



SCIENCE MADE SIMPLE

INTERIM RESULTS

Six months ended 30th June 2013

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

16th September 2013



EKF Diagnostics Holdings plc

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



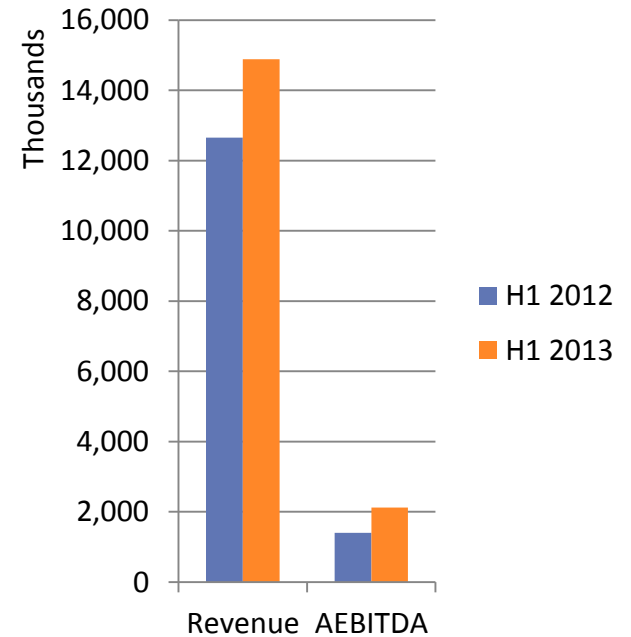
AGENDA

- H1 2013 financial highlights
- Strategic and operational overview
 - Point-of-care
 - Central laboratory
 - Molecular diagnostics and kidney biomarkers
- H1 2013 financial overview
- H2 2013 outlook
- Appendix

H1 2013 HIGHLIGHTS

Significant financial growth

- Group H1 2013 revenues + 17.7% to £14.89m (H1 2012: £12.65m)
 - Increasing visibility. Average monthly revenues up from £2.1m to £2.5m
 - Revenues from PoC up 23%
- Adj. EBITDA +51.6% to £2.12m (H1 2012: £1.40m)
- Cash generated from operations £1.56m
 - H1 2012: £0.15m
- Cash £3.14m
 - Full year 2012: £4.33m
 - Reflects deferred consideration payments of £1.43m

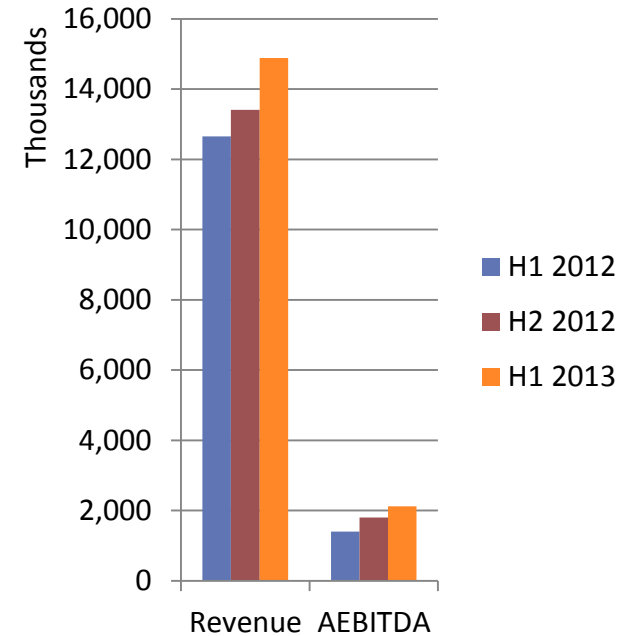


EKF
DIAGNOSTICS

H1 2013 HIGHLIGHTS

Six month comparison: 2012 - 2013

	H1 2013	H2 2012	H1 2012
Revenue	£14.89m	£13.41m	£12.65m
	+11%	+6%	
Adj. EBITDA	£2.12m	£1.80m	£1.40m
	+18%	+29%	



H1 2013 HIGHLIGHTS

A period of achievement

Strong organic revenue growth in core product lines H1 2013 v H1 2012:

- Quo-Lab and Quo-Test +115%
- Hemo Control / HemoPoint +15%
- Biosen C-Line and S-Line +24%

Management restructure:

- Richard Evans appointed as Chief Operating Officer
- David Corr appointed as Chief Technology Officer
- Paul Foulger appointed as Interim Finance Director

STRATEGIC FOCUS

Market size and growth (2012 estimates)

Point-of-care

- **HbA1c: \$550m**
 - CAGR 2007-12: 13%
- **Hb: \$325m**
 - CAGR: 5%
- **Target markets:**
 - Doctors' offices
 - Diabetes clinics
 - Hospitals
 - Sports clinics

Central laboratory

- **Clinical chemistry: \$6.9bn**
 - CAGR 2007-12: 2%
- **Target markets:**
 - Hospital labs
 - Private labs
 - RUO

Molecular diagnostics

- **MDx: \$4bn**
 - CAGR: 10-20%
- **Companion Dx: \$200m**
 - CAGR: 20-30%
- **Target markets:**
 - RUO
 - Pharma

EKF
DIAGNOSTICS

* Source: Kalorama, Worldwide market for IVD Tests, 2008

STRATEGIC EXECUTION

EKF Diagnostics Holdings plc

Point-of-care H1 revenues: £9.8m

- **Revenues +23% v. 2012**
- Rapidly growing market with differentiated product portfolio
- Improved distribution network
- Volume-driving OEM partnerships
- Revenue and profit **growth**

Central laboratory H1 revenues: £5.1m

- **Revenues +9% 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** delivery

Molecular diagnostics

- **Next generation healthcare opportunity in Companion Diagnostics**
- Opportunities across a wide spectrum of acute and chronic conditions
- Novel products initially for research
- **Primary value driver**

POINT-OF-CARE

H1 2013 delivery



Quo-Lab A1c

- Unit sales of analysers: 917 H1 2013 v 254 H2 2012
- 2.9% penetration into NycoCard market (c.42,000*)
- OEM deals with Human and IME-DC providing high volume of core business:
 - Human: 500 analysers and 1.2m tests in year 1. Forecast sales of 1.2k devices and 1.9m tests in year 2
 - IME-DC: 425 analysers and 301k tests in 2013. 875 analysers and 619k tests in 2014

Unit sales	H1 2013	H2 2012
Quo-Lab A1c analysers	917	254
Cartridges	194,650	28,000

Note: Quo-Lab launched Q3 2012



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

POINT-OF-CARE

H1 2013 delivery



Quo-Test A1c

- Multi-distributor approach in China from H2 2013 onwards
- Very positive studies from KOLs at Liverpool Royal, Barnet and Chase Farm Hospital Trusts and Swansea University
- US FDA CLIA waiver clinical trial scheduled to commence September 2013

Unit sales	H1 2013	H1 2012
Quo-Test A1c analysers	446	237
Cartridges	320,585	277,020

POINT-OF-CARE

H1 2013 delivery



Hemo Control / HemoPoint

- Growing presence in USA through Alere contract
 - Part of McKesson Medical Surgery Labzone
- Incremental growth of microcuvettes:
 - Correlation with the increase in the base of placed analysers
 - Consumable sales are the key contributor to margin growth in the Hemo range

Total unit sales (Alere sales)	H1 2013	H1 2012
Hemo Control analyser sales	2,337 (1,200)	2,583 (770)
Microcuvette sales*	152,991 (22,800)	101,179 (11,163)

* Sold in 50s

POINT-OF-CARE

H1 2013 delivery



Biosen C-Line and S-Line

- Unit sales of analysers +60%
- Rationalised range from six to three models
- Significant growth in Russia, Germany and China
- China is using Biosen as the gold standard for monitoring performance of blood glucose monitors

Unit sales	H1 2013	H1 2012
Biosen analysers	257	161

CENTRAL LABORATORY

H1 2013 delivery

Clinical chemistry and laboratory products

- Mature clinical chemistry products in mature market
- Continuing to deliver high margin sales and cash generation
- H1 2013 v H1 2012 sales +9%
- Regular bulk orders from Roche, Ortho Clinical Diagnostics, Sekisui Diagnostics, Cardinal and Fisher
- High volume products include reagents and calibrators for testing acetaminophen (Tylenol) and salicylate (Aspirin)
- β -HB sustained 2012 performance despite competitor returning to ketone testing market
- Growth opportunities outside USA being explored

Revenues	H1 2013	H1 2012
Roche	£1.2m	£0.9m
β -HB LiquiColor	£1.4m	£1.5m

MOLECULAR DIAGNOSTICS

Oncology biomarkers

- 360 Genomics acquired H1 2013
- Fully integrated into EKF Diagnostics Group
- Three products launched into RUO market ahead of expectations (BRAF, KRAS, EGFR)
- Product being evaluated by Central Biotechnology Services, Cardiff University. Early results have been very positive
- Sales and marketing campaign aimed at RUO segment and KOLs



DNA extraction technology

- Xtract protocol currently being validated
- Commercialisation late 2013 / early 2014

Xtract

EKF
DIAGNOSTICS

KIDNEY BIOMARKERS

sTNFR1

- Studies from France and Finland in draft. Publication Q4 2013
- Established a large scale trial with the Dublin Academic Medical Centre
- Identifying reference labs in USA prior to launch
- CE marked ELISA kit based on Joslin licence to be launched Q1 2014
- Significant interest from pharma industry as a Companion Diagnostics tool

RenaStat

- Project has progressed from development to Beta testing
- Clinical studies in Dublin Q4 2013
- Outcomes of studies will enable commercialisation of product in 2014
- Planned product launch Q2 2014



EKF
DIAGNOSTICS

H1 2013 FINANCIAL OVERVIEW

	H1 2013 £'000	H1 2012 £'000	+/-	Comments
Revenue	14.89 m	12.65 m	17.7 %	Significant sales growth across all regions
Gross profit	7.65 m	7.27 m	0.38 m	
Gross margin	51.3 %	57.4 %	-	Product mix
Operating profit	0.66 m	0.34 m	0.32 m	
PBT	0.19 m	0.15 m	0.04 m	
Adj. EBITDA	2.12 m	1.40 m	51.6 %	
Cash at bank	3.14 m	4.33 m*	-1.19 m	Deferred consideration paid (£1.43m)

* At 31.12.12



H2 2013: OUTLOOK

Continued growth

Point-of-care

- Tenders in pipeline for HemoPoint and Quo-Lab
- Driving growth through powerful distribution base including:
 - Alere (global and USA)
 - Cardinal, McKesson Medical Surgery, Fisher (USA)
 - Human (developing world)
 - IME-DC (Eastern Europe and former CIS nations)
- Quo-Lab and HemoPoint sales growth in South America
- Quo-Test and Biosen sales growth in China

Central laboratory

- Investigating OEM opportunities for new lab analyser
- Regulatory Affairs increasing base of registered countries for clinical chemistry range

Molecular diagnostics

- Launch of three more PointMan kits in Q3 2013
- CE marking of PointMan test kits
- Licensing opportunities
- Increased opportunities pending test results using whole blood

Acquisition

- Continued evaluation of several opportunities



OTHER GROWTH OPPORTUNITIES

2014 and beyond



STAT-Site M BHB and STAT-Site M Hgb strip-based analysers global launched Q2-Q3 2013



Haematocrit compensation on lactate sensor technology to provide a channel into the obstetric market. Premiere at Medica 2013



C-Reactive Protein to be launched on Quo-Lab platform Q2 2014

Xtract

DNA extraction technology undergoing trials at leading academic centre. Planned for release early 2014

R&D

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

EVV
DIAGNOSTICS



EKF
DIAGNOSTICS

SCIENCE MADE SIMPLE

THANK YOU

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

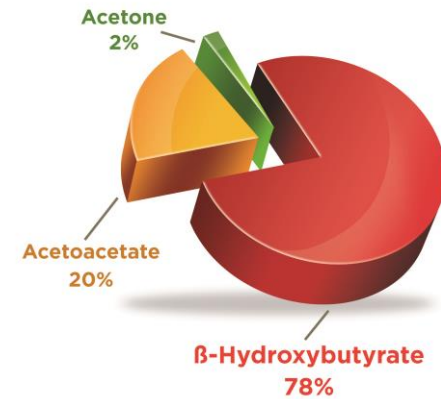
- Hemoglobin analysis in seconds
- Photometric, azide-methemoglobin method
- User friendly features minimise training time
- 1,000 tests using just 1 x 3V Li (CR 2032) type battery
- Operating range: 16° - 35° C (61° - 95° F)
- Humidity: 20% - 80% (non-condensing)
- Automatic calibration (uses CODE key)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





EKF
DIAGNOSTICS

SCIENCE MADE SIMPLE