



SCIENCE MADE SIMPLE

FINAL RESULTS

Twelve months ended 31st December 2013

Julian Baines, Group Chief Executive Officer
Paul Foulger, Finance Director

26th February 2014

EKF Diagnostics Holdings plc

A global point-of-care, central laboratory
and molecular diagnostics business.



AGENDA

- 2013 highlights
- Operational overview
 - Point-of-care
 - Central laboratory
 - Molecular diagnostics
 - Kidney biomarkers
- 2013 financial overview
- 2014 outlook
- Appendix

2013 HIGHLIGHTS

Incremental organic growth

Strong revenue growth (+22%) 2013 v 2012:

- Quo-Lab and Quo-Test +75%
- Hemo Control / HemoPoint +42%
- Biosen C-Line and S-Line +20%
- Beta-Hydroxybutyrate reagent +8%

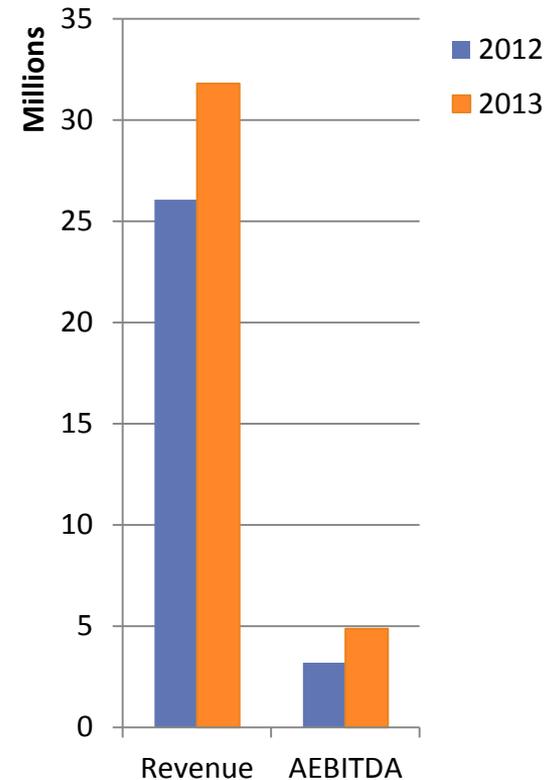
Good progress against key operational and commercial success targets:

- Build of Quo-Lab cartridge production line in Barleben, Germany completed. Live Q1 2014
- Establishment of EKF MDx and launch of seven PointMan test kits
- Retention of β -Hydroxybutyrate sales in USA despite competitive testing methodology returning to the market

2013 HIGHLIGHTS

Growth in revenues and AEBITDA

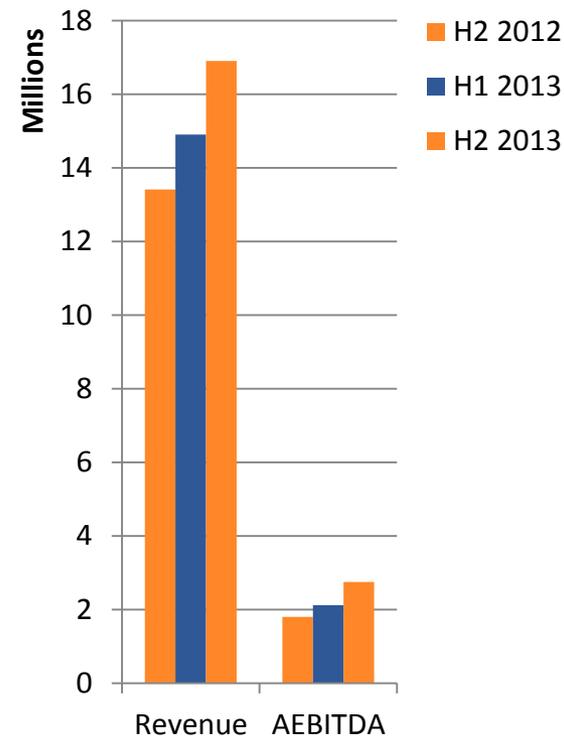
- Group full year revenues +22% to £31.80m (2012: £26.06m)
- Adj. EBITDA +51% to £4.82m (2012: £3.20m)
- Cash generated from operating activities £3.17m (2012: £2.52m)
- Cash £2.55m (2012: £4.33m)
 - Deferred consideration payments: £1.43m
 - Investment in MDx division: £0.95m
 - Building extension and plant investment at Barleben: £1.2m
 - Capitalised development costs: £1.1m



2013 HIGHLIGHTS

Six month comparison

	H2 2013	H1 2013	H2 2012
Revenue	£16.92m	£14.89m	£13.41m
	+14%	+11%	+6%
Adj. EBITDA	£2.70m	£2.12m	£1.80m
	+27%	+18%	+29%
Av. Monthly revenue	£2.82m	£2.48m	£2.24m



STRATEGIC EXECUTION

EKF Diagnostics Holdings plc

- FY revenues: £21.58m
- +25% v. 2012
- Rapidly growing market with differentiated product portfolio
- Improved distribution network
- Volume-driving OEM partnerships
- Revenue and profit **growth**

Point-of-care



- FY revenues: £9.17m
- +19% v. 2012
- Mature market
- High margin niche growth products provide point of difference
- Base product mix features low-margin, high volume commodity products
- Significant **cash flow**

Central laboratory



- Next generation healthcare opportunity in Companion Diagnostics
- Opportunities across a wide spectrum of acute and chronic conditions
- Novel tests for research-use-only market
- Drive **value** in mid-term

Molecular diagnostics



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POINT-OF-CARE

Global roll-out of Quo-Lab

Quo-Lab A1c

- Unit sales of analysers: 1,426 v 254 2012
- 4% penetration into NycoCard market (c.42,000*)
- Completion of new production line in Barleben Q1 2014

Quo-Test A1c

- Pull-through up 35% v 2012 from installed base c. 2,000 units



	Units sold 2013	Units sold 2012
Quo-Lab A1c analysers	1,426	254
Cartridges	453,400	28,000
Quo-Test A1c analysers	537	598
Cartridges	815,220	605,115
Total revenue	£2,891,673	£1,656,212

* Source: Ian Gilham, CEO, Axis Shield, 19 May 2011



POINT-OF-CARE

2013 delivery

Hemo Control / HemoPoint H2

- Growing presence in USA through Alere contract
 - Increased market share from 9% to 14% in 2013
- Incremental growth of microcuvettes:
 - Correlation with the increase in the base of placed analysers
 - Consumable sales are the key contributor to margin growth



	Unit sales 2013	Unit sales 2012
Hemo Control analyser	6,732	6,468
Microcuvettes	26,554,550	19,484,650
Total revenue	£7,903,686	£5,550,601

POINT-OF-CARE

Significant growth from an established product

Biosen C-Line and S-Line

- Analysers sold +31%
- Significant growth in Russia, Middle East and China
- Rationalised range from six to three models
- Biosen used as the gold standard for blood glucose monitor performance in China



	Unit sales 2013	Unit sales 2012
Biosen analysers	653	499
Tests	23,422,000	21,722,299
Total revenue	£6,518,431	£5,442,705

CENTRAL LABORATORY

Significant growth in mature market

Clinical chemistry and contract fermentation

- Total central laboratory sales 2013 v 2012 sales +19%
- Sustained 2012 performance from β -HB LiquiColor despite competitor returning to ketone testing market
- 858 US hospitals using β -HB by the end of 2013 (2012: 821)
- Exploring growth opportunities inside and outside USA
- Regular bulk orders for enzymes from Roche, Ortho Clinical Diagnostics, Sekisui Diagnostics, Cardinal and Fisher



Revenues	2013	2012	Var.
β -HB LiquiColor reagent	£3.14m	£2.91m	8%
Roche enzyme production	£1.94m	£1.44m	22%
Total Central Lab products	£9.17m	£7.69m	19%

MOLECULAR DIAGNOSTICS

Oncology biomarkers

- 360 Genomics acquired H1 2013
- Seven products launched into RUO market ahead of expectations (inc. BRAF, KRAS, EGFR, NRAS, JAK2)
- Evaluated at Institute of Life Sciences, Swansea University
 - Initial whole blood results were positive
- Further studies underway at leading international oncology centres



KIDNEY BIOMARKERS

sTNFR1 and 2

- Growing interest in applications of sTNFR1 & 2
 - Third party studies from France and Finland accepted for publication Q1 2014
- Qualified interest from pharma businesses for use as a Companion Diagnostics tool. Testing samples from pharma companies scheduled for Q1 2014
- Deepening relationship with Joslin Diabetes Center, Boston with view to roll-out sTNFR1 within their US affiliate network (48 hospitals)



RenaStat

- Dublin clinical study underway Q1 2014. Initial results expected Q3 2014
- Outcomes of studies will enable commercialisation of product
- Distributors in place to create reference sites once Dublin study completed



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CONSOLIDATED INCOME STATEMENT

	2013 £'000	2012 £'000	+/- £'000
Revenue	31,804	26,060	5,744
Gross profit	16,345	14,313	2,032
GP %	51.4%	54.9%	(3.5%)
Net admin. costs	(12,016)	(11,653)	(363)
Other income	495	542	(47)
AEBITDA	4,824	3,202	1,622
Share based payments	(709)	(537)	(172)
Exceptional items	1,840	618	1,222
Depreciation/amortisation	(3,554)	(3,079)	(475)
Operating profit	2,401	204	2,197
PBT	607	(196)	803
Tax	(1,500)	606	(2,106)
(Loss) / profit for the year	(893)	410	(1,303)

BALANCE SHEET: ASSETS

	Selected items	2013 £'000	2012 £'000	+/- £'000
Non-current assets	Property, plant, equipment	9,785	10,014	(229)
	Intangible assets	34,725	31,250	3,475
	Investments	250	250	0
	Deferred tax assets	903	973	(70)
	Total non-current assets	45,663	42,487	3,176
Current assets	Inventories	5,308	4,971	337
	Trade and other receivables	7,155	3,884	3,271
	Deferred tax assets	46	44	2
	Cash and cash equivalents	2,551	4,331	(1,780)
	Total current assets	15,060	13,230	1,830
Assets	Total assets	60,723	55,717	5,006

BALANCE SHEET: EQUITY & LIABILITIES

	Selected items	2013 £'000	2012 £'000	+/- £'000
Equity attributable	Total equity	40,992	39,427	1,565
Non-current liabilities	Borrowings	2,108	2,031	77
	Deferred considerations	5,471	3,114	2,357
	Deferred tax liabilities	3,442	3,793	(351)
	Retirement benefit obligation	103	112	(9)
	Total non-current liabilities	11,124	9,050	2,074
Current liabilities	Trade and other payables	4,189	3,743	446
	Deferred consideration	1,778	2,600	(822)
	Current income tax liabilities	1,998	200	1,798
	Deferred tax liabilities	380	417	(37)
	Borrowings	332	280	52
	Total current liabilities	8,677	7,240	1,437
	Total liabilities	19,801	16,290	3,511
Equity and liabilities	Total equity and liabilities	60,723	55,717	5,006

CASHFLOW

	2013 £'000	2012 £'000	+/- £'000
From operating activities	2,007	1,599	408
From investing activities	(2,216)	(1,602)	(614)
From financing activities	(1,560)	(885)	(675)
Net decrease in cash	(1,769)	(888)	(881)
Cash at end of year	2,551	4,331	(1,780)

2014: OUTLOOK

Continued growth

Point-of-care

- Sales strategy focuses on developing EKF's presence in existing markets:
 - Open up markets with small or no sales e.g. Biosen in Latin America, Quo-Test in Russia
 - Focus on volume markets which will drive production efficiencies e.g. Quo-Lab in India
- Significantly grow hemoglobin testing market share

Central laboratory

- Evaluating new lab analyser for OEM
- Extension of clinical chemistry range through four new product launches

Molecular diagnostics

- Focus on increasing EKF's presence within the molecular diagnostics market
- Western Europe and USA sales focus. Set up of distribution channels for RoW
- Increased opportunities pending test results using whole blood

Acquisition

- Continuing to evaluate new opportunities



OTHER GROWTH OPPORTUNITIES

2014 and beyond



SensPoint lactate analyser targeted at applications within the obstetric market



Extension of existing product portfolio through the addition of new features
e.g. network connectivity on Hemo Control



Augment kidney biomarker portfolio with new products. RenaStat and sTNFR1 launch 2015



Repurposing of PointMan kits for pancreatic cancer and female GU cancer



On going feasibility studies into menu expansion on current platforms and assessment of new multi-analyte platforms



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APPENDIX

Product portfolio



QUO-LAB

Glycated haemoglobin (HbA1c)

- 4 minutes to result
- 4 step procedure with instructions on-screen
- Boronate Affinity methodology
- Less than 3% CV at 7% A1c
- Measuring range: 4-15% A1c
- Unaffected by Hb variants
- Traceable to IFCC reference method
- Dual reporting in IFCC & DCCT values
- Stores up to 7,000 results
- Optional printer
- Barcode reader included



QUO-TEST

Glycated haemoglobin (HbA1c)

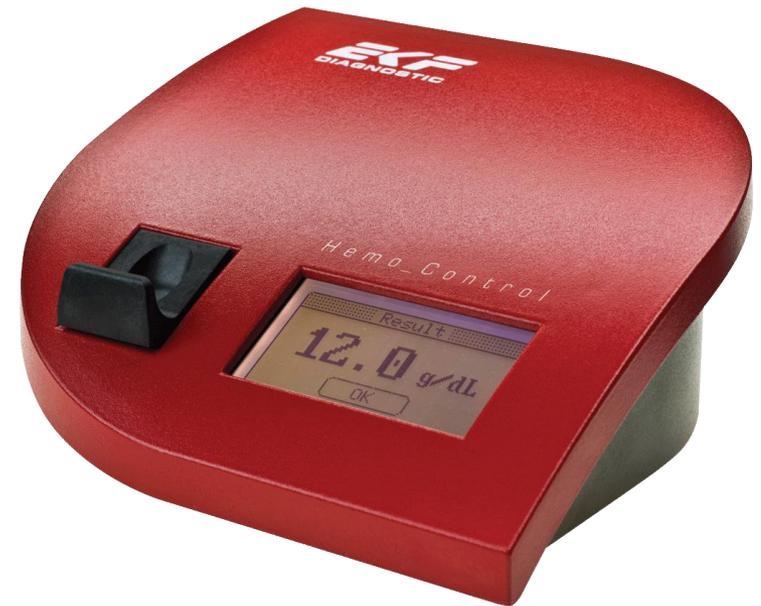
- 4 minutes to result
- Minimal training time and no maintenance
- Boronate Affinity methodology
- Less than 3% CV at 7% A1c
- Measuring range: 4-15% A1c
- Unaffected by Hb variants
- Traceable to IFCC reference method
- Dual reporting in IFCC & DCCT values
- Stores up to 7,000 results
- Connectable to a hospital LIS
- Barcode reader included



HEMO CONTROL

Haemoglobin

- Results in 25 seconds
- Simple to use, CLIA waived
- Backlit touch screen
- 8 μ l capillary or venous blood
- Less than 2% CV
- Calibrated to NCCLS reference
- Stores up to 4,000 results
- Lightweight and portable
- Internal lithium battery
- Connectable to hospital LIS



BIOSEN C-LINE and S-LINE

Glucose and lactate

- Rapid assay (30-40 seconds to result)
- Up to 112 results per hour
- 20 µl of capillary or venous blood
- Less than 1.5% CV
- Multi-lingual touch screen display
- Stores up to 1,000 results
- Connectable to hospital LIS
- Connects to standard printer
- Barcode option available
- 3 models in range (5, 20 and 63 samples)



LACTATE SCOUT+

- 10 seconds to result
- 0.2 µl of capillary blood
- < 3.4mmol/L: +/- 0.2mmol/L
- Stores up to 250 results
- 2 AA batteries provide 1,000 results
- Pre-calibrated sensors
- Operates in extreme temperatures
- And up to 85% humidity
- Integrated Bluetooth
- Pocket-sized and just 80g



STAT-SITE M

Haemoglobin

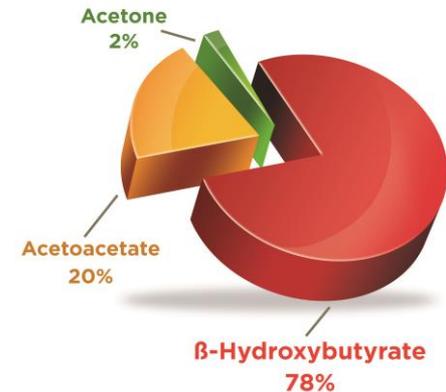
- Hemoglobin analysis in seconds
- Photometric, azide-methemoglobin method
- User friendly features minimise training time
- 1,000 tests using just 1 x 3V Li (CR 2032) type battery
- Operating range: 16° - 35° C (61° - 95° F)
- Humidity: 20% - 80% (non-condensing)
- Automatic calibration (uses CODE key)
- Pocket-sized and just 57g



BETA-HYDROXYBUTYRATE

Clinical chemistry

- Beta-Hydroxybutyrate (β -HB) is an enzymatic assay used on clinical chemistry analysers
- The test quantifiably detects the presence of the ketones in patients with suspected Diabetic Ketoacidosis (DKA)
- β -HB is the primary ketone produced by the body during DKA (78%)
- Alternative tests only detect 22% of ketones present
- β -HB manufactured at EKF sites in the USA
- STAT-Site β -HB strip test launched Q2 2013





Pointman BRAF

- Better identify patients diagnosed with metastatic melanoma who are suitable for treatment with Zelboraf

Pointman KRAS

- Help predict which patients diagnosed with colorectal cancer will not respond to novel therapies such as Erbitux and Vectibix

Pointman EGFR T790M

- Efficiently identify which patients undergoing treatment for non-small cell lung cancer are becoming resistant to treatments

Xtract

The problem: The bottleneck in any DNA/RNA lab analysis is the extraction step
Analysis needs a high quality sample

The solution: Xtract
Fewer steps than existing technology
Improves the integrity of the sample
Allows for automation and higher throughput
Applicable to multiple market sectors inc. pharma, academia and healthcare)

Lead product planned for launch 2H 2013





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