

# YEAR ENDED 31st DECEMBER 2014

Julian Baines, Chief Executive Officer Paul Foulger, Finance Director

16<sup>th</sup> March 2015



## **AGENDA**

#### Slide

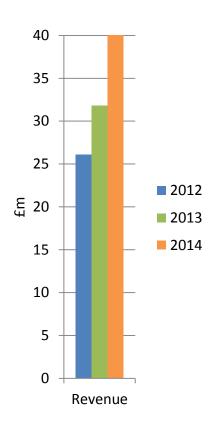
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## **HIGHLIGHTS**

#### Full Year 2014

- Revenues up 26% to £40.1m (2013: £31.8m)
- 18,000+ point-of-care analysers sold
- 56m+ tests sold
- Transfer of production of HbA1c analysers and tests to Barleben and organ injury biomarkers to Walton-on-Thames
- Significant network of collaborators for molecular products and services:
  - Massachusetts General Hospital
  - Greenville Hospital System
  - GILUPI
  - Pharma

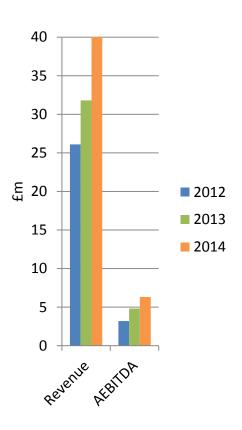




## **2014 FINANCIAL HIGHLIGHTS**

#### **Sustained financial performance**

- Underlying organic revenues increased by 6% YoY
- £6.5m revenue contribution from new acquisitions
- Gross profit up 22% to £19.9m (2013: £16.3m)
- AEBITDA up 31% to £6.3m (2013: £4.8m)
- Cash (used in)/generated from operating activities: (£3.2m)
   (2013: +£3.1m)
- Net cash £2.1m (2013: £0.1m)
- Negative impact of currency





## **CONSOLIDATED INCOME STATEMENT**

	Existing group 2014 £'000	Acquisitions 2014 £'000	Total 2014 £'000	Total 2013 £'000
Revenue	33,612	6,450	40,062	31,804
Gross profit	17,773	2,176	19,949	16,345
GP %	52.9%	33.7%	49.8%	51.4%
Net admin. costs	(12,137)	(1,926)	(14,063)	(12,016)
Other income	371	-	371	495
AEBITDA	6,007	250	6,257	4,824
Share based payments	(512)	-	(512)	(709)
Exceptional items	(3,268)	-	(3,268)	1,840
Depreciation / amortisation	(4,739)	(211)	(4,950)	(3,554)
Finance costs / income	(1,470)	(85)	(1,555)	(1,794)
Tax	(1,302)	(138)	(1,440)	(1,500)
(Loss) / profit for the year	(5,284)	(184)	(5,468)	(893)



## **BALANCE SHEET / CASHFLOW**

	2014 £'000	2013 £'000	Highlights
Intangible assets	93,522	34,725	<ul> <li>Intangibles from 3 acquisitions = £60.8m</li> </ul>
Inventories	5,793	5,308	<ul> <li>Inventories from acquisitions = £1.3m</li> </ul>
Trade / other receivables	16,115	7,155	<ul> <li>Includes £6.5m due from Mexican distributors</li> <li>Receivables from acquisitions = £2.1m</li> <li>VAT up by £1.7m</li> </ul>
Net cash	2,100	111	<ul> <li>Gross cash of £8.3m</li> <li>Facilities in place of £8.0m</li> <li>Real cash generated in 2014 of £4.5m</li> <li>Working Capital increase of £7.7m in 2014</li> </ul>
Deferred considerations	18,029	7,249	<ul> <li>£0.4m paid in 2014; Quotient vendors</li> <li>£1.4m paid in Jan 2015; DiaSpect vendors</li> <li>Nothing else due in 2015</li> </ul>
Trade / other payables	7,943	4,189	<ul><li>Payable from acquisitions = £1.6m</li><li>VAT up by £1.8m</li></ul>



## **CHALLENGES 2015**

Challenges	Mitigating actions
Limited lifespan of the DME panel in the USA	<ul><li>Reduced earn-out</li><li>Expanded portfolio</li></ul>
Delays in product registrations in China and USA for A1c analysers	<ul> <li>Counterbalanced by registrations in other countries</li> </ul>
Global pressure on healthcare costs	<ul> <li>POC and MDx portfolios provide cost saving solutions to health systems</li> </ul>
Capricious nature of the Russian economy	<ul> <li>Partly offset by increased sales of Biosen in China</li> </ul>
Relative strength of the pound	<ul> <li>Significant income from many international currencies</li> </ul>



## A CLEAR STRATEGY

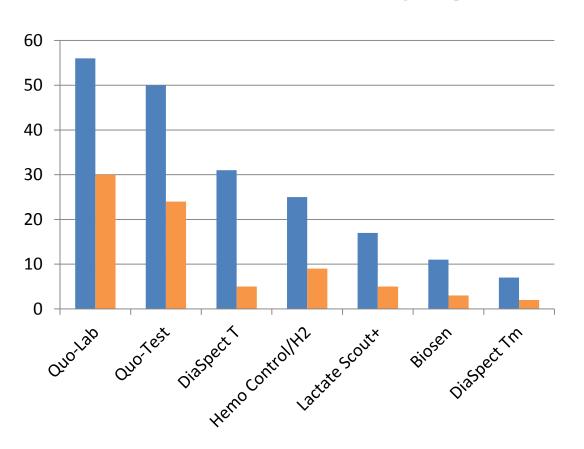
#### 2015 deliverables

Division	Objective	Actions
Point-of- Care	Drive revenues from business units: Hematology Diabetes Care Maternal & Women's Health	<ul> <li>Launch of Hemo Control with connectivity</li> <li>Expand DiaSpect distributor base</li> <li>Improved performance from key accounts:         <ul> <li>Fresenius, Alere, Human, Arkray,</li> <li>Multiclone, IME-DC</li> </ul> </li> <li>Expand product registrations for Biosen</li> <li>Launch of SensPoint lactate analyser</li> </ul>
Central Laboratory	Incremental revenues from new product launches	<ul> <li>Launch mid-range benchtop analyser</li> <li>Launch Procalcitonin and Glycated Serum Protein reagents</li> </ul>
Molecular Diagnostics	Exploit opportunities from existing portfolio	<ul> <li>PrecisionPath reimbursement</li> <li>Ferrer Incode in Corporate Wellness and Private Payer markets</li> <li>Pharma and medtech collaborations</li> <li>CE mark for PointMan</li> </ul>



## **EKF DIAGNOSTICS**

### **Country registrations**



- All Quo-Lab registrations are post launch in 2012
- 2015 focus to be on driving registrations for Biosen, Hemo Control and DiaSpect Tm
  - Registered
  - Pending



## **POINT-OF-CARE**

#### Hematology

- Revenues +£4,397k (+51%) YoY
- Acquisitions have consolidated EKF's position in the POCT market
  - 13,460 analysers sold
- Installed base delivering incremental growth in consumables
  - 16,405,700 tests sold
- OEM agreements with Alere (H2) and Fresenius (CompoLab TS)

	FY 2014 £k	FY 2013 £k	+/- £k	+/- %
Hematology	12,979	8,581	4,397	+51%

#### **EKF** range

DiaSpect T
DiaSpect Tm
HemataSTAT II
Hemo Control
HemoPoint H2
STAT-Site Hgb
UltraCrit+





## **POINT-OF-CARE**

#### **Diabetes**

- Revenues +£384k (4%) YoY
- Technology transfer of Quo-Test and Quo-Lab from UK to Germany completed Q3 2014:
  - Automated consumable production for both products
  - Centralised warehousing and shipping
  - Centralised Customer Service
- 1,900 analyser order from China for Biosen C-Line and S-Line:
  - 400 delivered in 2014
- 37% increase in sales of Quo-Lab analysers to 1,959

EKF range
Biosen
Quo-Lab
Quo-Test
SSM β-HB
ECF. 1 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3

	FY 2014 £k	FY 2013 £k	+/- £k	+/- %
Diabetes Care	9,794	9,410	383	4%



## **POINT-OF-CARE**

#### Maternal & Women's Health

#### Lactate

- SensPoint CE marking Q2
- European studies undertaken on three applications within obstetrics (birth medicine)
- Committee of Key Opinion Leaders established to agree protocols for use in the maternity suite
- Beta trials of SensPoint in seven locations in Europe
- Committee to publish recommendations Q3

#### Hematology

 Business Unit targeting Women and Infant Clinics and anaemia screening programmes for pregnant women and young children





## **EKF MOLECULAR**

#### **Product and services**

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#### 2014 achievements

- Massachusetts General Hospital Cancer Center collaboration led by Daniel Haber MD, PhD:
  - Circulating Tumour Cell (CTC) detection and analysis
- Establishment of fast-track CE marking team
- Multiple third party evaluations commissioned for PointMan:
  - GILUPI: CTC detection and analysis
  - Swansea University: Enable next generation sequencing of ctDNA
  - Kanazawa University Hospital, Japan: Real-time PCR of ctDNA



## POINTMAN v FOUNDATIONONE

## **Product comparison**







Number of genes	50	215	145
List price	\$2,000-\$4,000	\$5,800	TBD
Actionable targets	Yes	Yes	Yes
Database	Better (>25k)	Good (5k – 10k)	Better
Gene fusions	No	Yes	Yes
Medicare approval	Yes	No	n/a
PMA strategy	n/a	No	Yes



### **EKF MOLECULAR**

#### A clear outlook



#### 2015 deliverables

- Reimbursement from Medicare Administrative Contractors for PrecisionPath
- Private payer strategies for:
  - Ferrer Incode
  - Women's Health panel
  - Oncomine
  - Corporate Wellness panel
- Proof of clinical utility for existing DME panel
- Strengthen relationships with Greenville Hospital System
- Development of partnerships with large pharma CE marking of PointMan kits
- Transfer of PointMan production to Greenville, SC and attainment of ISO13485



## **EKF MOLECULAR**

#### **PointMan**

#### PointMan works with all types of biopsy material



CTCs, ctDNA, FFPE, cytology



#### And on all types of DNA sequencing technology

Next Generation, Sanger, rtPCR, MALDI-TOF, Pyrosequencing



Which is why leading cancer technology and drug developers use it

MGH, GILUPI, ANGLE



## **CENTRAL LABORATORY**

#### Clinical chemistry, centrifuges and enzymes

- Total central laboratory sales -£783k (-9%) YoY:
  - £400k negative impact due to currency fluctuations with US\$
  - £250k due to timing of Roche orders
- Growth contributions from:
  - Organic growth of β-HB LiquiColor reagent: +9%
  - STI centrifuges: £268k of incremental revenue

	FY 2014 £k	FY 2013 £k	+/- £k	+/- %
Central Laboratory	7,909	8,692	(783)	(9%)

#### **EKF** range

Clinical chemistry

Contract

fermentation

Enzymes

Liver & kidney biomarkers

Centrifuges





## **R&D UPDATE**

#### **sTNFR1 & 2**

- Growing interest in applications of sTNFR:
  - Third party studies from France and Finland accepted for publication 2014
- Increasing interest and revenues from large pharma to use sTNFR as a companion diagnostic in the development of drugs for renal disease
- Deepening relationship with Joslin Diabetes Center, Boston with view to roll-out sTNFR within their US affiliate network of 48 hospitals

#### **PKU**

- Technical feasibility project undertaken
- Platform provider identified
- Meeting with pharma and food companies in progress
- Sponsorship for US Regulatory Process
- Commercialisation forecast for Q1 2016

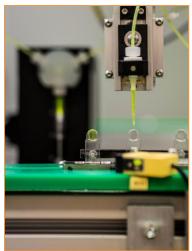




## FINANCIAL DELIVERABLES IN 2015

- Revenue growth of 10% from underlying business
- Full year benefit of Quo-Test and Quo-Lab manufacturing transfer to Germany
- Full year benefit of Dublin office closure
- Further anticipated actions:
  - Barleben expansion for efficiency savings
  - Increased volumes; more efficient utilisation of existing plants
  - Further consolidated manufacturing in key sites
  - Reduced cuvette wastage
  - Streamlined sales/production interface
  - Outsourcing of some instrumentation







## **SUMMARY**

- Management targeting 10% annual growth in 2015:
  - Approximately twice the industry standard rate of growth
- Specific actions in place to deliver growth:
  - Business Units to focus on developing distributor base, identifying market opportunities and launching products
  - Focus on obtaining regulatory approvals in key markets
  - Portfolio of molecular products and services to be delivered
- Pipeline of POC and Central Lab products for commercial launch or further collaboration and licensing with pharma





## **APPENDICES**



## **BALANCE SHEET: ASSETS**

	Selected items	FY 2014 £'000	FY 2013 £'000	+/- £'000
Non-current assets	Property, plant, equipment	10,568	9,785	783
	Intangible assets	93,522	34,725	58,797
	Investments	1,152	250	902
	Deferred tax assets	238	903	(665)
	Total non-current assets	105,480	45,663	59,817
Current assets	Inventories	5,793	5,308	485
	Trade and other receivables	16,115	7,155	8,960
	Deferred tax assets	45	46	(1)
	Cash and cash equivalents	8,346	2,551	5,795
	Total current assets	30,299	15,060	15,239
Assets	Total assets	135,779	60,723	75,056



## **BALANCE SHEET: EQUITY & LIABILITIES**

	Selected items	FY 2014 £'000	FY 2013 £'000	+/- £'000
Equity attributable	Total equity	87,376	40,922	46,454
Non-current liabilities	Borrowings	2,492	2,108	384
	Deferred considerations	9,536	5,471	4,065
	Deferred tax liabilities	13,258	3,442	9,816
	Retirement benefit obligation	-	103	(103)
	Total non-current liabilities	25,286	11,124	14,162
<b>Current liabilities</b>	Trade and other payables	7,943	4,189	3,754
	Deferred consideration	8,493	1,778	6,715
	Current income tax liabilities	2,171	1,998	173
	Deferred tax liabilities	756	380	376
	Borrowings	3,754	332	3,422
	Total current liabilities	23,117	8,677	14,440
	Total liabilities	48,403	19,801	28,602
<b>Equity and liabilities</b>	Total equity and liabilities	135,779	60,723	75,056



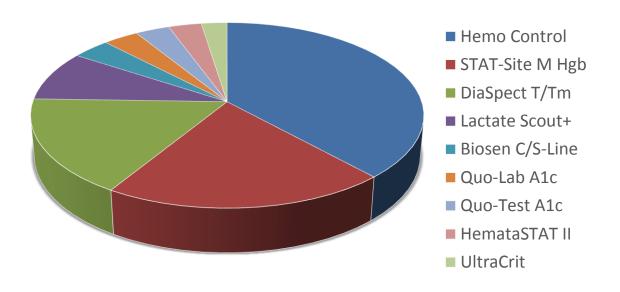
## **CASHFLOW**

	FY 2014 £'000	FY 2013 £'000	+/- £'000
Cash at beginning of period	2,551	4,331	(1,780)
From operating activities	(4,778)	2,007	(6,785)
From investing activities	(15,840)	(2,216)	(13,624)
From financing activities	26,390	(1,560)	27,950
Net increase / (decrease) in cash	5,772	(1,769)	7,541
Exchange gains / (losses)	23	(11)	34
Cash at end of period	8,346	2,551	5,795



	Approx. units
Hemo Control	31,905
STAT-Site M Hgb	17,107
DiaSpect T/Tm	13,972
Lactate Scout+	7,311
Biosen C/S-Line	2,992
Quo-Lab A1c	2,797
Quo-Test A1c	2,704
HemataSTAT II	2,605
UltraCrit	2,030
Total	83,423

## UNIT SALES OF ANALYSERS 2008 - 2014





Diabetes	Quo-Lab	Quo-Test	Biosen
Parameter	HbA1c	HbA1c	Glucose and lactate
Time to results	4 minutes	4 minutes	20-25 seconds
Accuracy	< 3% CV	< 3% CV	< 1.5% CV
Sample size	4 μΙ	4 μΙ	20 μΙ
Memory	7,000 results	7,000 results	1,000 results
Connectivity	LIS / printer	LIS / printer	LIS / printer
Manufactured	Germany	Germany	Germany
Other	Launched 2012	SFDA approval	SFDA approval









Anaemia	SSM Hgb	DiaSpect Tm/T	UltraCrit	Hemo Control	HemataSTAT
Parameter	Hemoglobin	Hemoglobin	Hematocrit	Hemoglobin	Hematocrit
Time to results	30 seconds	1 – 2 seconds	30 seconds	20 seconds	60 second spin
Imprecision	-	-	< 0.8% CV	< 2% CV	+/- 0.5%
Sample size	15 μΙ	10 μΙ	40 μΙ	8 μΙ	-
Memory	n/a	None	-	4,000 results	None
Connectivity	n/a	Bluetooth	-	Bluetooth, USB, LAN	-
Manufactured	USA	Germany	USA	Germany	USA
Other	CLIA waived	CLIA waived	FDA 510k	CLIA waived	FDA 510k













Lactate	Lactate Scout+	SensPoint	Biosen
Parameter	Lactate	Lactate	Glucose and lactate
Time to results	10 seconds	10 seconds	20-25 seconds
Accuracy	< 3.4 mmol/L +/- 0.2 mmol/L	< 3% CV	< 1.5% CV
Sample size	0.2 μΙ	0.2 μΙ	20 μΙ
Memory	250 results	5,000 results	1,000 results
Connectivity	PC / Bluetooth	PC / Bluetooth	LIS / printer
Manufactured	Germany	Germany	Germany
Other	Integrated Bluetooth	Beta launch summer 2014	SFDA approval
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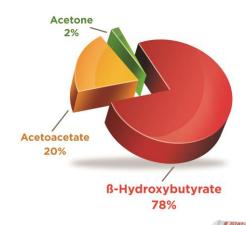




## **BETA-HYDROXYBUTYRATE**

#### 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)
- $\beta$ -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  $\beta$ -HB strip test launched Q2 2013







## **CENTRIFUGE RANGE**

Creamatocrit™	Measures the creamatocrit of mothers' milk and estimates the calories per ounce	
Micro12™	The Micro12 centrifuge is used for small volume separation	
PlasmaPrep-12™	High-speed bench top centrifuge designed to rapidly separate blood in original evacuated collection tubes	
SlidePrep Plus™	Produces a monolayer of cells onto a glass slide from any fluid suspension under the safest conditions possible	



## **ENZYME MANUFACTURING**

#### **EKF Life Sciences**

- Based in Elkhart, Indiana
- Certified ISO 13485: 2003 facility
- Relaunched as EKF Life Sciences 1<sup>st</sup> July 2014

#### Manufacturing:

- Bulk manufacture of enzymes used in clinical reagents
- Global distribution to a blue-chip roster of customers

#### **Contract manufacturing services**

Provides custom manufacturing, custom filling and custom packaging



## **NOVEL RENAL 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 Q3/4 2014
- Deepening relationship with Joslin Diabetes Center, Boston with view to roll-out sTNFR1 within their US affiliate network (48 hospitals)



## **MDx PRODUCTS: POINTMAN**



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

#### **KRAS**

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

#### EGFR T790M

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

#### JAK2

Myeloma testing

#### **NRAS**

• Used in colorectal cancer

#### ESR1

 Breast cancer detection and sensitivity to oestrogen receptor drugs



## **MDx SERVICES**

#### **Selah Genomics**



- Based in Greenville, South Carolina, USA
- CLIA certified 'test-as-a-service' molecular laboratory targeting three distinct customer segments: Doctors, pharmaceutical companies and healthcare providers
- Growing portfolio of molecular assays to support the development and application of personalised medicine. Current revenue streams include:
  - DME panel for testing cardiac
  - Women's health panel
- Selah is the chosen partner to perform next generation sequencing to support the newly launched Rare Tumour Centre (Greenville Health System, SC) utilising a molecular test panel comprising 230 genes from Foundation Medicine
- Gained an established and CLIA certified laboratory:
  - Supports the development of further Laboratory Developed Tests (LDTs) with expertise in next generation sequencing



# Thank you

