RNS Number : 7428Z EKF Diagnostics Holdings PLC 21 March 2012

EKF DIAGNOSTICS HOLDINGS PLC ("EKF", the "Company" or the "Group")

Final results for the year ended 31 December 2011

EKF Diagnostics Holdings plc (AIM: EKF), the growing in-vitro diagnostics company, announces its audited final results for the year ended 31 December 2011, a year of continued progress.

Financial Highlights (from continuing operations)

- Revenues more than tripled to £21.7m (2010: £6.5m) following a strong second half
- Gross margins improved to 48% (2010: 45%)
- Adjusted EBITDA (before exceptional costs and share based payments) of £1.6m (2010: £1.0m)
- Operating loss of £2.0m (2010: loss of £1.9m) reflects investment in people and infrastructure
- Loss before tax of £2.4m (2010: £2.1m) includes Stanbio acquisition costs
- · Cash at 31 December 2011 of £5.3m (2010: £3.2m)

Operational Highlights

- Acquisition of Stanbio for a maximum consideration of US \$25.9m
- Agreement signed with Alere Inc to distribute HemoPoint H2 analysers and cuvettes in the USA
- Major Mexico contract win 3,594 HemoPoint H2 analysers and related cuvettes cuvette replenishment order already underway
- SFDA approval for Quo-Test in China has helped drive increased sales
- Placement of 1,000th Quo-Test analyser (September 2011)
- Investment in key people and key infrastructure including £0.6m invested to triple manufacturing capacity for Quo-Test and Quo-Lab and move to a bigger manufacturing plant in Poland
- Strong product development pipeline with Quo-Lab, HbA1c analyser and our Biosen HbA1c and glucose analyser launched at Medica with commercial launches expected in first half of 2012
- Richard Evans appointed as Finance Director

Post Period End

- US State of New Mexico contract win 220 HemoPoint H2s (outside Alere Inc Agreement)
- US patent granted for HemoPoint H2 cuvettes
- Tony Wilks appointed as Group Head of Sales
- First shipment of HemoPoint H2 analysers and cuvettes to Alere Inc made in March 2012

David Evans, Executive Chairman of EKF, said:

"Today's announcement shows a year of continued progress towards our goal of building a successful, profitable, international IVD business with our results significantly better than our expectations. The progress to date in 2012 has been in line with our expectations in the first quarter. I am genuinely excited by the prospects for EKF Diagnostics and believe that the core team has the dynamism and desire to succeed which will power the business towards continued growth and success."

EKF Diagnostics Holdings plc David Evans, Executive Chairman Julian Baines, CEO Richard Evans, FD

Collins Stewart Europe Limited Jamie Adams / Mark Dickenson www.ekfdiagnostics.com Mob: +44(0)7740 084452 Mob: +44(0)7788 420 859 Mob: +49(0)160 351 9054

Tel: +44(0)20 7523 8000

Walbrook PR Limited Fiona Henson Tel: +44(0) 20 7933 8780 Mob: +44 (0) 7886 335 992 or fiona.henson@walbrookpr.com Mob: +44 (0) 7980 541 893 or paul.mcmanus@walbrookpr.com

Paul McManus

Chairman's Statement

Dear Fellow Shareholder

I have pleasure in reporting the results of EKF Diagnostics for the year ended 31 December 2011. It has been a year of continued progress with the year-end numbers being ahead of our expectations in large part due to the contribution made by our U.S. business.

Strategic direction

Before commenting on the results for the year I think it is worth reviewing where we are today and the future direction for the Group.

We made our first acquisition less than two years ago and since then we have made three further acquisitions including one in the financial year just ended. The primary, but not exclusive, focus has been on point of care diagnostics and our product areas have been defined by the companies we have acquired: haemoglobin, glycated haemoglobin, haematocrit, glucose, lactate and acute kidney injury.

In seeking to grow initially through a series of acquisitions there are inevitable challenges until one reaches a sufficient level of critical mass to drive significant cost synergies through the organisation, however, we are not yet at that level.

Our key challenges with a group spread over 9 locations are ones of communication and co-ordination. These challenges continue to be met and I am pleased with the progress that we have made, particularly in EKF Germany where we have moved from an owner-managed environment to one capable of living with the rigours of being a quoted company.

We will seek to grow both organically and via acquisition but it is important for shareholders to understand that we are not seeking to grow by acquisition at any cost in endeavouring to achieve a level of critical mass. We have reviewed many opportunities and reached advanced levels of negotiation on more than one occasion, but ultimately took the decision not to commit to a course of action where, although critical mass would have been achieved, it was unclear that future enhancements in shareholder value would have been realised. I hope that this sends a clear and obvious message that EKF is not engaged in growth by acquisition at any cost.

Looking forward, in terms of building future value, then I want the Group to focus in three areas;

Firstly, to identify areas of unmet clinical need where we believe, either organically or through acquisition, we can make a difference and provide a better outcome for both patient and clinician. In that regard we are currently reviewing a number of interesting opportunities, some of which fall within the framework of point of care and some which do not.

We are becoming more creative in our thinking as to how we exploit these opportunities. However, there is in reality a limit to how much we can leverage our existing research and development capability, although we are currently examining expansion of our lactate platform into new areas and the underlying Quotient technology into other disease tests. That, however, is insufficient for the demands I am placing on the organisation in my drive for future growth. Therefore, we are examining a number of opportunities which we are looking to access via corporate venturing or other creative mechanisms where that unique combination of innovation and entrepreneurship is captured. Easy to say and difficult to achieve, but we believe we have a number of such viable opportunities in our sights.

Secondly, to identify product licensing opportunities which will enhance our overall value to our distribution channel customers. We are in active negotiation to achieve this. We believe that we offer many companies market reach that they would not otherwise be able to achieve in a short timescale.

Thirdly, to extend our channel reach in Europe and Asia. We will achieve this by extending our direct sales channels in key territories and in Asia through partnerships that offer the patients in those countries more cost-effective solutions.

Acquisition of Stanbio

Stanbio Laboratory LP was acquired in June 2011 for a maximum consideration of \$25.9m. The Company raised approximately £12.4m net of expenses through the issue of ordinary shares to fund the acquisition.

Stanbio is an established 50 year old U.S. based medical diagnostic devices distribution and manufacturing business, with a strong brand and robust product sales. It sells a broad range of products (including EKF's Hemo Control device, under the brand name HemoPoint H2), both direct to a high quality customer base and also through a distribution network focused on North and South America. This network complements the existing EKF distribution channels. Stanbio has an FDA audited facility in Texas and a facility in Indiana.

Stanbio's product portfolio includes the manufacture and sale of chemical reagents used mainly in laboratories for use across a range of auto-analyser instruments; haemoglobin products primarily bought from EKF including both instruments and the microcuvettes; and rapid test strips (such as pregnancy tests) where Stanbio acts as a distributor of products manufactured by third parties.

Alere contract

At the same time as the acquisition of Stanbio we signed a contract with Alere Inc. under which we appointed them as exclusive distributor of our Hemo Control analyser (sold in the U.S. as the HemoPoint H2) in the USA. In November 2011 we received Clinical Laboratory Improvement Amendments (CLIA) waiver allowing the device to be sold under the Alere name in the United States and we shipped HemoPoint H2 instruments and cuvettes to them in March 2012. The Board believes that access to one of the largest direct sales forces in the North American point of care market will grow our market share in the U.S. haemoglobin testing market significantly.

Results overview

Revenue

Revenue for the year was £21.7m (2010: £6.5m). This represented organic growth of 64% in EKF Germany and 144% in Quotient over the same period previous year.

Gross Margin

Gross profit of £10.4m (2010: £2.9m) was achieved. This represents a gross margin of 48% (2010: 45%). 2010 gross margins have been restated to include certain direct costs which were previously included in administrative expenses.

Administration expenses and operating profits

Administration costs have risen as a result of the increased investment in sales and finance personnel to aid integration and to develop the business. Research and development expenditure was $\pm 0.9m$ (2010: $\pm 0.1m$) of which $\pm 0.6m$ was capitalised as development costs. The Group capitalises development expenditure only when a successful product launch is probable and otherwise charges expenditure to the income statement immediately. The charge for depreciation and the amortisation of intangibles was $\pm 2.3m$ (2010: $\pm 0.8m$). The operating loss was $\pm 2.0m$ (2010: $\pm 1.9m$).

Adjusted earnings before interest, tax, depreciation and amortisation

Earnings before interest, tax, depreciation and amortisation (EBITDA) for the year was $\pm 0.3m$ (2010: Loss $\pm 1.1m$). A more meaningful measure is considered to be Adjusted EBITDA of $\pm 1.6m$. (2010: $\pm 1.0m$) which excludes the effects of share based payments of $\pm 0.8m$ (2010: $\pm 0.2m$) and exceptional costs of $\pm 0.5m$ (2010: $\pm 1.9m$).

Exceptional items and share based payments

Following a revision to International Financial Reporting Standard 3 "Business combinations", acquisition costs are now expensed immediately. Acquisition costs expensed during the year were £0.4m (2010: £1.6m). IFRS 3 also requires that inventory within acquired businesses is uplifted to fair value, resulting in a £0.1m (2010: £0.3m) reduction in post-acquisition gross margin. These have been treated as exceptional costs. Charges for share based payments were £0.8m (2010: £0.2m).

Net finance costs

Net finance costs for the year were £0.3m (2010: £0.2m). This mainly represents the cost of servicing the small amount of debt acquired within EKF and Stanbio, and the interest element on deferred consideration on acquisitions, offset by interest on deposits.

Loss before tax

The loss before tax was $\pounds 2.4m$ (2010: $\pounds 2.1m$). The loss is in line with management expectations and was incurred because of the high level of exceptional items associated with acquisition costs, plus the investments required in the development of the Group.

Loss per share

The basic loss per share was 1.35p (2010: 3.51p). On a fully diluted basis the loss per share was 1.26p (2010: 2.11p) from continuing operations only.

Balance sheet

The Group had non-current assets at 31 December 2011 of £44.2m (2010: £26.1m). These consist of plant, property and equipment of £10.6m (2010: £5.5m), intangible assets of £33.1m (2010: £20.3m), available-for-sale assets of £0.3m (2010: £0.1m) and deferred tax of £0.2m (2010: £0.2m). The intangible assets mainly relate to the trade names, customer relationships, trade secrets, development costs and goodwill on acquisitions.

The Group had cash in hand at 31 December 2011 of £5.3m (2010: £3.2m).

The Group's main current assets are inventory totalling £4.8m (2010: £3.0m), and debtors of £4.3m (2010: £3.6m). Current liabilities are £9.5m (2010: £5.1m). Noncurrent liabilities, which consist of deferred consideration on acquisitions of £5.2m (2010: £4.2m), deferred tax liabilities of £4.4m (2010: £2.8m) relating to acquisitions and borrowings of £2.1m (2010: £0.3m).

Management and employees

We have sought to strengthen the management team during the period as we moved to establish a group structure and culture that is appropriate to meet the demands of a rapidly growing public listed company.

In February 2011 Richard Evans was hired by EKF firstly to oversee the transition in Germany from an owner-managed and controlled structure to one that was capable of achieving the growth demands being placed upon that organisation. During that transition period he worked with the previous owner Berthold Walther to ensure that change was achieved in as effective a manner as possible. Berthold will continue to work in an advisory capacity for the Group until the end of June 2012 and remains a significant shareholder. I would like to thank Berthold for his assistance in this transition period and for creating one of the foundation stones on which this Group is built.

In September Richard was appointed to Group Finance Director replacing Paul Foulger who had been undertaking the task on a part-time basis. I would like to thank Paul for all his hard work during his period at the helm. His talents have not been lost to the Group as he is continuing his involvement in the capacity of Company Secretary and his ongoing contribution is appreciated.

The day to day operations in Germany are being managed by Steffen Borlich who was recently appointed as a General Manager. Steffen brings with him over twenty years of experience working with EKF across several functions.

Following the acquisition of Stanbio the previous owner Bill Pippin has continued in his capacity as CEO and is very much committed to the continued growth of our operations in the Americas. We have been very fortunate to be able to retain someone of Bill's calibre to lead our American operations.

Yesterday we announced the appointment of Tony Wilks as Group Head of Sales. I have had the pleasure of working with Tony at IDS and I know he is capable of making a significant contribution to the EKF Group.

With the acquisition of Stanbio and investment in additional resources, our headcount had reached 295 by the year end. Our employees, both new and established, have had many challenges to face over the year and will have many more to deal with in 2012. The Board would like to thank them for their efforts during the past year. We are sure they will continue to show the same commitment and dedication in the next twelve months.

Outlook

We have had the benefit of a strong tail wind as we completed 2011 and we expect to continue to grow in 2012 in line with the current market expectation. Our first quarter's trading will be broadly in line with that. It is important that our 2011 result is seen in context and that none of us get carried away with a heightened sense of expectation. 2012 remains a transitional year.

We see the growth being achieved across a number of key areas:

- The launch of Quo-Lab and the striking of a distribution partnership arrangement with a larger IVD company.
- · The continued penetration of Quo-Test into world markets.
- The contribution from Alere.
- The continued process of tendering for Hemo Control and Hemopoint H2 in developing countries, in United Nations organisations and national blood banks.
- The launch of BHB to the wider diabetic community through the development of a near-patient diagnostic device.

We are also looking to achieve cost synergies throughout the Group which should result in increases in gross margin once fully implemented.

I am genuinely excited by the prospects for EKF Diagnostics and I believe that the core team have dynamism and a desire to succeed which will power the business towards continued growth and success.

David Evans Executive Chairman

Chief Executive's Review

EKF Diagnostics performed strongly in 2011 although we have some way to go before the business reaches its full potential. We have grown organically and through acquisition and have made good progress in developing our pipeline of new products. We also invested time and resources in assessing the Group's capabilities and completed the integration of the sales, marketing and finance functions. Alongside this we have instigated an on-going review of Group manufacturing practices.

It is my belief that these changes have put EKF in a strong position to tackle the challenges that lie ahead in 2012 and begin to realise its business ambitions.

Business performance

We conducted a detailed analysis of our installed customer and product base in 2011. As a result of this we were able to focus our sales effort much more effectively. Specifically, we have undertaken a structured review of distributors in territories with a low installed base and have set in motion a programme to drive volume in underperforming markets with the objective of increasing market share.

The strong second half was the result of a number of factors, including a large order for the Hemo Control haemoglobin analyser from the Mexican Institute of Social Security, the commencement of shipments of Hemo Control microcuvettes to Peru for an infant malnutrition programme and continued orders of the Quo-Test HbA1c analyser. It was pleasing to note that in Q4 we shipped our 1,000th Quo-Test analyser.

The increase in Quo-Test sales is primarily due to a more aggressive marketing strategy focused on placing products in clinics and small labs, particularly in China where in January we received approval from the Safety for Food and Drugs Administration ('SFDA').

Towards the end of 2011 we received a favourable report from SKUP (Scandinavian Evaluation of Laboratory Equipment for Primary Health Care). This study will enable us to promote Quo-Test to a wider market, particularly in Western Europe where rebates for health tests are significantly higher than in developing countries.

As mentioned in the Chairman's statement I am delighted to welcome Tony Wilks as Group Head of Sales. I am confident that Tony's experience and knowledge of the In-Vitro Diagnostics (IVD) sector will enhance the team that we already have in place and that he will play a key role in driving sales in 2012.

Channel development

It was particularly pleasing to win the tender in Mexico in the face of fierce competition. We were able to achieve this through close co-operation between EKF's manufacturing site in Germany and Stanbio's sales team in Texas. This approach validates the strategy behind the acquisition of Stanbio. The collaboration between the commercial and manufacturing departments across the Atlantic was very effective and I would like to thank all involved.

I am also delighted to be able to announce that in March 2012 we shipped the first consignment of HemoPoint H2 instruments and cuvettes to Alere Inc. in the United States under the terms of our 2011 agreement. The Board believes that access to Alere's direct sales force, one of the largest in the North American point of care market, will significantly grow our market share in the U.S. haemoglobin testing market.

Another reason for optimism is evidence that 'point of care' is beginning to establish itself in both Eastern Europe, where EKF has an established presence, and in Asia where growth is being stimulated by an increasing per capita GDP and a greater incidence of western diseases such as diabetes. With the introduction in 2012 of products aimed at emerging markets, such as Quo-Lab and STAT-Site M, we feel we have a product portfolio that meets the needs of the developing world at a price tailored to these markets.

Regulatory

We are in the process of engaging with the U.S. FDA via a Pre-IDE submission for our Quo-Test A1c analyser. Our application process, which is being managed by our expert teams at Quotient and Stanbio, is more rigorous than when previously submitted by Quotient prior to its acquisition by EKF. It is anticipated that the submission under 510k regulations will be made in 2012.

Investing in the future

Throughout 2011 we invested in people and infrastructure. As well as welcoming Richard Evans as Finance Director, Cormac Kilty has settled into his role as Chief Technology Officer. New divisional managers have been put in place in Argutus, Quotient and EKF-diagnostic in Germany. We have also appointed a Group Head of Marketing who leads our global marketing efforts, as well as a highly experienced team of regional sales managers and an experienced Group Manufacturing Manager. In May 2011 we opened a new manufacturing plant in Poland in order to cope with increased demand for Hemo Control cuvettes.

We continue to invest in Quotient's facility just outside London, both to improve manufacturing quality and to increase production capacity. During the year we

invested approximately £0.6m to triple the size of the facility to 900 m² and allow Quotient to meet increasing demand for Quo-Test and the anticipated demand for Quo-Lab. The new facilities include a state-of-the-art clean room, a dedicated Quality Assurance facility and expanded warehousing and storage. The investment programme at Quotient will continue through the first half of 2012.

Product development

The commercial launch of Quo-Lab, a low cost HbA1c analyser, and our Biosen HbA1c and glucose analyser are scheduled for the first half of 2012. We previewed the Quo-Lab with great success in November at Medica, the world's biggest medical trade fair. Partly as a result of this we are in advanced negotiations with a number of distributors for Quo-Lab. In addition we have received considerable attention from a number of larger companies who have expressed an interest in licensing the technology. These discussions are ongoing at the time of writing.

The addition of other analytes on to both the Quo-Test and Quo-Lab platforms are currently in development. It is anticipated that we will make further announcements during the second half of 2012.

Other new product development projects include a strip based version of the STAT-Site M analyser for testing haemoglobin and β -Hydroxybutyrate (BHB). We also expect to undertake the first in-situ trials of our point of care test for acute kidney injury towards the end of the year. This analyser will utilise two of our proprietary kidney markers.

Longer term opportunities include a development project for a point of care coagulation test, and a point of care test for Vitamin D.

In addition to the development of new products we have a number of programmes in place to drive down the costs of our existing products, thereby increasing margins and allowing them to be marketed to a wider range of customers.

The future

Although 2012 will be another challenging year, with significant sales and product development milestones to achieve, it is one we are looking forward to with optimism. We believe that we have the strategic, commercial and structural corner stones in place to fulfil our ambitions for the Group and its shareholders.

Julian Baines Chief Executive Officer

Consolidated income statement

	2011	2010
Notes	£'000	£'000

Continuing operations			
Revenue	2	21,658	6,483
Cost of sales		(11,277)	(3,572)
Gross profit		10,381	2,911
Administrative expenses		(12,906)	(5,271)
Other income		485	430
Operating loss		(2,040)	(1,930)
Depreciation and amortisation	2	(2,321)	(815)
Share based payment		(753)	(151)
Exceptional items	3	(534)	(1,919)
EBITDA before exceptional items and share ba	sed		
payment		1,568	955
Finance income	4	76	28
Finance costs	4	(396)	(187)
Loss before income tax	_	(2,360)	(2,089)
Income tax (charge)/credit	5	(198)	49
Loss for the year from continuing operations		(2,558)	(2,040)
Discontinued operations			
Loss for the year from discontinued operations		(187)	(1,372)
Loss for the year		(2,745)	(3,412)
Loss attributable to:		(2.00.0)	(2.425)
Owners of the parent		(2,884)	(3,435)
Non-controlling interest		139	23
		(2,745)	(3,412)
Loss per ordinary share from continuing and			
discontinued operations attributable to the			
equity holders of the Company during the			
year		Pence	Pence
From continuing operations			
Basic and diluted	6	(1.26)	(2.11)
From discontinued operations			
Basic and diluted	6	(0.09)	(1.40)
Continuing and discontinued operations	<i>c</i>	(4.5-1)	(2.51)
Basic loss per share	6	(1.35)	(3.51)

Consolidated statement of comprehensive income 2011 2010

	£'000	£'000
Loss for the year	(2,745)	(3,412)
Other comprehensive income: Actuarial loss on pension scheme Fair value adjustment in respect of available for sale	(2)	(11)
financial assets Currency translation differences Other comprehensive (loss)/income for the	155 (408) (255)	(6) 705 688
year Total comprehensive loss for the year	(3,000)	(2,724)
Attributable to: Owners of the parent Non-controlling interests Total comprehensive loss for the year	(3,126) 126 (3,000)	(2,747) 23 (2,724)

Consolidated statement of financial position

Group [•]	Group
2011	2010

	£'000	£'000
Assets		
Non-current assets		
Property, plant and equipment	10,629	5,467
Intangible assets	33,116	20,260
Investments in subsidiaries	-	- 217
Deferred tax assets	168 280	217 135
Available-for-sale financial assets Total non-current assets		
Current assets	44,193	26,079
Inventories	4,811	2,983
Trade and other receivables	4,273	3,625
Available-for-sale financial assets	51	100
Deferred tax assets	67	-
Cash and cash equivalents	5,338	3,192
Total current assets	14,540	9,900
Total assets	58,733	35,979
Equity attributable to owners		
Ordinary shares	2,512	1,681
Share premium account	38,372	23,013
Other reserve	244	244
Foreign currency reserves	1,577	1,972
Retained earnings	(5,664)	(3,686)
	37,041	23,224
Non-controlling interest	386	305
Total equity Liabilities	37,427	23,529
Non-current liabilities		
Borrowings	2,097	309
Deferred consideration	5,222	4,168
Deferred tax liabilities	4,434	2,796
Retirement benefit obligation	97	88
Total non-current liabilities	11,850	7,361
Current liabilities		,,501
Trade and other payables	4,793	3,969
Deferred consideration	2,932	-
Current income tax liabilities	317	210
Deferred tax liabilities	392	120
Borrowings	435	229
Provisions for other liabilities & charges	587	561
Total current liabilities	9,456	5,089
Total liabilities	21,306	12,450
Total equity and liabilities	58,733	12,450 35,979
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Consolidated Statement of cash flows Group

Cash Flow from operating activities	Notes	2011 £'000	2010 £'000
Cash used in operations Interest paid Income tax paid Net cash used in operating activities	8	(169) (158) (479) (806)	(1,010) (167) (232) (1,409)
Cash flow from investing activities Acquisition of subsidiaries, net of cash acquired Purchase of property, plant and		(8,689)	(8,463)
equipment (PPE) Purchase of intangibles Proceeds from sale of PPE		(1,555) (660) 15	(2,474) (4) 3
Proceeds from sale of intangible assets Proceeds from available-for-sale financial assets Interest received		1,220 78 8	562 - 28
Net cash used in by investing activities Cash flow from financing activities		(9,583)	(10,348)
Proceeds from issuance of ordinary shares		12,774	14,498

New bank loans	450	-
Repayments on borrowings	(451)	(2,616)
Dividend payment to non-controlling interest	(45)	-
Repayment of deferred consideration	(323)	-
Net cash generated by financing activities	12,405	11,882
Net increase in cash and cash equivalents	2,016	125
Cash and cash equivalents at beginning of year	3,192	3,037
Exchange gains on cash and cash equivalents	11	30
Cash and cash equivalents at end of year	5,219	3,192

Consolidated Statement of Changes in Shareholders' Equity

				Foreign			Non	
Consolidated	Share capital £'000	Share premium £'000	Other reserve £'000	currency reserve £'000	Retained earnings £'000	Total £'000	controlling interest £'000	Total equity £'000
At 1 January 2010	420	4,077	244	1,265	(386)	5,620	-	5,620
Comprehensive income					(2.425)	(2.425)	22	(2 412)
Loss for the year	-	-	-	-	(3,435)	(3,435)	23	(3,412)
Other comprehensive Income								
Actuarial loss on pension					(11)	(11)		(11)
Fair value adjustment in	-	-	-	-	(11)	(11)	-	(11)
respect of available-for-								
sale financial assets	-	-	-	-	(6)	(6)	-	(6)
Currency translation					(-)	(-)		(-)
Differences	-	-	-	707	-	707	(2)	705
Total comprehensive							. ,	
Income	-	-	-	707	(3,452)	(2,745)	21	(2,724)
Transactions with								
Owners								
Proceeds from shares issued	1,261	18,936	-	-	-	20,197	-	20,197
Share based payments	-	-	-	-	152	152	-	152
Total contributions by								
and distributions to owners	1,261	18,936			152	20,349	-	20,349
Non-controlling interests	1,201	10,930	-	-	152	20,349		20,349
arising							284	
on business combinations	-	-	-	-	-	-	204	284
At 1 January 2011	1,681	23,013	244	1,972	(3,686)	23,224	305	23,529
Comprehensive income								
Loss for the year	-	-	-	-	(2,884)	(2,884)	139	(2,745)
Other comprehensive								
income					(2)	(2)		(2)
Actuarial loss on pension	-	-	-	-	(2)	(2)	-	(2)
Fair value adjustment in respect of available-for-								
sale financial assets	_	_	_	_	155	155	-	155
Currency translation					155	155		155
differences	-	-	-	(395)	-	(395)	(13)	(408)
Total comprehensive				()		()	(/	(,
income	-	-	-	(395)	(2,731)	(3,126)	126	(3,000)
Transactions with owners								
Proceeds from shares issued	831	15,359	-	-	-	16,190	-	16,190
Dividends to non-controlling								
interest	-	-	-	-	-	-	(45)	(45)
Share based payments	-	-	-	-	753	753	-	753
Total contributions by							(45)	
and distributions to owners	831	15 250			753	16 042	(45)	16 000
At 31 December 2011	831 2,512	15,359 38,372	- 244	- 1,577	753 (5,664)	16,943 37,041	386	16,898 37,427
AL DI DECEMBER 2011	2,512	30,372	244	1,577	(3,004)	57,041	500	57,427

Notes to the final results

1. Basis of preparation

a. EKF Diagnostics Holdings Plc is a company incorporated in the United Kingdom. The Company is a public limited company, which is listed on the

AIM market of the London Stock Exchange.

- b. This preliminary announcement is an extract from the consolidated financial statements of the Company for the year ended 31 December 2011 and comprises the Company and its subsidiaries. The consolidated financial statements were authorised for issuance on 21 March 2012. These financial results do not comprise statutory accounts for the year ended 31 December 2011 within the meaning of Section 434 of the Companies act 2006. The financial information set out below does not constitute the Company's statutory accounts for the years ended 31 December 2010 or 2011 within the meaning of Section 434 of the Companies Act 2006, but is derived from those accounts. Statutory accounts for 2010 have been delivered to the Registrar of Companies and those for 2011 will be delivered following the company's Annual General Meeting. The auditors' reports on the statutory accounts for the years ended 31 December 2010 and 31 December 2011 were unqualified and do not contain statements under s498(2) or (3) Companies Act 2006.
- c. This financial information has been prepared in accordance with International Financial Reporting Standards ("IFRSs") and International Financial Reporting Interpretations Committee (IFRIC) interpretations as adopted by the European Union and with those parts of the Companies Act 2006 applicable to companies reporting under IFRS.
- d. Certain statements in this announcement constitute forward-looking statements. Any statement in this announcement that is not a statement of historical fact including, without limitation, those regarding the Company's future expectations, operations, financial performance, financial condition and business is a forward-looking statement. Such forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially. These risks and uncertainties include, amongst other factors, changing economic, financial, business or other market conditions. These and other factors could adversely affect the outcome and financial effects of the plans and events described in this announcement and the Company undertakes no obligation to update its view of such risks and uncertainties or to update the forward -looking statements contained herein. Nothing in this announcement should be construed as a profit forecast.
- e. While the financial information included in this preliminary announcement has been prepared in accordance with the recognition and measurement criteria of International Financial Reporting Standards (IFRSs), this announcement does not itself contain sufficient information to comply with IFRSs. The Company will publish its full financial statements for the year ended 31 December 2011 by 20 April 2012, which will be available on the Company's website at <u>www.ekfdiagnostics.com</u> and at the Company's registered office at 14 Kinnerton Place South, London SW1X 8EH. The Annual General Meeting will be held on Wednesday 23 May 2012.

2. Segmental Reporting

Management has determined the Group's operating segments based on the monthly management reports presented to the Chief Operating Decision Maker ('CODM'). The CODM is the Executive Directors and the monthly management reports are used by the Group to make strategic decisions and allocate resources.

The principal activity of the Group is the design, development, manufacture and selling of diagnostic instruments, reagents and certain ancillary products. This activity takes place across various countries, US, Germany, Poland, Russia, United Kingdom and Ireland, and as such the Board considers the business primarily from a geographic perspective. Although not all the segments meet the quantitative thresholds required by IFRS 8, management has concluded that given the recent acquisitions, all segments should be maintained and reported, given potential future growth of the segments.

The reportable segments derive their revenue primarily from the manufacture and sale

of medical diagnostic equipment. Other services include the servicing and distribution of other Company products under separate distribution agreements.

Currently the key operating performance measures used by the CODM are Revenue and adjusted EBITDA.

The segment information provided to the Board for the reportable segments for the year ended 31 December 2011 is as follows:

2011	Germany	UK	USA	Ireland	Poland	Russia	Switzerland (Discontinued)	Other	Total
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
Income statement									
Revenue	11,430	1,074	8,396	799	1,062	3,233	-	-	25,994
Inter segment External revenue	(4,247) 7,183	(80) 994	- 8,396	- 799	(9) 1,053	- 3,233	-	-	(4,336) 21,658
Adjusted EBITDA*	1,883	(1,024)	2,056	(245)	251	436	-	(1,789)	1,568
Exceptional costs	-	-	(137)	-	-	-	-	(397)	(534)
Share based payment	-	-	-	-	-	-	-	(753)	(753)
EBITDA Depreciation	1,883 (622)	(1,024) (106)	1,919 (131)	(245) (44)	251 (13)	436 (4)	-	(2,939) (5)	281 (925)
Amortisation	(595)	(197)	(262)	(187)	(111)	(44)	-	-	(1,396)
Operating profit/(loss)	666	(1,327)	1,526	(476)	127	388	-	(2,944)	(2,040)
Net finance costs	(156)	-	(146)	-	(1)	-	-	(17)	(320)
Income tax	86	39	(241)	(1)	(14)	(67)	-	-	(198)
Discontinued operations	-	-	-	-	-	-	(187)	-	(187)
Retained profit/(loss)	596	(1,288)	1,139	(477)	112	321	(187)	(2,961)	(2,745)
Segment assets									
Operating assets	17,709	7,167	21,948	2,881	1,417	1,027	53	25,526	77,728
Inter segment assets	(1,104)	(25)	-	-	-	-	-	(23,204)	(24,333)
External operating assets	16,605	7,142	21,948	2,881	1,417	1,027	53	2,322	53,395
Cash and cash equivalents	782	42	1,210	55	14	473	19	2,743	5,338
Total assets	17,387	7,184	23,158	2,936	1,431	1,500	72	5,065	58,733
Segment liabilities									
Operating liabilities	10,138	3,069	18,758	910	215	86	32	9,899	43,107
Inter segment liabilities	(7,383)	(2,634)	(13,534)	(631)	(151)	-	-	-	(24,333)
External operating liabilities	2,755	435	5,224	279	64	86	32	9,899	18,774
Borrowings	840	-	1,677	-	15	-	-	-	2,532
Total liabilities	3,595	435	6,901	279	79	86	32	9,899	21,306
Other segmental information									
Non current assets - PPE	3,443	735	4,412	96	208	32	-	1,703	10,629
Non current assets - Intangibles	10,000	5,669	13,973	2,203	820	451	-	-	33,116

2010	Germany	UK	Ireland	Poland	Russia	Switzerland (Discontinued)	Other	Total
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
Income statement								
Revenue Inter segment External revenue Adjusted EBITDA Exceptional costs Share based payment EBITDA Depreciation Amortisation	5,844 (1,560) 4,284 1,044 - 1,044 (342) (304)	185 - 185 (91) - - (91) (11) (44)	50 - 50 (37) - - (37) (3) (15)	486 - 486 151 - - 151 (6) (64)	1,478 - 1,478 18 - - 18 (3) (23)	- - - - - -	- (130) (1,919) (151) (2,200) -	8,043 (1,560) 6,483 955 (1,919) (151) (1,115) (365) (450)
Operating profit/(loss)	398	(146)	(55)	81	(8)	-	(2,200)	(1,930)
Net finance costs	(247)	-	-	-	-	-	88	(159)
Income tax	(17)	12	77	(11)	(12)	-	-	49
Discontinued operations	-	-	-	-	-	(1,372)	-	(1,372)
Retained profit/(loss)	134	(134)	22	70	(20)	(1,372)	(2,112)	(3,412)
Segment assets								
Operating assets	21,551	6,075	2,183	1,284	688	1,534	9,100	42,415

Inter segment assets	(1,090)	-	-	-	-	(1,344)	(7,194)	(9,628)
External operating assets	20,461	6,075	2,183	1,284	688	190	1,906	32,787
Cash and cash equivalents	811	76	202	13	203	112	1,775	3,192
Total assets	21,272	6,151	2,385	1,297	891	302	3,681	35,979
Segment liabilities								
Operating liabilities	12,702	1,438	517	304	178	14	6,387	21,540
Inter segment liabilities	(7,473)	(775)	-	(35)	-	464	(1,809)	(9,628)
External operating liabilities	5,229	663	517	269	178	478	4,578	11,912
Borrowings	538	-	-	-	-	-	-	538
Total liabilities	5,767	663	517	269	178	478	4,578	12,450
Other segmental information								
Non current assets - PPE	3,378	243	112	56	8	-	1,670	5,467
Non current assets - Intangibles	11,006	5,573	2,111	1,022	548	-	-	20,260

*- Adjusted EBITDA excludes exceptional costs and share based payments

Other primarily relates to the Holding company and head office costs.

Disclosure of Group revenues by geographic location is as follows:

	2011	2010
	£'000	£'000
Americas		
United States of America	4,751	888
Rest of Americas	3,683	1,028
Europe, Middle East and Africa (EMEA)		
Germany	3,097	975
United Kingdom	153	45
Rest of Europe	2,568	1,016
Russia	3,244	1,528
Middle East	423	208
Africa	1,077	189
Rest of World		
China	1,273	355
Asia	1,365	224
New Zealand / Australia	24	27
Total revenue	21,658	6,483

Revenues of approximately £2.3m are derived from a single external customer. These revenues are attributable to the USA segment.

3. Exceptional items

Included within Administrative expenses and costs of sales are exceptional items as shown below:

	Note	2011 £'000	2010 £'000
Exceptional items includes:			
- Transaction costs relating to business combinations	а	397	1,582
- Loss on stock	b	137	337
Exceptional items - continuing		534	1,919
Exceptional items - discontinued	С	49	354

(a) Transaction costs relating to business combinations. The Group incurred acquisition expenses of £397,000 (2010 - £1,582,000) associated with the acquisitions of subsidiaries which are included within administrative expenses in the consolidated income statement.

- (b) Loss on stock included within cost of sales
 - Under the requirements of IFRS 3 'Business combinations' the value of inventory acquired with the acquisitions of subsidiary was uplifted to its sales value less cost to sell. The post acquisition impact of selling the acquired inventory at its uplifted sales value has been to reduce gross profit by £137,000 (2010 £337,000).
- (c) Discontinued exceptional items relate to an impairment charged in 2011 and 2010.

4. Finance income and costs

	2011 £'000	2010 £'000
Interest expense: - Bank borrowings - Finance lease liabilities - IAS 19 interest expense - Interest on other loans - Deferred consideration-unwinding of discount Finance costs Finance income	126 13 7 80 170 396	47 2 5 113 20 187
 Interest income on cash and short term deposits Other interest Finance income 	4 72 76	28 - 28
Net finance costs	320	159

5. Income tax expense

Current tax:	2011 £'000	2010 £'000
Current tax on loss for the year	586	132
Total current tax	586	132
Deferred tax:		
Origination and reversal of temporary differences	(388)	(181)
Total deferred tax	(388)	(181)
Income tax charge/(credit)	198	(49)

The tax on the Group's loss before tax differs from the theoretical amount that would arise using the standard tax rate applicable to the profits of the consolidated entities as follows:

Loss before tax	2011 £'000 (2,360)	2010 £'000 (2,089)
Tax calculated at domestic tax rates applicable to UK standard rate of tax of 25% (2010:28%) Tax effects of:	(590)	(585)
 Expenses not deductible for tax purposes Losses carried forward Impact of different tax rates in other jurisdictions Tax charge/(credit) 	369 322 97 198	201 331 4 (49)

There are no tax effects on the items in the statement of comprehensive income.

(a) Basic

Basic loss per share is calculated by dividing the loss attributable to equity holders of the Company by the weighted average number of ordinary shares in issue during the year.

Loss attributable to equity holders of the Company	2011 £'000 (2,884)	2010 £'000 (3,435)
Loss from continuing operations attributable to equity holders of the Company Loss from discontinued operations attributable to equity holders of the Company	(2,697) (187)	(2,063) (1,372)
Weighted average number of ordinary shares in issue Basic (loss) per share Basic (loss) per share from continuing operations Basic (loss)/earnings per share from discontinued operations	213,580,118 (1.35) pence (1.26) pence (0.09) pence	97,800,087 (3.51) pence (2.11) pence (1.40) pence

(b) Diluted

Diluted earnings per share is calculated by adjusting the weighted average number of ordinary shares outstanding to assume conversion of all dilutive potential ordinary shares. The Company has three categories of dilutive potential ordinary share: equity based long term incentive plans, equity based bonus incentive plans and share options. Due to the loss in the year the dilutive potential ordinary shares have no dilutive effect.

7. Dividends

There are no dividends paid or proposed by the Company in either year.

8. Cash used from operations

Loss before income tax Adjustments for:	Group 2011 £'000 (2,360)	Group 2010 £'000 (2,089)
- Discontinued activities	(187)	(1,372)
- Depreciation	925	365
- Amortisation and impairment charges	1,396	804
- Impairment of available asset for sale	49	-
- Share based payments	753	152
- Loss on disposal of intangibles	-	414
 Foreign exchange gains on operating activities Net finance costs / (income) 	(122) 320	(155) 159
Changes in working capital - Inventories	(23)	80
- Trade and other receivables	(488)	5,775
- Trade and other payables	(432)	(5,143)
Net cash used in from the operations	(169)	(1,010)

9. Acquisitions

Acquisition of Stanbio Laboratory LP

On 17 June 2011, the Group through its subsidiary undertaking, EKF Diagnostics Inc acquired Stanbio Laboratory LP, a US based medical diagnostic devices distribution and manufacturing business.

The goodwill of £4,750,000 arising from the acquisition is attributable to the expected

future profitability of the acquired business and synergies expected to arrive from the incorporation of the business within the Group.

The following table summarises the consideration paid for Stanbio Laboratory LP and the amounts of the assets acquired and liabilities assumed recognised at the acquisition date.

	£'000
Consideration at 17 June 2011	
Cash	8,696
Equity instruments (16,189,675 ordinary shares - to be issued in 3 tranches at each	
anniversary of the acquisition)	3,416
Deferred consideration	3,985
Total consideration	16,097
Acquisition-related costs (included in administrative expenses in the	
consolidated income statement for the year ended 31 December 2011) (note 3)	3974
Recognised amounts of identifiable assets acquired and liabilities	
assumed	
Cash and cash equivalents	7
Property, plant and equipment	4,339
Trade names - included in intangibles	1,118
Customer relations - included in intangibles	6,963
Trade secrets - included in intangibles	602
Research and development costs	236
Inventories	1,805
Trade and other receivables	1,380
Trade and other payables	(1,240)
Borrowings	(1,240) (1,666)
Deferred tax liabilities	(1,000) (2,197)
Total identifiable net assets	11,347
Goodwill	4,750
Goodwin	4,750

The fair value of the 16,189,675 ordinary shares to be issued in 3 tranches at each anniversary of the acquisition, as part of the consideration paid for Stanbio Laboratory LP was based on the average closing price per share over the ten consecutive trading days ending a day before the agreement day.

The contingent consideration arrangement requires the Group to pay the former owner of Stanbio Laboratory LP additional consideration agreed at a maximum of 7,162,000(£4,448,000) of which \$500,000 (£323,000) has been paid since the completion. The majority of the consideration is linked to EBITDA and Revenue targets over a 4 year period post acquisition. The Directors believe that there is a near 100% probability that these payments will be made in full. However, the value has been discounted to its net present value to \$6,415,000 (£3,985,000) using a rate of 5.50% to reflect the time value of money. Unwind of the discount in the post-acquisition period totals \$134,000 (£86,000) and has been included in the finance expense in the income statement (note 4).

The fair value of inventories is $\pm 1,805,000$. Finished goods and work in progress inventories have been uplifted by $\pm 137,000$ to sales value less cost to complete and cost to sell.

The revenue included in the consolidated statement of comprehensive income since 17 June 2011 contributed by Stanbio Laboratory LP was £8,396,000. Stanbio Laboratory LP also contributed retained profit of £1,059,000 over the same period. Had Stanbio Laboratory LP had been consolidated from 1 January 2011, the consolidated statement of comprehensive income, would show revenue of £13,500,000 and profit of £1,486,000.

10. Annual Report & Accounts

Copies of the audited Annual Report & Accounts for the year ended 31 December 2011 will be posted to shareholders and may also be obtained from the Company's registered office at 14 Kinnerton Place South, London, SW1X 8EH.

This information is provided by RNS The company news service from the London Stock Exchange

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