



# **Maelor plc**

**28 October 2003**

**MAELOR PLC  
Interim Results for the six months to 30 September 2003**

**Highlights**

- Net loss for half year was £726,560, a 45% reduction over the same period last year
- CE Mark accreditation achieved
- ContiSol developed and launched within six months
- Volplex wins several tenders in the UK
- OptiFlo UK community market share a record high of 39% in July 2003

Commenting on the results Chief Executive, Stephen Appelbee, said:

“One of the most exciting developments during the period has been the authorisation allowing Maelor to apply its own CE Mark. This enables us to market medical devices throughout Europe following approval from a single regulatory authority.”

**For further information contact:**

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## **CHAIRMAN & CHIEF EXECUTIVE OFFICER'S STATEMENT**

We are pleased to report the interim results for the half year to 30 September 2003. These are a demonstration of the further progress that has been made in commercialising Maelor's products.

One of the most exciting developments during the period has been the authorisation allowing Maelor to apply its own CE Mark. This enables us to market medical devices throughout Europe following approval from a single regulatory authority.

In the six months since CE Mark certification we have completed the development of ContiSol™, our own brand of urethral catheter irrigation solutions. Concurrent with our development programme we also signed three distributorship agreements and then launched the product in both Spain and Greece through our local partners, Laboratorios CAIR España and M. S. Jacovides respectively. The first sales of ContiSol will be included in our results for the full year.

Volplex®, our succinylated gelatin plasma substitute sold by Cambridge Laboratories, and OptiFlo™, our range of catheter irrigation solutions sold in the UK and Italy by Bard Limited, continue to show progress in their respective markets. The market in which Cambridge Laboratories has achieved success is accessed through a process of competitive tender; however, the full benefit in terms of sales will not become apparent until the second half of this financial year.

## **FINANCIAL RESULTS**

The Company's loss for the six months to 30 September 2003 was £726,560, a reduction of 45% over the same period last year. Revenue from sales during the six months amounted to £321,954, a 5% increase over the same period last year, and at 30 September 2003 cash balances were £2.2 million.

Prudent cuts in overheads and improved cost management continue to benefit our cash flow. With the added sales which may be anticipated as a result of recently secured Volplex tenders, the outlook for the full year is encouraging. It remains the Board's objective to continue the development of the Company's product range in order to achieve profitability within the shortest practical period.

## **MARKETED PRODUCTS**

### **Volplex**

The UK market for blood replacement products is dominated by local and regional hospital tenders, which are often awarded on an annual or biennial basis. As a result, penetration of this market is dependent on the timing of these tenders.

We are pleased to be able to announce that Volplex has already been successful in winning several important contracts, including the North East Purchasing Group and Yorkshire Division tenders, as well as sharing in the country's largest award, the Central

Division. Potentially these tenders represent over £1.5 million of sales from our marketing partner, Cambridge Laboratories, to hospitals.

As previously reported, we expect Marketing Authorisation Application (MAA) approval in Argentina and Bangladesh in this financial year, with Australia and South Africa most likely to follow in 2004/5.

### **ContiSol**

Your Board is pleased to report that a third product range is now adding to Maelor's revenue stream. In April 2003, following rigorous independent scrutiny, Maelor was authorised to apply its own CE Mark to medical devices. Within six months the Company has already developed and launched its own brand of urethral catheter irrigation solutions, ContiSol, in Spain and Greece. While these launches are too recent for any sales to feature in the interim statement, we look forward to seeing the revenue included in the second half of this financial year.

Outside of Argentina and those European territories where distributors have already been appointed, we are actively seeking partners to roll out ContiSol as quickly as possible in other countries worldwide.

### **OptiFlo**

Our distributor, Bard Limited, sells our range of urethral catheter maintenance solutions in the UK and Italy under the OptiFlo brand. Once again Bard's marketing strength has increased the product's prescription market share, and it reached 39% of the community sector in the UK (Source: IMS, July 2003). Following heavy sampling in Italy at the time of launch, sales there are starting to increase.

The clinical work necessary to gain approval for OptiFlo in Canada is also starting. The authorities in North America currently consider that the product should be regarded as a drug, rather than a device. This makes the regulatory process much more complex and expensive, and we are putting forward what we consider to be a compelling case for the authorities to change their stance on this product, rather than deny patients the benefits of OptiFlo.

## **DEVELOPMENT PRODUCTS**

### **TendaGel™**

As previously reported, the MAA for TendaGel has been submitted to the UK Medicines and Healthcare products Regulatory Agency (MHRA) for approval. While we await their ruling, we are conducting an extensive commercial review with our partner, Bard, to assess the true potential for this product. In the years since we signed our distribution agreement with Bard our manufacturing costs for TendaGel have inevitably risen and, in many cases, in-market prices for lubricating gels have fallen. The commercial situation has been further clouded by the MHRA's view that TendaGel might be considered to be a device, rather than a drug. Your Board is confident that a mutually acceptable solution can be found prior to MHRA approval.

As evidence of TendaGel's clinical safety and efficacy, an interim analysis of the Phase III clinical trials data was presented at the World Congress of Endourology in Montreal in September, and the authors concluded that TendaGel was effective when used in cystoscopy and had safety advantages over the competing products with which it was compared. There was also a trend towards investigator preference for TendaGel.

### **Micelle propofol**

We have been encouraged by the initial reception given to micelle propofol by potential partners but, as has been widely reported elsewhere, major pharmaceutical companies are showing an increasing reluctance to support products in clinical development. We would ideally like to take the product through to commercial launch ourselves because of the advantages of our formulation. Recognising the cost implications of this course of action, however, we continue to believe that it is prudent at this stage to seek an appropriate partnership deal for the final development phase of micelle propofol. Such an alliance will only be considered on terms which properly reflect the considerable market potential which exists for this product.

In the meantime, we are moving forward and will complete some additional trials ourselves, in order to add value to the product proposition.

Our UK and Ireland partner for veterinary micelle propofol, Dechra plc, reports that the batches required for stability testing have now been manufactured, and we expect approval for this product in 2004. Interest in veterinary micelle propofol in mainland Europe has resulted in negotiations for the European rights, which we hope to conclude soon.

### **New product acquisitions**

Negotiations continue as we implement our strategy of acquiring a portfolio of products in critical and palliative care. Only products or businesses which will accelerate our drive to profitability are being considered.

### **OUTLOOK**

Together with our marketing partners, we will continue to capitalise on the commercial opportunities that exist for our three marketed products, OptiFlo, Volplex and ContiSol. In the second half of this financial year we can expect further Volplex tender successes in the UK, as well as MAA approvals in Argentina and Bangladesh. We will also be seeking to accelerate the worldwide rollout of ContiSol.

Your Board also looks forward to the timely approval of the TendaGel MAA in the UK, and agreement with Bard on the subsequent marketing strategy. Our number one priority, however, is to unlock the potential of our most valuable product, micelle propofol.

Alastair Macpherson  
Chairman

Stephen Appelbee  
Chief Executive Officer

## CONSOLIDATED PROFIT AND LOSS ACCOUNT

for the six months ended 30 September 2003

	Unaudited Six months ended 30 September 2003 £	Unaudited Six months ended 30 September 2002 £	Audited Year ended 31 March 2003 £
<b>Turnover</b>	<b>321,954</b>	307,863	1,169,744
Cost of sales	(143,367)	(170,145)	(804,413)
<b>Gross profit</b>	<b>178,587</b>	137,718	365,331
Research and development	(400,892)	(832,157)	(1,565,268)
Administration	(563,885)	(690,207)	(1,159,346)
<b>Operating loss</b>	<b>(786,190)</b>	(1,384,646)	(2,359,283)
Interest receivable and similar income	43,080	25,117	38,679
Interest payable	(1,380)	(1,108)	(2,208)
<b>Loss on ordinary activities before taxation</b>	<b>(744,490)</b>	(1,360,637)	(2,322,812)
Taxation recoverable	17,930	48,834	245,882
<b>Retained loss attributable to the Group</b>	<b>(726,560)</b>	(1,311,803)	(2,076,930)
Basic loss per ordinary share	(2.13p)	(6.19p)	(9.37p)
Diluted loss per ordinary share	(2.13p)	(6.19p)	(9.37p)

The Group's activities are classified as continuing.

There were no recognised gains or losses in the above financial period, other than the losses noted above.

Technical salaries were disclosed within Administration in the 2002 interim statement. These costs have been reclassified and disclosed within Research and development. The directors consider that this change presents a more appropriate view of the Group's performance.

**CONSOLIDATED BALANCE SHEET**

at 30 September 2003

	<b>Unaudited</b> <b>30 September</b> <b>2003</b> £	Unaudited 30 September 2002 £	Audited 31 March 2002 £
<b>Fixed assets</b>			
Tangible assets	<b>344,623</b>	396,823	360,231
<b>Current assets</b>			
Stock	<b>135,340</b>	176,595	100,075
Debtors	<b>583,520</b>	632,345	596,862
Cash at bank and in hand	<b>2,207,002</b>	773,298	3,294,656
	<b>2,925,862</b>	1,582,238	3,991,593
<b>Creditors: amounts falling due within one year</b>	<b>(286,021)</b>	(377,078)	(639,642)
Net current assets	<b>2,639,841</b>	1,205,160	3,351,951
Total assets less current liabilities	<b>2,984,464</b>	1,601,983	3,712,182
<b>Creditors: amounts falling due after more than one year</b>	<b>(3,268)</b>	(5,764)	(4,426)
<b>Net assets</b>	<b>2,981,196</b>	1,596,219	3,707,756
<b>Capital and reserves</b>			
Called up share capital	<b>3,410,458</b>	2,118,297	3,410,458
Share premium account	<b>12,154,094</b>	10,569,591	12,154,094
Revaluation reserve	<b>66,969</b>	67,989	67,479
Profit and loss account	<b>(12,650,325)</b>	(11,159,658)	(11,924,275)
<b>Shareholders' funds – equity</b>	<b>2,981,196</b>	1,596,219	3,707,756

## CONSOLIDATED CASH FLOW STATEMENT

for the six months ended 30 September 2003

	Unaudited Six months ended 30 September 2003 £	Unaudited Six months ended 30 September 2002 £	Audited Year ended 31 March 2003 £
Cashflow from operating activities	(1,118,313)	(1,381,705)	(2,066,285)
Returns on investments and servicing of finance	43,512	24,009	40,406
Taxation received	-	-	320,690
Capital expenditure	(11,362)	(5,217)	(11,131)
<b>Cash outflow before financing</b>	<b>(1,086,163)</b>	<b>(1,362,913)</b>	<b>(1,716,320)</b>
Financing	(1,491)	(1,901)	2,872,864
<b>(Decrease)/increase in cash in the period/year</b>	<b>(1,087,654)</b>	<b>(1,364,814)</b>	<b>1,156,544</b>

## RECONCILIATION OF NET CASH FLOW TO MOVEMENT IN NET FUNDS

for the six months ended 30 September 2003

	Unaudited Six months ended 30 September 2003 £	Unaudited Six months ended 30 September 2002 £	Audited Year ended 31 March 2003 £
<b>(Decrease)/increase in cash in the period/year</b>	<b>(1,087,654)</b>	<b>(1,364,814)</b>	<b>1,156,544</b>
Cash outflow from decrease in debt and lease financing	1,491	1,901	3,800
<b>Changes in funds resulting from cash flows</b>	<b>(1,086,163)</b>	<b>(1,362,913)</b>	<b>1,160,344</b>
<b>Net funds at the start of the period/year</b>	<b>3,287,452</b>	<b>2,127,108</b>	<b>2,127,108</b>
<b>Net funds at the end of the period/year</b>	<b>2,201,289</b>	<b>764,195</b>	<b>3,287,452</b>

## RECONCILIATION OF OPERATING LOSS TO OPERATING CASH FLOWS

for the six months ended 30 September 2003

	Unaudited Six months ended 30 September 2003 £	Unaudited Six months ended 30 September 2002 £	Audited Year ended 31 March 2003 £
Operating loss	(786,190)	(1,384,646)	(2,359,283)
Depreciation charge	28,809	54,454	96,960
Profit on sale of fixed assets	(1,839)	-	-
(Increase)/decrease in stocks	(35,265)	(34,267)	42,253
Decrease in debtors	29,460	158,479	66,385
(Decrease)/increase in creditors	(353,288)	(175,725)	87,400
<b>Net cashflow from operating activities</b>	<b>(1,118,313)</b>	<b>(1,381,705)</b>	<b>(2,066,285)</b>

## **NOTES**

for the six months ended 30 September 2003

1. The interim results for the six months ended 30 September 2003 are unaudited. The financial information set out in this statement does not constitute statutory accounts within the meaning of the Companies Act 1985. The comparative figures for the financial year ended 31 March 2003 are not the statutory accounts for the financial year but are abridged from those accounts which have been reported on by the Group's auditors and delivered to the Registrar of Companies. The report of the auditors was unqualified and did not contain a statement under section 237(2) or (3) of the Companies Act 1985.

2. The tax credit in the profit and loss account relates to the surrender by the Group of Research and Development losses.

3. The interim results, which were approved by the Board of directors on 24 October 2003, are prepared on the basis of the accounting policies set out in the annual financial statements of the Group for the year ended 31 March 2003.

Whilst further progress has continued to be made by the Group during the period, profitable trading is yet to be established. Cash will continue to be absorbed until at least this point in time, and until further products become income generating. The Board will continue to monitor the progress of the acquisition, development and launch of new products and the financial position in order to ensure that the Group continues to have sufficient funding to continue in business. For this reason, they continue to adopt the going concern basis in preparing the financial statements.

Copies of this interim statement will be sent to shareholders on 7 November 2003 and will be available from the Group's registered office at:

Riversdale,  
Cae Gwilym Road,  
Newbridge,  
Wrexham,  
LL14 3JG.