), a developer and marketer of oncology and haematology drugs. From mid-2010 to late 2012, Mr Cohen served as Chief Executive Officer of Vessix Vascular, Inc., a developer of a novel percutaneous radiofrequency balloon catheter renal denervation system used to treat uncontrolled hypertension. In November 2012, during his tenure as CEO, the company was acquired by Boston Scientific Corporation (NYSE:BSX) in a structured transaction valued at up to \$425 million.

**Simon Hubbert**  
**Chief Executive Officer**

(Bio above)

**Simon Neathercoat FCA**  
**Non-Executive Director**

Simon Neathercoat FCA joined Lombard Medical as Non-Executive Chairman in October 2007. Having qualified as a Chartered Accountant he spent most of his career in Investment Banking with Dresdner Kleinwort Wasserstein and Hoare Govett advising Companies and Boards of Directors and has an in depth knowledge of 'City Practices' and Corporate Governance.

Mr Neathercoat broad experience included developing corporate strategies and their implementation for public and private companies including take-overs, acquisitions and disposals of companies and assets and financing via the Capital Markets. He has extensive knowledge as a Senior Independent Director with Audit, Remuneration and Nomination Committee experience.

**Timothy Haines**  
**Non-Executive Director**

Timothy Haines aged 53 joined the Board on May 31 2011, he has more than 25 years of international management experience in the life sciences industry. Before joining Abingworth in September 2005 he was Chief Executive of an Abingworth portfolio company, Astex Therapeutics. Mr Haines was with Astex for more than five years and was instrumental in establishing it as one of the leading UK biotechnology companies. Previously, Mr Haines was Chief Executive of two divisions of the publicly-listed medical technology company, Datascope Corp. Prior to Datascope; he held a number of other senior management positions in the U.S. and Europe. Mr Haines has a BSc from Exeter University and an MBA from INSEAD. Mr Haines is a former Director of the BioIndustry Association and currently sits on the Venture Committee of the British Venture Capital Association. His current other directorships include Abingworth LLP, Chroma Therapeutics Limited, Intelligence Medical Implants, Kspine Inc (formerly Vertech Inc), Stanmore Implants Worldwide Limited and XCounter.

**Craig Rennie**  
**Non-Executive Director**

Craig Rennie joined the Board in October 2007 and is Chairman of the Remuneration Committee. He has worked in the international pharmaceutical industry for over 30 years, initially in increasingly senior sales and marketing positions with Beechams in the UK, and subsequently in international management posts with the Wellcome Foundation. After almost 20 years based overseas, Mr Rennie returned to the UK in 1995 and, having established his own company, was subsequently appointed Chief Executive and President of a newly established, US venture-backed biotechnology company. In January 1999, Mr Rennie was appointed Chief Executive of Penn Pharmaceuticals where he led a primary MBO in 2000 and a secondary MBO and refinancing in 2004, when he assumed the role of Chairman and Chief Executive. Having worked throughout South East Asia, the Middle East, South America and Europe, Mr Rennie brings unparalleled international operational experience to the Board.

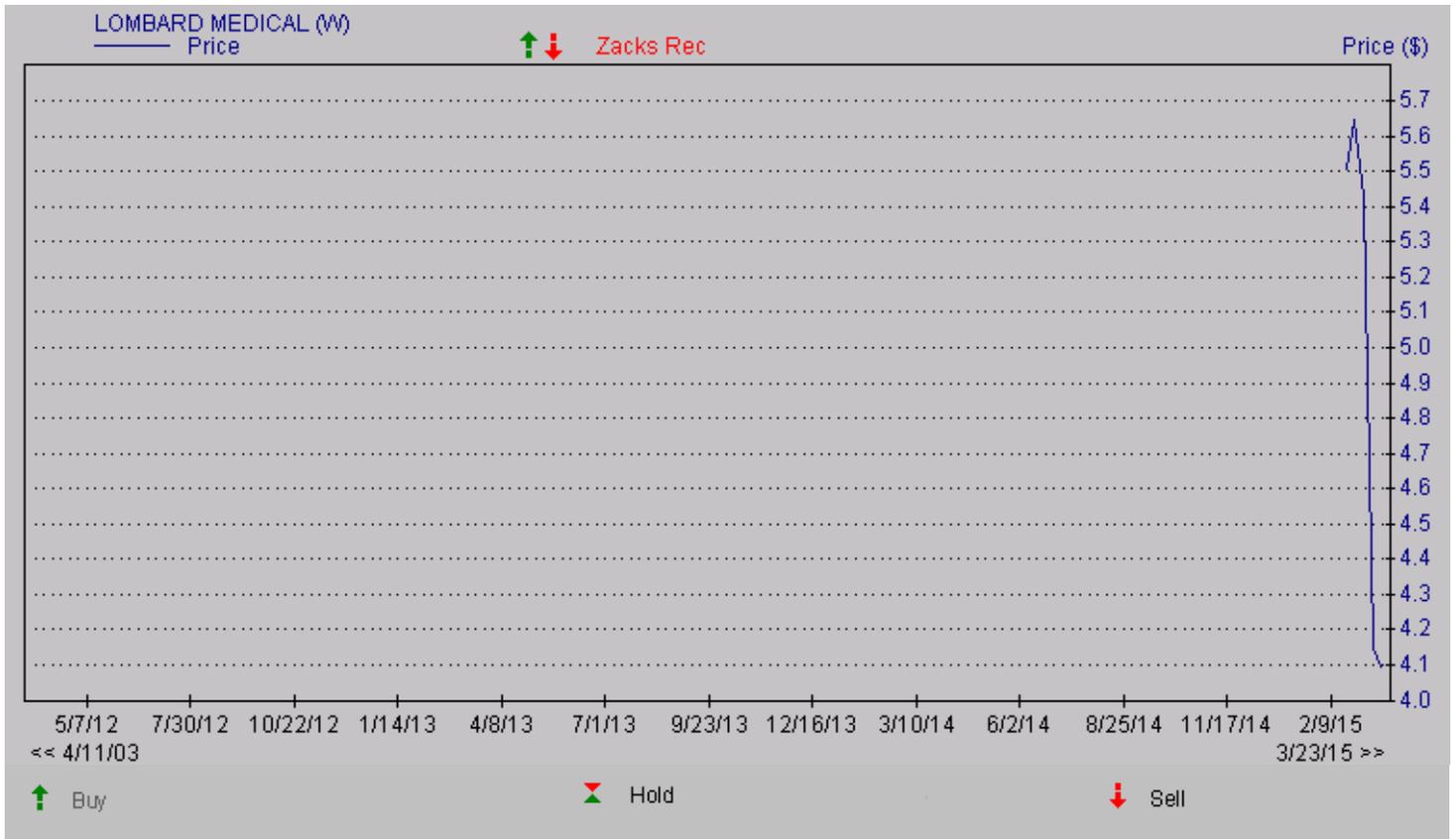
**John Rush**  
**Non-Executive Director**

John Rush joined Lombard Medical as CEO in 2009, and appointed Non-Executive Chairman in 2011, before stepping down in April 2013. Before joining Lombard Mr Rush was President and CEO of North American Scientific, Inc. (NASDAQ: NASM). He re-organized the Company and led an investor group initiative to take the Company private. The new organization is focused on commercializing temporary implants for local radiation delivery. Mr Rush was also President and CEO of MicroTherapeutics, Inc (NASDAQ: MTIX), an interventional neuroradiology company with operations in US and Europe. He orchestrated a successful sale of the company to ev3. Prior to MTIX, Mr Rush spent 10 years with Scimed Life Systems/Boston Scientific in various management roles, including General Manager of Boston Scientific's Asia Pacific business based in Singapore. Mr Rush has extensive domestic and international experience, with a core sales and marketing background.

**Michael Carrel**  
**Non-Executive Director**

Michael Carrel serves as Chief Executive Officer of AtriCure, Inc. Under his leadership, AtriCure is executing on the company's promise to decrease the global atrial fibrillation (Afib) epidemic and heal the lives of those affected by investing significantly in education, clinical science and product innovation. He is developing a customer-centric culture, encouraging his team to listen intently to physicians and patients and responding with products that make Afib treatment safer and less complex to encourage adoption by more physicians around the world. Prior to his tenure at AtriCure, Mr. Carrel served as the President and Chief Executive Officer of Vital Images, a global leader of advanced imaging software for use in disease screening, clinical diagnosis and therapy decision making and planning – for over 6,000 customers, in 90 countries. The company was publicly-traded (NASDAQ: VTAL), until acquired by Toshiba Medical Systems Corporation in June of 2011. Prior to Vital Images, Mr. Carrel was President and CEO of Zamba Corporation, a publicly-traded technology company, and Chief Financial Officer of NextNet Wireless, a privately-held provider of non-line-of-sight plug and play broadband wireless access systems, now part of Motorola. He is currently on the American Heart Association Board of Directors for the Cincinnati and Minneapolis chapters. Mr. Carrel holds a B.S. in Accounting from Pennsylvania State University and an M.B.A. from the Wharton School at the University of Pennsylvania.

# HISTORICAL ZACKS RECOMMENDATIONS



## DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research (“Zacks SCR”), a division of Zacks Investment Research (“ZIR”), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

### ANALYST DISCLOSURES

I, Brian Marckx, CFA, CFA, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

### INVESTMENT BANKING, REFERRALS, AND FEES FOR SERVICE

Zacks SCR does not provide nor has received compensation for investment banking services on the securities covered in this report. Zacks SCR does not expect to receive compensation for investment banking services on the Small-Cap Universe. Zacks SCR may seek to provide referrals for a fee to investment banks. Zacks & Co., a separate legal entity from ZIR, is, among others, one of these investment banks. Referrals may include securities and issuers noted in this report. Zacks & Co. may have paid referral fees to Zacks SCR related to some of the securities and issuers noted in this report. From time to time, Zacks SCR pays investment banks, including Zacks & Co., a referral fee for research coverage.

Zacks SCR has received compensation for non-investment banking services on the Small-Cap Universe, and expects to receive additional compensation for non-investment banking services on the Small-Cap Universe, paid by issuers of securities covered by Zacks SCR Analysts. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, equity research, investment management, non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per client basis and are subject to the number of services contracted. Fees typically range between ten thousand and fifty thousand USD per annum.

### POLICY DISCLOSURES

Zacks SCR Analysts are restricted from holding or trading securities placed on the ZIR, SCR, or Zacks & Co. restricted list, which may include issuers in the Small-Cap Universe. ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Each Zacks SCR Analyst has full discretion on the rating and price target based on his or her own due diligence. Analysts are paid in part based on the overall profitability of Zacks SCR. Such profitability is derived from a variety of sources and includes payments received from issuers of securities covered by Zacks SCR for services described above. No part of analyst compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in any report or article.

### ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but are not guaranteed as to be accurate nor do we purport to be complete. Because of individual objectives, this report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

### ZACKS RATING & RECOMMENDATION

ZIR uses the following rating system for the 1133 companies whose securities it covers, including securities covered by Zacks SCR:  
Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters.  
Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.  
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 24.4%, Hold/Neutral- 53.0%, Sell/Underperform – 19.1%. Data is as of midnight on the business day immediately prior to this publication.