

Lombard Medical Technologies plc



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LMT

Date:	14.04.09
Share price p	2.45
52 week High/Low p	13.5/0.5
Issued share cap m	791
Market cap £m	19.5

Lombard Medical Technologies PLC (Lombard Medical) discovers, develops, assembles and markets innovative cardiovascular devices with a particular focus in the area of stent-graft, stapling systems and polymer coatings for implantable medical devices.

Fund raising, advancement of Aorfix™ clinical trial in the US (PYTHAGORAS, for neck angulations between 0° and 90°) and its label extension in Europe, along with the implementation of cost reductions measures across the business have been some of the major focus areas for Lombard Medical's management in 2008.

- The fund raisings in 2008 and at the beginning of this year (totalling £14.4m net) have provided some financial 'breathing space' enabling the Company to concentrate on Aorfix™ US clinical trial which is drawing to a close.
- In 2008 sales almost doubled to £1.95m (2007:£1m). Aorfix™ sales up by 78% to £1.6m versus £0.9m the previous year and the number of implants more than doubled to 347 from 163. **Gross margins improved significantly to 43.2%** from 21.3%. Costs reduction measures were introduced in Q4 resulting in 20% personnel reduction and further cuts in Q1 2009 have been implemented almost halving the headcount. Operating costs increased to £12.2m from £11.6m with R&D accounting for 61.6% or £7.5m (2007: £6.4m). During the year, £276k relating to the outstanding amount from EndoArt sale and almost £2m in R&D credits were entered into the P&L, and a non-cash impairment charge of £874k was also recorded. The financial year ended with **a loss of £9.9m** (2007: -£10m) and negative EPS of 7.5p (2007: -15.6p) based on an enlarged issued share capital of 132.4m shares.
- At the 31st Charing Cross Symposium in London clinicians reported very good performance data on Aorfix™ and included information on high-angle-neck cases.
- The Company has put on the 'back burner' both the EndoRefix™ clinical trial and the development of the thoracic stent graft with the aim to retain as much cash as possible to complete the Aorfix™ US clinical trial and increase the commercial activities in Europe. Cash balances at the end of 2008 were **£0.8m** and at the end of Q1 2009 **£4.8m**.
- Critically a great deal of expectation is pinned on the timing and size of a possible US (or even global) distribution agreement for Aorfix™, which will have a transformational effect for Lombard Medical. We have altered our forecasts to reflect the termination of the distribution and licensing agreement with Medtronic, Inc. on EndoRefix™, and for the introduction of cost saving measures. Additionally, in Q1 2009 the issued share capital swelled to 791.3m lowering our fair share price share range to **12p-15p** (from 18p-21p).

Strong news flow in the coming weeks/months will prove very important for the future of the Company (label extension in Europe and completion of the US clinical trial in Q2 2009 and the partnering agreement in 2009) and we will review our valuation as progress is made and visibility over future prospects becomes clearer.

Lombard Medical is quoted on AIM and investors should be aware that shares traded on AIM are subject to lighter due diligence than shares quoted on the main market and are therefore more likely to carry a higher degree of risk than main market companies.

Equity Development contact

Hannah Crowe

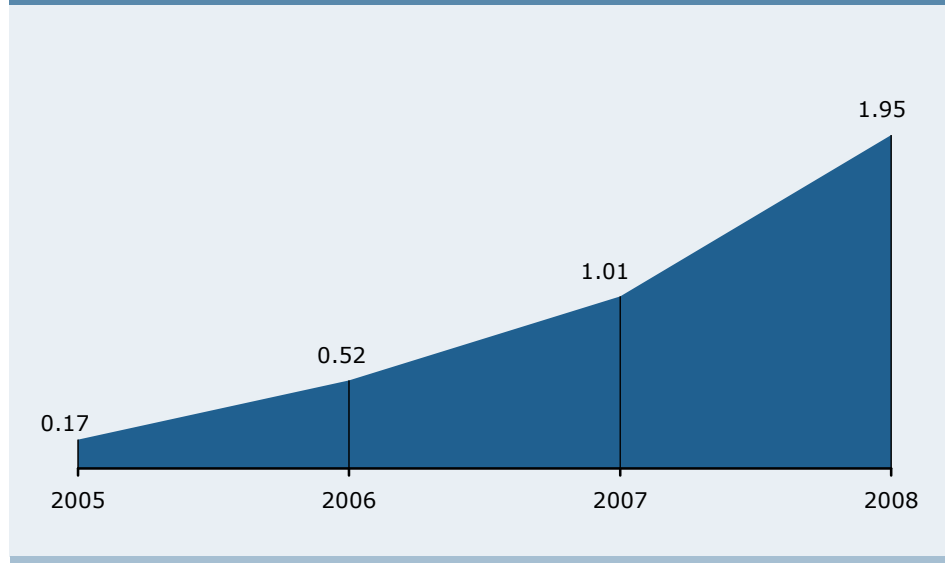
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FY2008 RESULTS

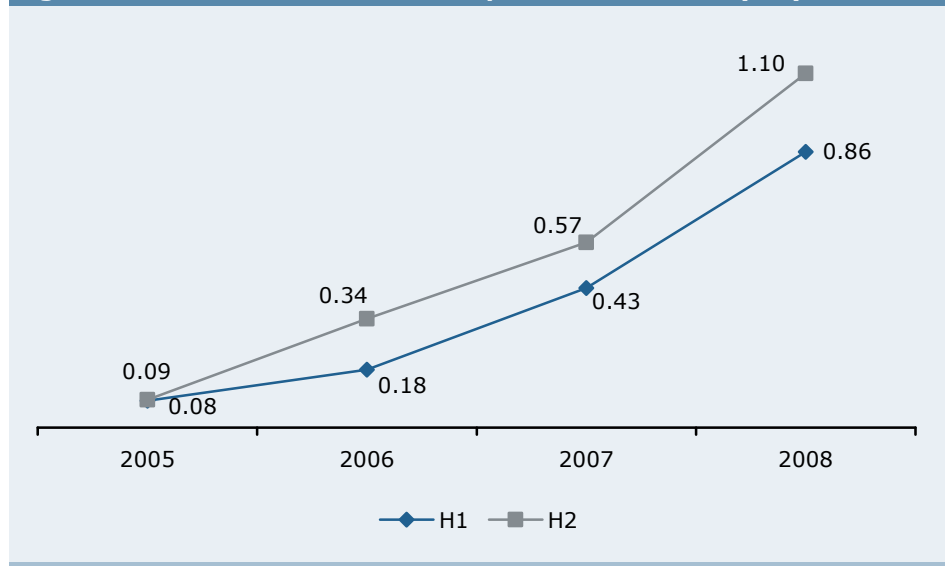
Revenues grew by almost 94% to £1.95m (FY2007: £1.01m) and maintained the trend of higher sales (*in value terms*) in the second half of the year. However, the largest percentage increase was reported in the H1 '08 with 97.5% versus 40.6% for the same period the previous year and sales accounted for about 44% or £0.86m; whereas in H2 '08 sales increased by 91.3%, versus 70.3% in H2 '07 and accounted for just over 56% or £1.1m.

Figure 1: Annual revenues for the period 2005-2008 (£m)



Company Data

Figure 2: Interim revenues for the period 2005-2008 (£m)

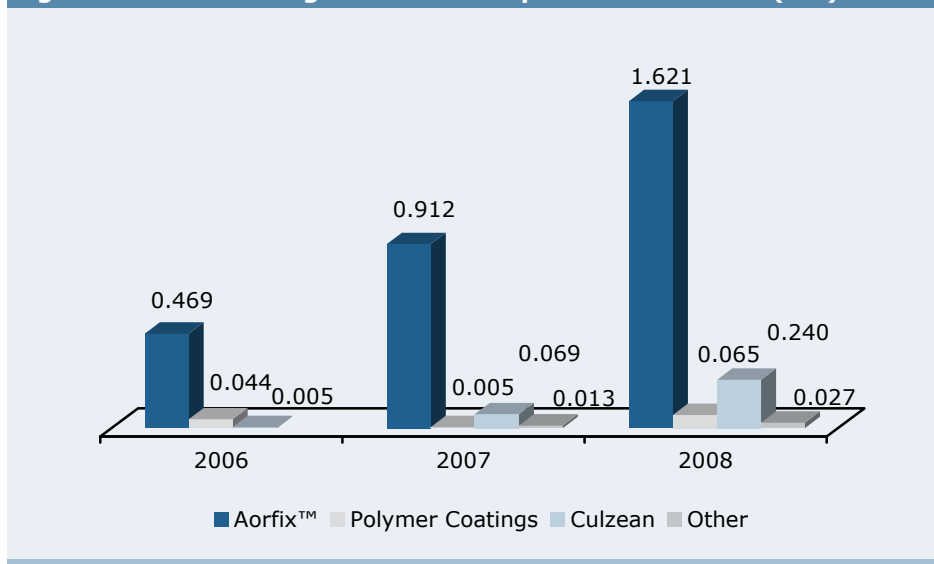


Company Data

Aorfix™ sales accounted for c.83% of total revenues or £1.6m (FY 2007: £0.9m) and increased by c.78%. Polymer Coatings licence fees and provisions of services contributed with £65k (FY2007: £5k) and Culzean Medical, acquired in June 2007, posted £240k (FY2007: £69k).

Aorfix™ sales up by almost 64%

Figure 3: Revenue origination for the period 2006-2008 (£m)



Company Data

Regional spread

USA

Geographically, revenue weights have changed quite substantially with sales in the US increasing by almost 3 folds to £0.49m (FY2007: £0.16m) representing **c.25%** of total revenue. Growth was driven by the increased rate of implantations that reached 77 stent grafts in FY2008 versus 28 the previous year.

Sales in the US increased by almost 3 folds

The US clinical trial has moved considerably forward. By the end of 2008, 38 (8 at the beginning of the year) centres were fully trained and qualified to treat high-angle neck aneurysms. Post period one more centre was added.

Two of the three arms of the US clinical trial have been completed. In the next 3 months the Company is aiming to enrol the remaining 41 patients with high-neck-angulation needed to achieve the 120 implants required by the FDA. Although, under the terms of the IDE, data from 160 patients is required the Company intends to treat up to 200 patients to compensate for any patient loss during the 12-month follow-up period.

UK

Aorfix™ is sold directly in the UK and sales almost doubled to £0.45m (FY2007: £0.23m) and accounted for almost 23% of total revenues with the number of implants increasing to 94 from 49 in 2007.

Sales in the UK almost doubled

In the UK, Aorfix™ achieved 6% of market share in Q4 2008 and competes with a number of active fixation stent grafts including: **Talent** by Medtronic (supra-renal fixation); **Excluder** AAA endoprosthesis by WL Gore (infra-renal fixation – 9% UK

6% market share in the UK

market share); **Zenith** AAA endovascular by Cook Medical (supra-renal fixation); and the just launched (July 2008 in Europe) **Endurant™** by Medtronic (infra-renal fixation). Endurant™ addresses AAA patients with tortuous anatomies including those aneurysms that have short necks; some literature mentions also high neck angulations but no specific data appear to be available. Endurant™ US clinical trial started last summer and completion is expected in 2013 (www.clinicaltrials.gov).

Aorfix™ is expected to receive a label extension in Europe in Q2 2009 after having submitted the relevant data to the TÜV in September 2008. The label extension will widen the treatment spectrum to include those patients with neck angulations between >65° - 90° who would otherwise require an open surgery (20% of market) **as there are no EVAR systems currently commercially available for these patients, making Aorfix™ the only AAA commercialised stent graft covering all the anatomies.**

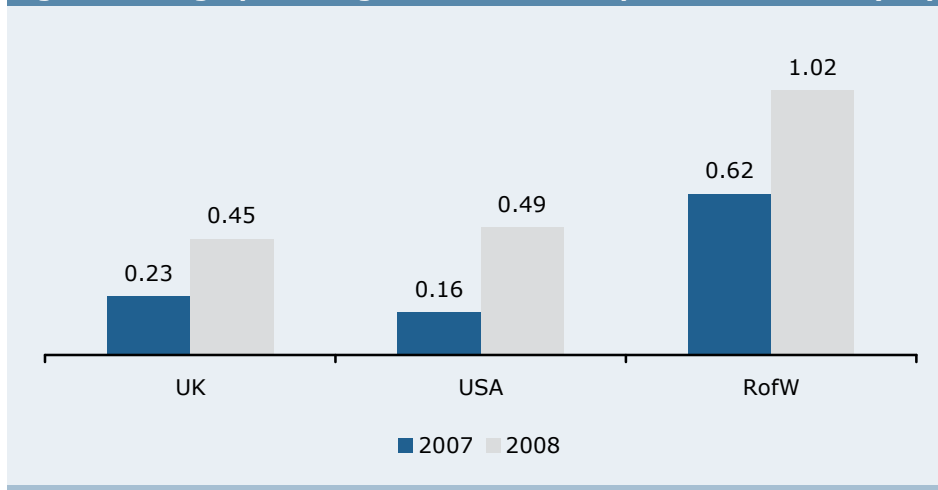
In February 2009, NICE recommended the use of AAA stent grafts in those patients that present with an un-erupted infra-renal AAA. In the UK, the estimated AAA prevalence varies from 1.3% to 12.7% depending on the age group studied and the definition of AAA. The incidence of symptomatic AAA in men is approximately 25 per 100,000 at age 50, increasing to 78 per 100,000 in those older than 70 years.

The implementation of a national screening programme for AAA is under way with a few centres started screening in March 2009. The number of centres is expected to be increased by roll-out over the next 5 years. In England alone approximately 2,700 procedures for the repair of un-ruptured AAA are carried out each year and just over 52% (1,400) are EVARs.

RoW

Aorfix™ is distributed in 21 European countries, including Russia where it received the regulatory approval last November and in Latin America (Brazil and Argentina) through a network of 12 national distributors supported by clinical specialists and coordinated by a marketing director. Sales' revenues in these territories increased by 65% to £1.0m. The number of implants in Continental Europe more than doubled to 143 from 67 and in Latin America almost doubled to 33 from 19.

Figure 4: Geographical segmentation for the period 2007-2008 (£m)



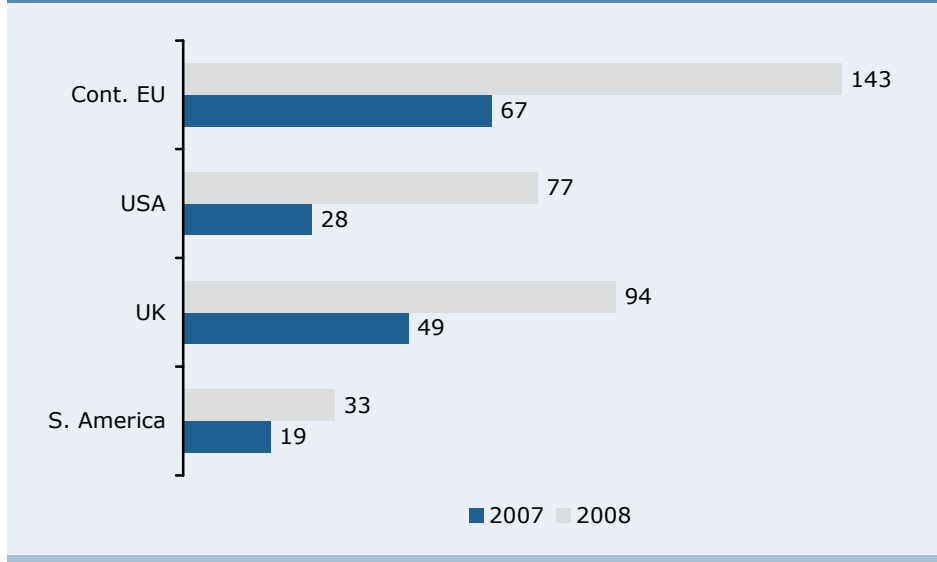
Company Data

Aorfix™ label extension in EU is expected in Q2 2009

UK AAA national screening started in March 2009

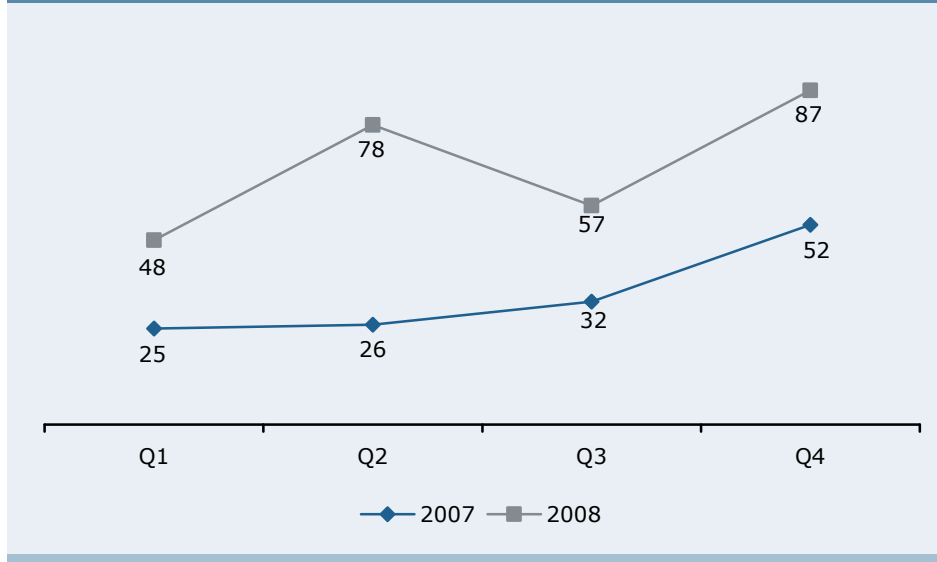
Across all regions the total number of patients treated during the year has more than doubled to **347** from **163** the previous year:

Figure 5: Number of implants in 2007-2008



Company Data

Figure 6: Number of implants (ex US clinical trial) per quarter



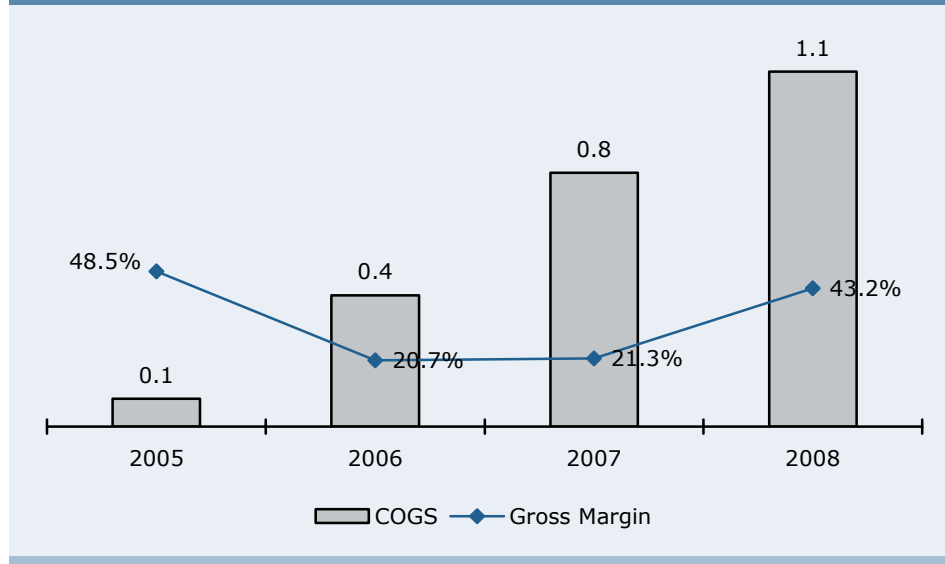
Company Data

Aorfix™ has now been used in **over 800 patients worldwide**, and the Company is collecting a growing body of good clinical data on the device through the Retrospective Aorfix™ Data Retrieval (**RADAR**) voluntary clinical registry that now contains follow-up data on about **619 cases** a combination of commercial cases (500) and clinical trials. The Company’s implant registry include information on some extreme anatomies where implantation was performed in patients with neck-angulations >90° (100°, 110° and 120°).

Gross margin improved to 43.2%

The overall increase in sales and the introduction of minor changes in manufacturing processes have substantially improved gross margins, achieving 43.2% to £0.8m when compared with 21.3% and £0.2m in the same period last year. However, the full year gross margin was slightly lower than that reported in H1 due to the timing of the receipt of the licence fees and lower production volumes in H2.

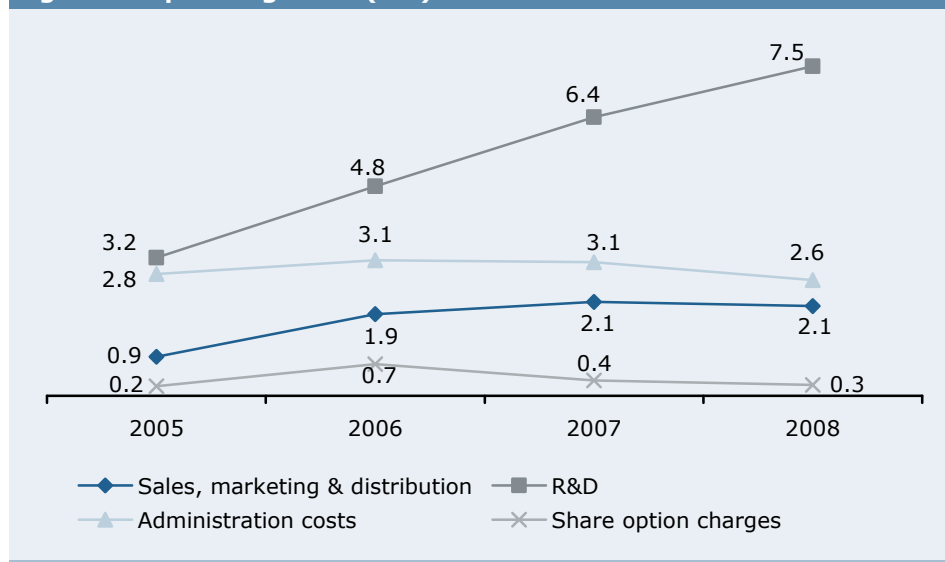
Figure 7: COGS (£m) & Gross margins



Company Data

Operating costs (including share option charges) increased by c.5.8% to £12.2m (FY2007: £11.6m).

Figure 8: Operating costs (£m)



Company Data

R&D reported the largest increase, up by just over 18% to £7.5m (FY2007: £6.4m) reflecting the costs encountered to support the ongoing clinical trials both in the US (PYTHAGORAS and EndoRefix™) and Europe (ARBITER II).

Sales, marketing and distribution were slightly lower to £2.05m (FY2007: £2.14m). Administration expense, including redundancy costs of £257k, decreased to £2.6m from £3.1m in 2007.

Given the difficult financial position of the Company, in Q3 the management embarked on a cost reduction exercise aiming to bring down the annual cash burn at around £6m and as a result all the existing R&D projects, namely EndoRefix™ and the thoracic stent graft have been put on the 'back burner', concentrating primarily on the completion of Aorfix™ US clinical trial and increase commercial sales in Europe.

EndoRefix™ clinical trial in the US was suspended after having enrolled 63 out of 95 patients required; preliminary clinical data is expected sometime in May 2009. Post-period was announced the termination, by mutual consent, of the distribution and licensing agreement with Medtronic, Inc.

Part of the reorganisation programme saw an initial reduction in headcount by 21 in Q4 2008 and was followed by an additional 30 in Q1 2009 bringing down the total number of staff to 58 from 109.

The amount held in escrow (£276k) by Allergan, Inc., the acquirer of EndoArt, due in February 2009 was received in March 2009, but recognised in the 2008 accounts, both as a profit received from the disposal of an investment and as a debtor, as no warranty claims were made by Allergan at the end of 2008. The shareholding interest in Vascular Concepts was written down, resulting in a non-cash impairment charge to the P&L of £874k.

R&D tax credits of almost £2m were recognised being a combination of credits relating to £1.1m for 2007 and an accrual of £900k being the estimated amount for 2008.

In 2008, the Company completed two fund raising rounds totalling £8.5m net. £7.1m (net) was raised in January by issuing 54.2m shares at 14p and £1.4m (net) in unsecured convertible loan notes in October.

Post-period, in January 2009, an additional cash injection of **£5.6m** (net) was achieved through the placing of 561.5m ordinary shares at 1p each and £0.5m of 5-year convertible loan notes. The Company underwent a capital reorganisation as the Placing (436.5m) and Subscription (125m) shares were issued at half of the then 2p nominal value. Qualifying Shareholders and Employees were given the opportunity to subscribe up to £2.2m at the same terms and condition as per the fund raising which raised a further £0.3m through the issue of 26.7m shares. Additionally, holders of the Existing Convertible Loan Notes (ECLN) (£1.7m (net £1.4m)) received 1 New Ordinary Share for each 2.5p nominal ECLN and resulted in 66.9m shares before accrued interest. The enlarged issued share capital, ex-ECLN conversion, stands at 791.3m shares, almost 6x the number of shares at end of 2008.

Net loss for the year was slightly lower than in 2007 at £9.9m versus £10m the previous year, resulting in a negative EPS of 7.46p (2007: 15.55p) and calculated on an enlarged shareholding base of 132.4m ordinary shares when compared to 64.3m in 2007.

Cost reduction exercise

Personnel halved

2 financing rounds in 2008

Cash injection post period

Going forward

Aorfix™ impressive clinical performance over time (in some cases data up to 36-months) remains well within NICE's guidelines as shown in the table below. Additionally, in some cases the aneurysm sack was reduced by >25%.

Table 1: Aorfix™ comparative data and NICE guidelines				
Description	Aorfix™ (Apr 2009)	Aorfix™ (Apr 2008)	Aorfix™ (Sep 2007)	NICE Guidelines (Incl. EUROSTAR references) (March 2006)
30 day mortality (fit for open surgery)	1.45% n=619 patients	1.3% n=366 patients	2%	2%
Stent migration at 12-months	0% (n=343)	<1%	0%	1%
Wire fracture at 12-months	<0.5% (n=343)	<1%	0%	3%
Aneurysm rupture at 36-months	0% (n=64)	0%	0%	0.9%
Endoleaks at 12-months	10.5% (7.6% type II) (n=343)	5.3% (3.5% type II)	13.75% of total	19% (mainly type II)

Company data

At the **31st Charring Cross Symposium** in London very good data was presented on Aorfix™ performance and included information such as: all cause mortality rate at 30-days for patients with high-angle-neck of just 1.47%, significantly lower than that for open surgery (4.8%). No patency or stent migration was observed at 1-year (73 patients) and endoleak rates of 20.5% similar to the average rates reported in studies for less difficult anatomies. Whereas endoleaks in cases with neck angles of <60° (111 patients) was just 9% (7.2% type II). Overall, in 97% of cases there was a decrease or no change in aneurysms' sac diameter, demonstrating that the aneurysm was under control.

The clinical registry provides strong body of evidence that will undoubtedly continue to drive sales growth in the future. Additionally, in the UK, the implementation of the national screening programme for AAA started in March 2009 with the number of centres gradually increasing over the next 5 years and the granting of the label extension in Europe will be another important factor in the marketing expansion of Aorfix™. The management has confirmed once again their intention to divest non-core investments, but no guidance on the timeline and/or amounts that could be gained from the sale of these assets has been given and have not been included in the forecasts.

We have altered our forecasts also to take into account the termination of the distribution and licensing agreement with Medtronic, Inc. In 2009, revenues from Aorfix™ are expected to grow at a similar rate as in 2008 and gross margins to achieve 50% this year and improving further thereafter.

The awaited distribution agreement for Aorfix™ will have a transformational effect for Lombard Medical not only providing technology validation, but also making available the much needed financial resources to enable them to move forward with the development of the organisation. **Our forecasts do not include any up-front fees or other amounts that could be generated from such an agreement.**

With the cost reduction strategy in place and the substantial reduction in R&D expense as the PYTHAGORAS clinical trial in the US draws to completion,

operating costs are expected to decrease substantially (43%) in 2009 and decrease further achieving a 'maintenance level' throughout the period considered and will be adjusted over time as more clarity emerges on the commercial and R&D strategy going forward as per news flow in the next weeks/months. Sales and marketing has been greatly reduced by 28% to c.£1.5m (2008: c£2.1m). A restructuring charge of £0.4m has been included in 2009 forecast.

The signing of a partnering agreement in 2009 or early 2010 will also avoid the need for Lombard Medical to come back to the markets for further dilutive financing. The current issued share capital stands at 791.3m shares, almost **6x** the number of shares at end of 2008.

The high dilution effect has caused our fair price range to slide to 12-15p / share, using a discounted PER methodology, from 18-21p as previously stated.

Table 2: Profit & Loss						
Y-end December (£m)	2006A	2007A	2008A	2009E	2010E	2011E
Revenues	0.5	1.0	2.0	3.2	5.1	8.7
COGS	-0.4	-0.8	-1.1	-1.6	-2.5	-4.2
Gross profit/loss	0.1	0.2	0.8	1.6	2.6	4.5
Sales, marketing and distribution	-1.9	-2.1	-2.1	-1.5	-1.5	-1.6
R&D	-4.8	-6.4	-7.5	-4.3	-3.6	-3.6
Admin costs	-3.1	-2.7	-2.4	-2.1	-2.1	-2.1
Share option charge	-0.7	-0.4	-0.3	-0.3	-0.3	-0.3
	-10.5	-11.6	-12.2	-8.1	-7.5	-7.6
Exceptional items	-	1.1	0.3	-0.4		
Impairment	-	-0.8	-0.9			
Total operating costs	-10.5	-11.3	-12.8	-8.5	-7.5	-7.5
Operating profit/loss	-10.4	-11.0	-12.0	-6.9	-4.9	-3.0
Net Interest	0.6	0.2	0.1	0.2	0.1	0.1
Pre-tax profit/loss	-9.8	-10.8	-11.9	-6.8	-4.8	-2.9
Tax	0.6	0.8	2.0	0.5	0.5	0.5
Profit/Loss for the year	-9.2	-10.0	-9.9	-6.3	-4.3	-2.4
EPS p	-18.5	-15.6	-7.5	-0.8	-0.5	-0.3
<i>Weighted av. no. of shares</i>	<i>49.7</i>	<i>64.3</i>	<i>132.4</i>	<i>791.3</i>	<i>791.3</i>	<i>791.3</i>
<i>y-o-y revenue growth</i>	<i>105.9%</i>	<i>94.8%</i>	<i>93.9%</i>	<i>61.7%</i>	<i>61.1%</i>	<i>71.5%</i>
<i>Aorfix™ sales growth</i>	<i>179.9%</i>	<i>97.3%</i>	<i>73.7%</i>	<i>80.0%</i>	<i>166.1%</i>	<i>175.0%</i>
<i>Gross margins</i>	<i>20.7%</i>	<i>21.3%</i>	<i>43.2%</i>	<i>50.0%</i>	<i>51.0%</i>	<i>52.0%</i>

ED estimates

Table 3: Balance sheet						
£m	2006A	2007A	2008A	2009E	2010E	2011E
Fixed assets	5.4	4.6	3.6	3.5	3.5	3.4
Current Assets	5.9	4.5	4.4	4.5	1.6	0.6
Current Liabilities	1.8	2.6	2.3	2.1	2.1	2.2
Net Current Assets	4.1	2.0	2.1	2.4	-0.5	-1.6
Long-term liabilities			1.4	0.5	0.5	0.5
TOTAL NET ASSETS	9.5	6.5	4.3	5.5	2.5	1.4

ED estimates

Table 4: Cash Flow

£m	2006A	2007A	2008A	2009E	2010E	2011E
Cash flow from Operations	-10.2	-9.5	-10.5	-5.9	-3.2	-1.4
Cash Flow from Investing	-2.3	1.1	-0.2	0.3	0.0	0.0
Net Interest	0.4	0.2	0.2	0.2	0.2	0.2
Net cash flow before financing	-12.1	-8.3	-10.5	-5.5	-3.1	-1.2
Cash Flow from Financing	0.1	6.6	8.6	5.9	0.0	0.0
Change in liquid funds	-12.0	-1.7	-1.9	0.5	-3.1	-1.2
Cash at beginning of the period	16.3	4.4	2.7	0.8	1.3	-1.8
Cash at the end of the period	4.4	2.7	0.8	1.3	-1.8	-3.1

ED estimates

Board of Directors

Simon John Neathercoat – Non-executive Chairman

Brian Howlett – Chief Executive Officer

Tim Hall – Finance Director

Richard Johnston – Non-executive Director

Professor Martin Rothman – Independent Non-executive Director

Michael Stevens – Senior Independent Non-executive Director

Dr. Timothy Cook – Non-executive Director

Craig Robert Rennie – Non-executive Director

Senior Management

Peter Phillips – Managing Director, Cardiovascular Devices

Rhod Jones – Company Secretary

Scientific Advisory Board

Professor Brian Hopkinson

Professor Martin Rothman

Ronald Fairman

Rodney White

APPENDIX

Table 5: EVAR (Endo Vascular Aneurism Repair) vs. OSR (Open Surgical Repair)

Advantages	Disadvantages
<ul style="list-style-type: none"> • Reduced time under general anaesthesia; • Reduced operative mortality and aneurysm related mortality over the medium term; • Elimination of the pain and trauma associated with major abdominal surgery; • Reduced length stay in hospital and ICU; and <ul style="list-style-type: none"> • Decreased blood loss; • Wider addressable population. 	<ul style="list-style-type: none"> Development of endovascular leaks: <ul style="list-style-type: none"> • Type I when graft does not seal completely and blood continues to flow in the aneurysm; • Type II when blood flows from small vessels in the aneurysm; • EVAR patients may require CT (computerised tomography) or ultrasound scans to check for endoleaks; <ul style="list-style-type: none"> • Higher rates of complications and re-intervention leading to open repair; and • EVAR procedure is £543 more expensive than OSR (£9,893) in the UK.

ED

I certify that this report represents my own opinions
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