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# LIDCO GROUP PLC

# INTERIM RESULTS FOR THE SIX MONTHS TO 30 JUNE 2001

### Sales teams established in UK and USA, with encouraging early customer response

LiDCO Group plc ("LiDCO" or "the Company"), the UK-based cardiovascular monitoring company, today announces its maiden interim results for the six months to 30 June 2001.

## Highlights

- In February, lithium chloride injectate was approved by the Medicines Control Agency, enabling commercialisation of the LiDCO and PulseCO Systems in the UK to commence following the IPO
- US Food and Drug Administration approved PulseCO System in July 2001, allowing the start of sales in the USA
- Direct sales forces in UK and USA recruited, trained and actively engaged in sales activity
- After only 10 weeks of sales in the US, early results indicate support for LiDCO's 'capital equipment' business model
- Commercial activities are being co-ordinated out of the Company's newly established sales and marketing office at Granta Science Park, Cambridge
- Successful flotation on AIM in July 2001 raised £15 million (gross)
- Operating loss of £1.23 million (2000: £261,000) reflecting gearing-up of the Company's operations in anticipation of commercial production and launch in the USA and UK

Commenting on the results, Terry O'Brien, Chief Executive of LiDCO, said:

"Following the flotation, we are now in a position, with experienced direct sales and marketing forces in the UK and the USA, to accelerate commercialisation of our products in these markets. We have had an excellent reception in hospitals and indications are that customers are willing to purchase our technology in accordance with our capital equipment-purchasing model. We are pleased with the performance to date which confirms that the objectives outlined in the business plan are realistic and achievable. The Board looks forward to the future with great anticipation and expectation."

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## NOTES TO EDITORS

#### LiDCO Group plc

LiDCO researches, develops, manufactures and sells innovative monitors and medical devices primarily for critical care and cardiovascular risk hospital patients who require real-time cardiovascular monitoring. The Group currently has two principal products both of which are patent protected: the LiDCO System (disposable sensor product) and the PulseCO System (monitoring product). The Company's principal customers are hospitals. The Company floated on AIM in July 2001.

#### Benefits of the LiDCO and PulseCO systems

- *Minimally invasive* LiDCO's cardiovascular monitoring technology simply utilises the existing blood pressure monitoring signal which is available via the peripheral arterial catheter which is already inserted in the radial artery of the arm of patients undergoing surgery or in critical care. This contrasts with the current market leading product, a thermodilution pulmonary artery catheter, which requires insertion in a patient's heart.
- *Easy to use* the technology takes less than five minutes to set up and apply. In addition, nurses as well as doctors can use the equipment.
- *Easy to interpret* LiDCO has developed user-friendly interface software which, the Board believes, will aid the interpretation of complex real-time cardiovascular information at a patient's bedside.
- *Comprehensive data* the innovative sensor, electronics and software technology allows the monitoring of the key physiological readings of blood pressure and cardiac output thereby allowing the calculation of oxygen delivery to the body tissues.
- *Widely applicable* the technology can be applied in a number of critical care situations including cardiac surgery, major surgery, post-operative cardiovascular and surgical monitoring, intensive care and high dependency units.

## CHAIRMAN'S STATEMENT

### Introduction

This is the Company's first results statement since its flotation on AIM in July 2001. The financial results cover the six months ended 30 June 2001 and therefore predate the Company's flotation and milestone USA Food and Drug Administration (FDA) approval of the PulseCO System. The description of the operational performance of the Company covers the first six months of 2001 and trading to date. Substantial commercial progress has been made and the results are in line with the Board's expectations.

## The market

The Board estimates that in 2001 the worldwide market for electronic processing and display equipment, and the associated disposables for cardiovascular monitoring will be approximately £1.65 billion. In addition, each year at least 10 million arterial lines are placed in at-risk surgery and critical care patients who would benefit from cardiovascular monitoring both during and after major surgery. There is a growing awareness in the medical community that in order to improve patient outcome and simultaneously reduce the cost of care, additional parameters of blood flow and oxygen delivery, as well as blood pressure and heart rate, are required in at-risk surgical procedures and at the critical care patient's bedside.

The current market-leading product that provides the additional measurement of blood flow is the thermodilution pulmonary artery catheter. The Board believes that this product has a number of limitations, including its invasiveness, procedural complexity, lower reliability and interpretation difficulties. As a result, this device is only used in a limited number of the acute conditions where these measurements would be useful.

In response to market need, LiDCO has developed and registered products that can be applied to the majority of at-risk surgery and critically ill patients. The Board believes that the Company's technologically advanced and minimally invasive cardiovascular monitoring equipment and disposables technology, the LiDCO and PulseCO Systems respectively, are accurate and reliable, easy to use and interpret. Their use may also significantly reduce costs and improve standards of care by the reduction of both adverse events and intensive care days. In our view, there is no other company in the cardiovascular monitoring and disposables market which can comprehensively meet this overall need.

#### Sales and marketing

While it is only a matter of 10 weeks since we launched the LiDCO and PulseCO Systems in the USA and 4 weeks in the UK, we are pleased with progress made and the level of market penetration achieved.

## Sales strategy

The Company's strategy is to identify potential customers and, following an evaluation period, to prioritise selling activity with customers who demonstrate an interest in changing from the existing invasive pulmonary artery catheter to the Company's minimally invasive technology, have capital budgets to accommodate the change and are prepared to purchase both the Company's monitoring equipment and disposables. Specifically, the Company is focusing on surgery and intensive care

applications and is pursuing a strategy predominantly based upon the sale of capital equipment, as opposed to placing capital equipment and recovering the cost through the subsequent sale of the associated disposables.

The sales process consists of four phases:

- Product demonstration
- Field trials
- Sales proposals, and
- Sales closure

In our business model, we have estimated that each sale will take several months, although it is too early to extrapolate the average length of the sales cycle.

# Sales infrastructure

The Company has started to build experienced, direct sales and marketing teams in both the UK and USA for the initial commercial phase. These territories represent approximately two thirds of the market for our products. Having a direct sales operation ensures optimal focus and control, decreases the possibility that the Company's independence of action will be compromised and broadens its options in the future.

Since the flotation of the Company, the sales organisation in the USA has grown substantially and currently comprises ten sales representatives, increasing to 14 by January 2002. The UK sales organisation has been fully recruited with eight sales representatives and support personnel. The Board believes that the ability to attract experienced sales and marketing professionals reflects the quality of the underlying product. Overall, the sales force is now trained and actively engaged in sales activities. In other EU countries and the Far East, LiDCO has chosen not to develop a direct sales organisation and relationships are being established with independent distributors.

The necessary marketing infrastructure, organisation and marketing tools to support the Company's commercial strategy have also been put in place. Commercial activities are now being co-ordinated out of the Company's newly established sales and marketing office at Granta Science Park, Cambridge.

# **Current trading**

Since obtaining regulatory approval, the Company's sales activity has accelerated. To date, the Company has contacted 113 hospitals in the USA alone. Of these, 98 hospitals have expressed an interest in the Company's technology, meet the criteria specified by the Company and are classified as 'active accounts'; 33 'active accounts' have made a purchase or requested a sales proposal and over 80% of these 33 accounts are pursuing a capital equipment purchase route. The Company estimates on average, that the initial capital purchase will be two LiDCO and four PulseCO units, generating an average sale of £50,000 per account with ongoing disposable revenue stream from the installed base of monitors.

A key sale in the USA has been to the Holy Cross Hospital, Ft. Lauderdale, a leading cardiovascular hospital, where the cardiovascular surgery and associated intensive care unit has purchased six PulseCO and two LiDCO Systems. Our product will be used primarily as a replacement for the market leading pulmonary artery catheter in the operative theatre for both traditional cardiac surgery and minimally invasive 'off-pump' patients, as well as in the post-operative intensive care unit.

Although initial results support our 'capital equipment' business model, the sales effort is still at an early stage and we have insufficient data to derive definitive conclusions. The Board is closely auditing key aspects of the business model such as account closure rates, time to closure and ongoing disposable usage rates. We will keep our shareholders updated on progress.

## Manufacturing

The Company has successfully undertaken several manufacturing initiatives, including the diversification of key raw materials suppliers, ensuring adequacy of supply of sub-contracted components, further automation of key manufacturing equipment and expansion of sensor manufacturing capacity.

# **Clinical activity**

A near term objective is to establish the Company and its technology as a viable partner for the critical care, anaesthesia and cardiac/major surgical communities. It is therefore important that key influencers within the medical community continue to validate and promote the use of the Company's technology in its targeted applications.

For this purpose, we have maintained an academic research base in the Department of Applied Physiology at St Thomas' Hospital, London and continue to conduct trials of our technology in a range of hospitals. Positive results have been achieved from trials on the PulseCO System from the University of Texas, Berlin Heart Centre and Southampton University Hospital. These results will be presented at:

- The American Association of Anesthesiology (New Orleans, October 2001);
- World Congress on Intensive Care (Sydney, November 2001), and
- The Cardiothoracic Techniques and Technology Meeting (La Hoya, Florida, January 2002).

Further studies are in progress at Duke University, Stanford University and the University of Chicago. Collectively there have been 41 publications and presentations on the Company's monitoring technology. A full bibliography is available on the website, www.lidco.com.

## **Regulatory affairs**

In February 2001, the Company received notification from the Medicines Control Agency that approval had been granted to market the lithium chloride injectate, enabling the Company to begin commercialisation of the LiDCO and PulseCO Systems in the UK. Marketing authorisation for the lithium chloride injectate in other EU countries is being pursued via the EU mutual recognition procedure and is anticipated in 2002.

In July 2001, the Company received approval from the FDA to market the PulseCO System enabling it to begin commercialisation of the LiDCO and PulseCO Systems in the USA.

In the Far East, our Japanese distributor, Nipro Corporation, has concluded its first phase of registration by completing its LiDCO System clinical trials with positive results.

## **Research and development**

Research and development continues to be key to the Company's strategy to expand the new product pipeline. To date, the Company has applied for 15 patents, of which 11 have been granted, two have been accepted and two are pending. Currently, the Company is pursuing five research

projects, three development projects and two product application developments. Key projects cover patient fluid volume management, a PulseCO / LiDCO combined unit and cardiology applications.

## **Financial performance**

The results for the first half of the year are in line with the Board's expectations. Turnover for the six months ended 30 June 2001 was  $\pounds 102,000$  (2000:  $\pounds 459,000$ ). The majority of the difference was the result of a  $\pounds 404,000$  termination payment in 1Q 2000 with respect to the Byk Gulden licence. The operating loss was  $\pounds 1.23$  million (2000:  $\pounds 261,000$ ), reflecting the gearing-up of the Company's operations in anticipation of commercial production and launch of our newly approved cardiovascular monitoring products in the USA and UK.

The cash position at the period end was  $\pounds 2.8$  million (2000:  $\pounds 1.3$  million) and as at 26 September 2001, stands at approximately  $\pounds 14.4$  million following the Company's flotation on AIM in July 2001 when gross proceeds of approximately  $\pounds 15$  million were raised.

## Outlook

Following the flotation, we are now in a position, with experienced direct sales and marketing forces in the UK and the USA, to accelerate commercialisation of our products in these markets. We have had an excellent reception in hospitals and indications are that customers are willing to purchase our technology in accordance with our capital equipment-purchasing model. We are pleased with the performance to date which confirms that the objectives outlined in the business plan are realistic and achievable. The Board looks forward to the future with great anticipation and expectation.

T. William Alexander

Executive Chairman 26 September 2001

# INDEPENDENT REVIEW REPORT TO LIDCO GROUP PLC

#### Introduction

We have been instructed by the company to review the financial information for the six months ended 30 June 2001 which comprises the profit and loss account, the balance sheet, the cash flow statement and related notes. We have read the other information contained in the interim report and considered whether it contains any apparent misstatements or material inconsistencies with the financial information.

#### **Directors' responsibilities**

The interim report, including the financial information contained therein, is the responsibility of, and has been approved by the directors. The directors are responsible for preparing the interim report in accordance with the Rules of the London Stock Exchange, which require that the accounting policies and presentation applied to the interim figures are consistent with those applied in preparing the preceding annual accounts except where any changes, and the reasons for them, are disclosed.

#### **Review work performed**

We conducted our review in accordance with the guidance contained in Bulletin 1999/4 issued by the Auditing Practices Board for use in the United Kingdom. A review consists principally of making enquiries of group management and applying analytical procedures to the financial information and underlying financial data and based thereon, assessing whether the accounting policies and presentation have been consistently applied unless otherwise disclosed. A review excludes audit procedures such as tests of controls and verification of assets, liabilities and transactions. It is substantially less in scope than an audit performed in accordance with United Kingdom Auditing Standards and therefore provides a lower level of assurance than an audit. Accordingly, we do not express an audit opinion on the financial information.

#### **Review conclusion**

On the basis of our review we are not aware of any material modifications that should be made to the financial information as presented for the six months ended 30 June 2001.

DELOITTE & TOUCHE Chartered Accountants 26 September 2001 Hill House 1 Little New Street London EC4A 3TR

# **PROFIT AND LOSS**

	Note	Six months ended 30 June 2001 (unaudited) £'000	Six months ended 30 June 2000 (unaudited) £'000	Year ended 31 December 2000 (audited) £'000
<b>TURNOVER</b> Cost of sales	2	102 (64)	459 (91)	634 (204)
Gross profit		38	368	430
Administration expenses		(1,268)	(629)	(1,703)
OPERATING LOSS		(1,230)	(261)	(1,273)
Interest receivable and similar income Interest payable and other expenses		81	47	145 (6)
LOSS ON ORDINARY ACTIVITIES BEFORE TAX		(1,149)	(214)	(1,134)
Tax on loss on ordinary activities		-	-	-
LOSS ON ORDINARY ACTIVITIES AFTER TAX		(1,149)	(214)	(1,134)
Equity minority interests	3	225	19	218
LOSS FOR THE PERIOD		(924)	(195)	(916)
Loss per share (£)	4	(46.2	(9.8)	) (45.8

# **BALANCE SHEET**

	Note	30 June 2001 (unaudited) £'000	30 June 2000 (unaudited) £'000	31 December 2000 (audited) £'000
FIXED ASSETS				
Tangible assets		51	66	49
Intangible assets		310	220	250
		361	286	299
CURRENT ASSETS				
Stocks		716	554	518
Debtors		98	28	41
Cash at bank and in hand		2,838	1,328	4,368
		3,652	1,910	4,927
CREDITORS: amounts falling due within one year		(507)	(333)	(427)
NET CURRENT ASSETS		3,145	1,577	4,500
TOTAL ASSETS LESS CURRENT LIABILITIES		3,506	1,863	4,799
CREDITORS: amounts falling due after more than one year		(595)	(735)	(665)
NET ASSETS		2,911	1,128	4,134
CAPITAL AND RESERVES Called up share capital		_	_	_
Profit and loss account		(4,398)	(2,756)	(3,476)
EQUITY SHAREHOLDERS' DEFICIT		(4,398)	(2,756)	(3,476)
Equity minority interests	3 3	(503)	(3)	(202)
Non-equity minority interests	3	7,812	3,887	7,812
		2,911	1,128	4,134

Signed on behalf of the Board of Directors

Richard J Mills Director 26 September 2001

# **CASH FLOW**

	Note	Six months ended 30 June 2001 (unaudited) £'000	Six months ended 30 June 2000 (unaudited) £'000	Year ended 31 December 2000 (audited) £'000
Operating loss		(1,230)	(261)	(1,273)
Depreciation and amortisation Increase in stocks (Increase)/decrease in debtors Increase/(decrease) in creditors		39 (198) (57) 8	(84) 47 (373)	50 (48) 34 (348)
Net cash outflow from operating activities		(1,438)	(671)	(1,585)
Returns on investment and servicing of finance		81	47	139
Capital expenditure and financial investment		(173)	(4)	(66)
Cash outflow before financing		(1,530)	(628)	(1,512)
Financing	5		47	3,971
(Decrease)/increase in cash in the period		(1,530)	(581)	2,459

#### NOTES

#### 1. NATURE OF THE FINANCIAL INFORMATION

The interim results have been prepared in accordance with applicable accounting standards. The particular accounting policies adopted are the same as those adopted in the financial statements for the year ended 31 December 2000.

The Company's financial statements for the year ended 31 December 2000 have been filed at Companies House. The financial statements contained an unqualified audit report and no statement under s237 of the Companies Act 1985.

#### 2. TURNOVER

Turnover for the six months ended 30 June 2000 was increased by £404,000 of income recognised on the termination of the Byk Gulden licence agreement. This matter has been fully disclosed both in the 2000 financial statements and in the listing prospectus.

#### 3. MINORITY INTEREST

Admission to the Alternative Investment Market of the London Stock Exchange ("AIM") occurred on 5 July 2001, five days after the end of the financial period. The restructuring of the group agreed by the shareholders in February 2001, under which the minority holdings in LiDCO Limited would be bought out in exchange for shares in LiDCO Group, was conditional upon admission and is therefore deemed to have occurred on 5 July 2001. Since that date there has been no minority interest.

#### 4. LOSS PER SHARE

Loss per share is calculated by dividing the loss attributable to ordinary shareholders by 20,000, being the 100 ordinary shares of  $\pounds 1$  each in issue throughout the period, adjusted to reflect the sub-division effective upon admission to AIM.

If the loss per share were restated to reflect the 70,844,561 shares in issue following admission the loss per share for the six months ended 30 June 2001 would be 1.3p (six months ended 30 June 2000: loss of 0.3p, year ended 31 December 2000: loss of 1.3p).

#### 5. FINANCING

Following admission to AIM, gross proceeds £15.0 million were received by the Group on 5 July 2001. Net proceeds of the flotation were £12.8m.

#### 6. DIVIDENDS

It remains the Company's policy that no dividends will be paid until future operations have provided appropriate levels of distributable profits.

#### 7. DISTRIBUTION

Copies of this statement are being sent to all shareholders and will be available for collection free of charge from the Company's registered office at 16 Orsman Road, London N1 5QJ.