# FOR IMMEDIATE RELEASE 29 September 2004

#### LiDCO GROUP PLC

## INTERIM RESULTS - SIX MONTHS ENDED 30 JUNE 2004

LiDCO, the UK-based, AIM-traded cardiovascular monitoring company, announces continuing progress in its third year of commercialisation of its products, with the first half of 2004 being the final foundation period prior to a significant expansion of sales activities through LiDCO's recently expanded distributor network.

## 1.1 Corporate Events and Significant Distribution Expansion

- A placing of £3.7m (net) of new shares was completed in June 2004, giving additional working capital to support the new US, German and Austrian distributor programmes and additional R&D
- Final contracts have been signed appointing four regional distributors in the US
- German & Austrian distributors were appointed (June) sales have commenced in both territories
- Final lithium chloride registration in Italy (in September) sales commenced
- In May 2004, a contract was signed with Philips Medical Systems to create a communications link between LiDCO's proprietary stand-alone monitoring system and Philips' patient monitor. The necessary software has been developed and launch of the software is expected around the end of this year

## 1.2 Financial Highlights of the Period

- Continued transition from a capital sales model to an annuity revenue stream. Sensor and fee for use volumes increased by 76% across the period
- Annuity revenue now represents 65% of sales up from 20% in 2002 and 45% in 2003
- Total revenues of £0.915m (£1.655m) which adjusted for a major stocking order from Japan in 2003 and licence fees increased by 11.5% to £0.88m (£0.789m)
- Reduced administrative expenses down 8% (£2.910m against £3.158m in 2003) and cash usage down 25% (£1.573m against £2.094m in 2003)
- Despite the reduced admin expenses and cash use the pre-tax loss was higher (by 17%) at £2.295m due to the additional margin in 2003 (£0.52m) generated from the Japanese stocking order and the continued effects of the shift from capital to annuity revenue
- Loss per share slightly higher at 2.91p (2003: 2.58p)
- Gross margins improved: 80% disposables (up 3%) and monitors 74% (up 11%)

# 1.3 Commercial Highlights

- The number of PulseCO/LiDCO*plus* monitors sold/placed during the period increased by 23% (76 against 62) in USA, UK and Europe
- Sensor and fee per use volumes up 76% to 7,614 from 4,315
- Significant expansion in sales activities commenced in second half of year

Revenue Summary – Showing Transition to Annuity Stream				
Sales detail	June 2004	<b>June 2003</b>		
	£'000	£'000		
Capital	321	1,139*		
Sensors - Standard price	296	292		
- Up charge price	219	55		
Sensors total revenue	515	347		
Monitor fee per use	44	-		
Licence fees	35	169		
Total	915	1,655		
Installed base (number of monitors)	667	469		

<sup>\*</sup> Includes stocking order of £0.71m from Japan

Dr Terry O'Brien, Chief Executive, stated "Following the progress made this year in finding, negotiating with and appointing distributors in the US, Germany and Austria, distributor sales activities in these territories have begun and I am encouraged by the progress they are already making. The additional sales in these territories will add to our existing and growing annuity revenue, further reducing our dependence on revenue from lumpy and less predictable capital sales. The Directors believe that the annuity sales growth will continue and translate into our first profits on a monthly basis by the end of 2005."

The Directors have decided to change the Company's financial year-end from 31 December 2004 to 31 January 2005. The Directors believe that a January year-end is more suitable date operationally. The Company will therefore announce audited results for the 13 month period 1 January 2004 to 31 January 2005.

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#### Private Client Investment Advisors Presentation

Starting at 12.30 p.m. for 1 p.m. and finishing no later than 2.00 p.m. today. A lunchtime presentation to private client investment advisors will be given at the offices of Bankside Consultants, 123 Cannon Street, EC4N 5AU.

The investor presentation 'Interim Results – Half year ended  $30^{th}$  June 2004' will available on the LiDCO website (www.lidco.com).

#### **Notes for Editors**

LiDCO is a leading developer of minimally invasive, computer-based hemodynamic monitoring equipment and disposables used primarily for the management of critical care and cardiovascular risk hospital patients. The Company's current products are:

- the LiDCOplus and PulseCO monitors, computer-based platforms for displaying a range of real-time continuous hemodynamic parameters including cardiac output, oxygen delivery and fluid volume; and
- the LiDCO disposable for accurately determining cardiac output in a minimally-invasive manner.

LiDCO was founded in 1991 by Doctors Terry O'Brien (the current CEO), David Band (the current Scientific Director), Robert Linton and Jiri Kratochvil and by King's College, London. LiDCO's head office is in Hoxton, London N1, whilst its sales offices are located in the Granta Science Park, Cambridge and in Dallas, Texas.

## CHIEF EXECUTIVE OFFICER'S STATEMENT

Maximising the value from the commercialisation of products such as LiDCO's requires a substantial and geographically extensive sales network. So far this year the Company has made strong progress in its objective of building such a network, with the appointment of four new distributors in the US and two in Germany and Austria.

Attracting high quality specialist distributors requires a patented product, local clinical champions and sales prices and margins that allow both parties to make a profit commensurate with the investments necessary to access the market

The Company's approach of direct sales in the USA and the UK has been instrumental in establishing revenues and sales models with a premium price and margin. In parallel we actively encouraged independent product validation studies by recognised opinion leaders. Successful trials were concluded in Japan, UK, USA, Belgium, Germany and Spain. Therefore, at the beginning of 2004 we felt that we had a sufficiently compelling product with widespread clinical validation to finalise the appointment of a global network of quality independent distributors of sufficient reach to broadly expand sales.

By June 2004 we had achieved an installed base of 667 monitors in more than 200 hospitals, of which almost half (310) had been sold or placed in US institutions. We have the only minimally invasive cardiovascular monitoring technology to achieve a significant penetration of the US market. An example of LiDCO's success is that one US hospital has purchased 18 LiDCO*plus* monitors i.e. one of our monitors was positioned at each bed in the operative room and associated intensive care department. In my experience this degree of adoption at such an early stage of marketing was unprecedented and reflected both the appropriate nature of the technology and the readiness of the market for a change. The products have been demonstrated to not only have the necessary performance, but also the potential to reduce direct costs and replace the market leading invasive catheter based technology. Furthermore, many of our customers are using our minimally invasive approach in new patient populations not previously deemed suitable for cardiovascular monitoring.

In conclusion, sales in the first half of 2004 should be interpreted as being indicative of the final preparative phase prior to a significant increase in sales activities through our recently expanded distributor network. In order to support the sales expansion in the US and Continental Europe and finance product development the Company concluded a placing of shares in June raising approximately £3.7 million (net). It was very gratifying to see a number of our existing investors supporting this financing round and at the same time we were able to welcome a number of new institutional investors.

#### FINANCIAL & TRADING REVIEW

Turnover was £0.915m, down from £1.655m in the same period in 2003. This was expected as the first half 2003 revenue was supplemented by a large monitor stocking order of £0.71m by Nipro Corporation, our Japanese distributor, combined with one-off licence fee income (£99k). Due to early stage of marketing, coupled to the capital selling cycle for monitors in Japan, we were not expecting a major restocking order until 2005. However, revenues in the more comparable UK, US and Continental EU territories rose by 12.5%. Top line revenue across the period was temporarily suppressed by our shift in the second half of 2003 from an early focus on capital sales (necessary to enhance initial revenues and prove monitor value), towards annuity based models. However, progress on the underlying business and annuity growth is clear, evidenced by the greater increase in the installed base of monitors during the period (rising by 23% to 667 units) when compared to the same period in 2003 and the 77% increase in sensor usage to 7,614 units (2003: 4,315). The percentage of turnover represented by annuity income (fee per use, sensor sales and licence fees) has grown from 20% in 2002, to 45% in 2003 and now stands in the first six months of 2004 at a very encouraging 65%.

With the appointment of the new distributors, the number of sales people representing our products in the US, Germany, Austria and Italy has recently seen a sharp increase. The additional contribution from these territories is expected to deliver higher growth in both placement of monitors and associated annuity revenue in the second half of this year.

The gross profit of £603,000 represents a gross margin of 66% (2003: 70%) - 80% for disposables (up 3%) and 74% for monitors (up 11%).

Continuing with active cost management, administrative expenses fell by 9% during the period (£2,910,000 against £3,158,000). Despite this continued reduction in costs the net loss was up on the period in 2003 (£2,295,000 against £1,845,000), due to the higher revenue seen in 2003 from the Japanese stocking order and the targeted shift in sales model in the US from capital to up charge and rental models. However, this was partially offset by the lower costs and only resulted in a modest increase in the loss per share of (2.91p against 2.58p).

## UK

Turnover increased by 46% to £367,000 (2003: £252,000) with sensor sales up 82% at 2,880 (2003:1,580).

In 2003, the UK became the first territory where the use of newer minimally invasive products approached that of the traditional, more invasive catheters. Given the cost constraints affecting the UK's National Health Service, this demonstrates that hospitals are willing to make investments that are regarded as relatively low-cost and high-value propositions. We continue to believe that UK sales will continue to advance.

## US

During the first half of 2004, sales to US customers were made through our direct US-based sales force. Although monitors placed or sold were up 28% at 46 against 36 in 2003, with sensor/fee for use sales up 66% at 3,434 (2003: 2,065), turnover fell modestly to £316,000 (2002: £392,000) due to the transition from capital sales of monitors towards up charge and rental/fee per use mo dels coupled with the effects of the weakening dollar (£43,000). In anticipation of the appointment of the US distributors there was also a reduction in US sales people by three people (to six overall).

The US is the biggest single market and represents approximately 50% of our potential worldwide sales. As part of our strategy to establish a network of regional agents in the US, four distributors have been signed up and are undergoing sales training. We now have access to about 40% of the US hospital market for cardiovascular monitoring. Discussions with additional distributors for other new territories are ongoing. Our new distributors have commenced early sales activities and they are expected to make an increasing sales contribution starting in the fourth quarter of 2004. Commercial terms agreed with our distributor partners involve the payment of a monitor rental to LiDCO. US hospitals will be billed on a rental or up charge basis.

# **Continental Europe**

Sales progress in Continental Europe was affected by regulatory body administration delays in the implementation of our January 2003 EU mutual recognition approvals at the country level. This was particularly so in Italy and Austria where final lithium approval was only granted in September and January respectively. Nevertheless, sales have started to grow well with turnover 64% higher at £161,000 (2003: £98,000) and sensor sales up 61% at 900 against 560 in 2003.

We expect major growth in sensor sales in the second half of the year – particularly in Germany, Austria and Italy, where LiDCO's products were recently launched. These territories represent one third of the European market value for our technology.

## Japan and Rest of World

Sales in the RoW at £36,000 were slightly down due to the phasing of capital sales to distributors (2003: £47,000) but as with other territories sensor sales for the period, at 400, showed a considerable increase over the same period in 2003, when 110 sensors were sold.

Following the product launch in Japan in November 2003, Nipro Corporation, the Company's Japanese distributor, initiated the training of its 200-strong sales force in February 2004 and began sales activity. Having purchased 100 monitors last year which Nipro is currently selling to Japanese hospitals via the capital sales route, no further stocking order is expected in 2004. In addition to anesthesia and critical care, Nipro sees additional sales opportunities in the measurement of cardiac output in chronic renal dialysis patients and in the pacing and catheter lab cardiology markets. These are two new applications for our technology. Nipro is a major supplier of renal dialysis equipment in Japan and worldwide. During the first half of 2004 Nipro concluded three trials with noted Japanese University centres underpinning the domestic marketing approach. In partnership with Nipro we can see the beginning of a significant market for our monitoring products in Japan.

## RESEARCH AND DEVELOPMENT AND PRODUCT APPLICATIONS

In May 2004, LiDCO signed a contract with Philips Medical Systems to create a communications link (VueLink interface) between LiDCO's proprietary stand-alone monitoring system and Philips' patient monitors. I'm pleased to announce that the software has now been developed and launch of the software (version 3.0) is expected around the end of this year. This version of the software will also have a number of additional product features – screen improvements for additional ease of use, video clips / text tutorial ability and improved data handling features.

Our other development activities centre on additional product applications that can be added to our platform monitor through further developments to the software - particularly the user interfaces. Specifically, we expect to add further functionality (during 2005) in terms of the optimisation of high risk surgery patients, which we believe to be a considerable unexploited market opportunity.

## Improving outcomes and reducing costs in high-risk surgery patients

Perioperative optimisation is the preventative manipulation of patients' physiological parameters during the period around surgery to ensure adequate oxygen delivery to the brain and other critical organs. These optimisation protocols have a positive influence on patient outcomes. The increasing recognition of the advantages of preventative cardiovascular management we believe has increased the market for our minimally invasive and portable technology.

This month (September) saw the early conclusion of a major surgical outcome trial at St Ge orge's Hospital, Tooting where LiDCO's technology was used to optimize major surgery patient's blood flow and oxygen delivery to the body. The goal of the trial is to quantify the effect of such a treatment on morbidity (organ damage) and hospital bed stay days. Results of this trial should be available in late 2004 or early 2005.

In conjunction with a number of leading hospitals, LiDCO is developing the LiDCO *plus* user interface to allow the nurse-led optimisation of fluid administration to such patients. This will reduce the risks and costs associated with improving outcomes in surgery patients using more invasive technologies. Tests are in progress to validate the use of our technology in this application.

Looking ahead, we are also assessing the potential to use completely non-invasive (skin applied) sensor technology with the LiDCOplus monitor to identify and optimize high-risk surgery patients.

# Potential Neonatal Application for the LiDCOplus Monitor

Monitoring of cardiovascular status in the unwell pre-term baby (neonate) is mostly limited to the continuous measurement of blood pressure through an umbilical artery catheter. However, these blood pressure values, although useful, may not accurately reflect actual tissue perfusion with oxygen. The continuous measurement of cardiac output and estimation of oxygen delivery in these very small babies has not been possible, except intermittently by echocardiography. Researchers from the Clinical Science Department (Child Health), University of Bristol, UK have shown in a neonatal model (1.5 kg) that continuous analysis of cardiac output is possible with the LiDCOplus Monitor. The cardiac output trend derived from our monitor shows a closer correlation to changing tissue oxygen perfusion than standard arterial blood pressure monitoring. They conclude that "This methodology is applicable to

the term and preterm infant in assessing cardiovascular function, using either a standard umbilical catheter, or a peripheral arterial line." The LiDCOplus Monitor is not registered for use in subjects less than 40 kgs in weight; however, this work has encouraged us to further investigate the potential for sales of the LiDCOplus Monitor in neonatal intensive care units. If an attractive business case can be made then the appropriate steps will be taken for registration of this new clinical indication.

# **REGULATORY AFFAIRS**

Regulatory approval for the lithium chloride injection has been applied for in additional territories: Norway, Sweden, Denmark and Ireland. Mutual recognition approval for all territories are expected in the fourth quarter of 2004. Implementation of these EU mutual recognition approvals and launch in these territories are likely in the first half of 2005.

Terry O'Brien Chief Executive Officer 28 September 2004

#### 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 2004, which comprises the consolidated profit and loss account, the consolidated balance sheet, the consolidated cash flow statement and related notes 1 to 4. 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.

This report is made solely to the company, in accordance with Bulletin 1999/4 issued by the Auditing Practices Board. Our work has been undertaken so that we might state to the company those matters we are required to state to them in an independent review report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the company, for our review work, for this report, or for the conclusions we have formed.

# 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 also responsible for ensuring 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 2004.

DELOITTE & TOUCHE LLP London

Chartered Accountants 28 September 2004

# CONSOLIDATED PROFIT AND LOSS ACCOUNT For the six months ended 30 June 2004

	Six months ended 30 June 2004 (unaudited)	Six months ended 30 June 2003 (unaudited) (restated) £'000	Year ended 31 December 2003 (audited) (restated) £'000
TURNOVER	915	1,655	2,717
Cost of sales	(312)	(501)	(808)
Gross profit	603	1,154	1,909
Administrative expenses	(2,910)	(3,158)	(6,090)
OPERATING LOSS	(2,307)	(2,004)	(4,181)
Interest receivable and similar income	12	47	68
LOSS ON ORDINARY ACTIVITIES BEFORE TAX	(2,295)	(1,957)	(4,113)
Tax on loss on ordinary activities		112	238
LOSS ON ORDINARY ACTIVITIES AFTER TAX	(2,295)	(1,845)	(3,875)
Loss per share (basic and diluted) (p)	2.91	2.58	5.34

The prior period restatements are due to a change in accounting policy, as set out in note 2.

# CONSOLIDATED BALANCE SHEET As at 30 June 2004

As at 50 Julie 2004	30 June 2004 (unaudited) £'000	30 June 2003 (unaudited) (restated) £'000	31 December 2003 (audited) (restated) £'000
FIXED ASSETS			
Tangible assets	1,300	1,233	1,305
Intangible assets	335	544	421
	1,635	1,777	1,726
CURRENT ASSETS			
Stocks	1,522	1,979	1,665
Debtors	974	1,812	1,201
Cash at bank and in hand	3,659	1,881	1,600
	6,155	5,672	4,466
CREDITORS: amounts falling due within one year	(622)	(677)	(515)
NET CURRENT ASSETS	5,533	4,995	3,951
TOTAL ASSETS LESS CURRENT LIABILITIES	7,168	6,772	5,677
CREDITORS: amounts falling due after more than one year	(163)	(233)	(198)
NET ASSETS	7,005	6,539	5,479
CAPITAL AND RESERVES			
Called up share capital	491	357	386
Share premium account	17,080	12,430	13,396
Merger reserve	8,513	8,512	8,513
Other reserve	(60)	(38)	(88)
Profit and loss account	(19,019)	(14,722)	(16,728)
EQUITY SHAREHOLDERS' FUNDS	7,005	6,539	5,479

The prior period restatements are due to a change in accounting policy, as set out in note 2.

# CONSOLIDATED CASH FLOW STATEMENT For the six months ended 30 June 2004

	Six months ended 30 June 2004 (unaudited)	Six months ended 30 June 2003 (unaudited) (restated) £'000	Year ended 31 December 2003 (audited) (restated) £'000
Operating loss	(2,307)	(2,004)	(4,181)
Depreciation and amortization Decrease in stocks Decrease/(increase) in debtors Increase/(decrease) in creditors	318 143 227 72	260 313 (445) (164)	655 627 166 (361)
Net cash outflow from operating activities	(1,547)	(2,040)	(3,094)
Returns on investment and servicing of finance	12	47	68
Capital expenditure and financial investment	(205)	(101)	(344)
Cash outflow before financing	(1,740)	(2,094)	(3,370)
Financing	3,799	1	996
Increase/(decrease) in cash in the period	2,059	(2,093)	(2,374)

The prior period restatements are due to a change in accounting policy, as set out in note 2.

## NOTES TO THE INTERIM STATEMENT

#### 1. NATURE OF THE FINANCIAL INFORMATION

The financial information has been prepared in accordance with generally accepted accounting principles in the UK and was approved by the Board on 28 September 2004. Except as described in note 2, the accounting policies applied in preparing the financial information are consistent with those adopted and disclosed in the Group's statutory accounts for the year ended 31 December 2003.

These results are unaudited and the financial information does not constitute statutory accounts as defined under section 240 of the Companies Act 1985. The financial information for the year ended 31 December 2003 has been derived from the Group's statutory accounts for that period, as filed with the Registrar of Companies. The auditors' report on the statutory accounts for the year ended 31 December 2003 was unqualified and did not contain statements under section 237 (2) or (3) of the Companies Act 1985.

## 2. RESTATEMENT OF COMPARATIVE FIGURES

Following the introduction of UITF 38 ("Accounting for Employee Share Ownership Trusts") the company has restated its figures relating to its investment in the LiDCO Group Plc Employee Benefit Trust. This change has had the effect of transferring the Investments balance of £60,000 (2003: £38,000) directly to reserves. An impairment of £4,000 in the six months ended 30 June 2003 and a reversal of impairment of £46,000 in the year ended 31 December 2003 have now been taken directly to reserves. Changes in the value of shares held in the Trust are no longer shown in the Company's results.

#### 3. DIVIDENDS

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

# 4. DISTRIBUTION OF THE INTERIM STATEMENT

Copies of this statement will be available for collection free of charge from the Company's registered office at 16 Orsman Road, London N1 5QJ. An electronic version will be available on the Company's website, www.lidco.com.