



SCIENCE MADE SIMPLE

HALF YEARLY REPORT

Six months ended 30th June 2014

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15th September 2014

AGENDA

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KEY ISSUES TO ADDRESS



The business strategy for EKF Molecular Diagnostics and Selah Genomics



How EKF Diagnostics will meet its full year market expectations



MOLECULAR DX STRATEGY



Acquisition rationale:

- All pharma companies are required by the FDA to explore the identification of novel biomarkers to allow more accurate use of new drugs
- Leverage Selah and PointMan products to support Phase 1 drug trials:
 - Allows drugs to be tested on targeted patient populations
 - Enables pharma to establish drug efficacy earlier in development
 - Improves decision making process in drug development
- Very early access to novel biomarkers evolving from ITOR (oncology) trials
- Ability to launch new commercial products into the US market through its own CLIA laboratory (see product pipeline on next slide)
- Develop and optimise novel biomarker assays using proprietary EKF technology (PointMan) within CLIA laboratory background
- Immediate access to significant revenue generating opportunity as a leading genomic medicine service provider within the US



PRODUCT PIPELINE

Assay	Development	Validation	Algorithm/Reporting	Palmetto GBA (CMS / Medicare) Tech. Assessment	Public Payer	Private Payer
My MED INCODE. (DME)	Complete	Complete	Complete.	N/A - existing codes already established for these assays. Currently only reimbursed for cardiovascular patients being considered for treatment with Plavix. Cash pay is available in some sales channels.		
Women's Health Panel	Complete	Complete	Complete.	N/A - existing codes already established for these assays.		
 PrecisionPath	Complete	Complete	Complete.	Complete.	TA submitted to CMS (Palmetto GBA) on 6/23/14. Awaiting response.	Finalizing selection of private payer reimbursement consultants.
My CARDIO INCODE.	Complete	Complete	Complete.	Complete.	TA submitted to CMS on 8/14/14. Initial CMS response seeks additional evidence of clinical utility. Drafting appeal.	Not started
My THROMBO INCODE.	Complete	Complete	Will commence now that CIC is in place. Algorithm placement will go quickly since infrastructure for Cardio inCode can be copied.	In progress. Estimated completion by mid-Sept.	Not started	Not started
My SUDD INCODE.	Complete	In progress	Server for MiSeq has been ordered. Ferrer will be ready to complete and install GUI interface in September.	Not started	Not started	Not started
My NUTRI INCODE.	In progress	Not started	Will receive OpenArrays in mid-September. Validation should take 2-3 weeks. October timeframe for assay availability.	N/A - this will be a cash pay assay only.		
Preimplementation Genetic Screening	In progress	Not started	Not started	N/A - this will be a cash pay assay only.		
Oncomine CancerPanel	In progress	Not started	Server was installed. Issues with hardware / software compatibility. Will re-install in 1-2 weeks. Negotiating payment terms for reagents.	Not started	Not started	Not started

CURRENT TRADING AND OUTLOOK

Point-of-care:

- Improved automation of Quo-Test and Quo-Lab will allow higher volume of production and increase margins
- Volume deals from key OEM partners in Eastern Europe and Asia for A1c and Hb analysers
- Large Biosen analyser deal in China
- Half year of revenue from DiaSpect including upside from registration of OEM TM analyser in China and Japan
- Half year of revenue from STI inc. volume commitment from US distributor for HemataSTAT II
- High volume tenders in Africa and Mexico

Central laboratory:

- Comprehensive sales campaign in Asia to grow market share
- New chemistry product launches: Procalcitonin, glycated albumin, electrolytes
- Initial orders from pharma for sTNFR1

Molecular diagnostics:

- New product launches from Selah Genomics



H1 2014 HIGHLIGHTS

Continued revenue growth: £16.77m vs. H1 2013 £14.89m (+13%)

- Underlying organic growth: £15.40m vs. £14.89m (+3.4%)
- Less: Adverse currency effect in 2014 of (£1.08m)
- Add: Acquisitions in 2014 of £2.44m

Continued AEBITDA growth: £2.22m vs. H1 2013 £2.12m (+5%)

- Underlying organic growth: £2.22m vs. £2.12m (+5%)
- Less: Adverse currency effect in 2014 of (£0.34m)
- Add: Acquisitions in 2014 of £0.34m

	H1 2014	H1 2013	H1 2012	H1 2011
Revenue	£16.77m	£14.89m	£12.65m	£7.38m
AEBITDA	£2.22m	£2.12m	£1.40m	£0.21m



ORGANISATIONAL STRUCTURE

EKF Diagnostics Holdings Plc



Point of care

Central
Laboratory

Molecular

Diabetes

Hematology

Women's
health/
Ambulatory/
Sport

Chemistry

Enzymes

Oncology

Thrombosis
Sudden
Death
Sepsis

BUSINESS UNIT SUMMARY

- **H1 2014 rev: £11.4m**
- **+16% v. H1 2013**
- Steady growth as a result of increasingly large base of installed units
- Volume-driving OEM partnerships and other large customer orders
- Revenue and profit **growth**

Point-of-care



- **H1 2014 rev: £4.1m**
- **-18% v. H1 2013**
- Mature market
- Disproportionate impact of £ v \$ exchange rates
- Timing of Roche enzyme orders
- B-HB LiquiColor reagent +6% YoY
- **High margin** niche products

Central laboratory



- **H1 2014 rev: £1.3m**
- Revenues generated from just 10 weeks of trading
- Portfolio of tests in development
- Endorsement of PointMan from leading US oncology centre
- Drive **value** in mid-term

Molecular diagnostics



POINT-OF-CARE

Haematology

- Revenues + £1.72m (+51%) H1 2014 v H1 2013
- Acquisitions have consolidated market presence
- Commercial integration of DiaSpect and STI complete
- Growing installed base delivering incremental growth in consumables
- Significant opportunities following acquisition of DiaSpect:
 - Tenders in Africa
 - Fresenius Kabi OEM
 - Direct competition to HemoCue 301 analyser (leading reagent-free brand)
- Complementary opportunities following acquisition of STI:
 - Haematocrit measurement required in some blood banks
 - Applications within elite and performance sport

EKF range

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



	H1 2014 £k	H1 2013 £k	+/- £k	FY 2013 £k
Hemo Control / HemoPoint H2	4,055	2,978	1,077	7,904

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DIAGNOSTICS

POINT-OF-CARE

Diabetes

- Technology transfer of Quo-Test and Quo-Lab from Walton-on-Thames, UK to Barleben, Germany completed:
 - 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:
 - Consumables order expected to follow
- Development of new platform for hand-held β -HB meter:
 - Whole blood test to compete with Abbott Xceed Pro and Nova Max Plus
 - Launch Q1 2015

EKF range

Biosen
Quo-Lab
Quo-Test
SSM β -HB



	H1 2014 £k	H1 2013 £k	+/- £k	FY 2013 £k
Biosen	2,654	2,954	(300)	6,518
Quo-Test / Quo-Lab	1,296	1,411	(115)	2,892

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DIAGNOSTICS

POINT-OF-CARE

Lactate (Sport/Women's Health/Sepsis)

- New applications for lactate outside of sports medicine:
 - Obstetrics
 - Sepsis

Obstetrics

- European studies undertaken on three applications within obstetrics (birth medicine)
- New market opportunity with considerable revenue potential
- Beta trials of SensPoint from October 2014

Sepsis

- Existing market for POC lactate testing in ambulatory environment, esp. North America
- Ongoing dialogue with global market leader to supply Lactate Scout+

EKF range

Lactate Scout+
SensPoint



EKF
DIAGNOSTICS

CENTRAL LABORATORY

Clinical chemistry and enzymes

- Total central laboratory sales H1 2014 v H1 2013 sales -19%
- Timing issues:
 - Enzyme orders from Roche
 - Asian distributors
- Sustained growth of β -HB LiquiColor reagent: +6% YoY
- Revenue growth expected from new products to be launched H2 2014:
 - Procalcitonin (Q3)
 - Glycated albumin (Q4)
 - Electrolytes (potassium, sodium, chloride) (Q4)

EKF range

Clinical chemistry
 Contract fermentation
 Enzymes
 Liver & kidney biomarkers



Revenues	H1 2014 £k	H1 2013 £k	+/- £k	FY 2013 £k
β -HB LiquiColor reagent	1,517	1,433	84	3,137

CENTRAL LABORATORY

Kidney biomarkers

sTNFR1 and 2

- Increased profile and awareness of sTNFR1/2:
 - Prestigious award and key note address by lead scientist at American Diabetes Association annual meeting in June 2014
 - Multiple papers published in key journals underpinning the value of the marker
- Early clinical adaption underway in Dublin and multiple projects underway at other sites in Europe and US
- First revenues (c. £50k) in Q3/4 conducting trials on behalf of pharma

EKF range

Kidney and liver biomarkers

sTNFR1 and 2



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DIAGNOSTICS

CONSOLIDATED INCOME STATEMENT

	H1 2014 £'000	H1 2013 £'000	+/- £'000	FY 2013 £'000
Revenue	16,766	14,887	1,879	31,804
Gross profit	7,912	7,648	264	16,345
GP %	47.2%	51.4%	(4.2%)	51.4%
Net admin. costs	(5,864)	(5,645)	(219)	(12,016)
Other income	168	121	47	495
AEBITDA	2,216	2,124	92	4,824
Share based payments	(273)	(231)	(42)	(709)
Exceptional items	(1,489)	510	(1,999)	1,840
Depreciation/amortisation	(2,326)	(1,744)	(582)	(3,554)
Operating profit	(1,872)	659	(2,531)	2,401
PBT	(2,468)	191	(2,659)	607
Tax	(159)	(1,134)	975	(1,500)
(Loss) / profit for the year	(2,627)	(943)	(1,684)	(893)

BALANCE SHEET: ASSETS

	Selected items	H1 2014 £'000	H1 2013 £'000	+/- £'000	FY 2013 £'000
Non-current assets	Property, plant, equipment	10,137	9,971	166	9,785
	Intangible assets	96,258	36,605	59,653	34,725
	Investments	1,152	250	902	250
	Deferred tax assets	862	977	(115)	903
	Total non-current assets	108,409	47,803	60,606	45,663
Current assets	Inventories	6,414	5,691	723	5,308
	Trade and other receivables	9,915	5,342	4,573	7,155
	Deferred tax assets	44	47	(3)	46
	Cash and cash equivalents	11,122	3,138	7,984	2,551
	Total current assets	27,495	14,218	13,277	15,060
Assets	Total assets	135,904	62,021	73,883	60,723




BALANCE SHEET: EQUITY & LIABILITIES

	Selected items	H1 2014 £'000	H1 2013 £'000	+/- £'000	2013 £'000
Equity attributable	Total equity	86,727	41,900	44,827	40,922
Non-current liabilities	Borrowings	2,235	2,234	1	2,108
	Deferred considerations	16,803	5,237	11,566	5,471
	Deferred tax liabilities	15,849	3,911	11,938	3,442
	Retirement benefit obligation	115	128	(13)	103
	Total non-current liabilities	35,002	11,510	23,492	11,124
Current liabilities	Trade and other payables	6,057	4,879	1,178	4,189
	Deferred consideration	2,829	2,132	697	1,778
	Current income tax liabilities	1,535	1,103	432	1,998
	Deferred tax liabilities	66	241	(175)	380
	Borrowings	3,688	256	3,432	332
	Total current liabilities	14,175	8,611	5,564	8,677
	Total liabilities	49,177	20,121	29,056	19,801
Equity and liabilities	Total equity and liabilities	135,904	62,021	73,883	60,723

CASHFLOW

	H1 2014 £'000	H1 2013 £'000	+/- £'000	2013 £'000
Cash at beginning of period	2,551	4,331	(1,780)	4,331
From operating activities	(3,317)	1,007	(4,324)	2,007
From investing activities	(14,587)	(793)	(13,794)	(2,216)
From financing activities	26,377	(1,535)	27,912	(1,560)
Net increase/(decrease) in cash	8,473	(1,321)	9,794	(1,769)
Exchange gains/(losses)	98	128	(30)	(11)
Cash at end of period	11,122	3,138	7,984	2,551

AND FINALLY

			
Acquired	July 2010	October 2010	June 2011
Revenue growth since acquisition	45%	775%	64%



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THANK YOU

APPENDIX

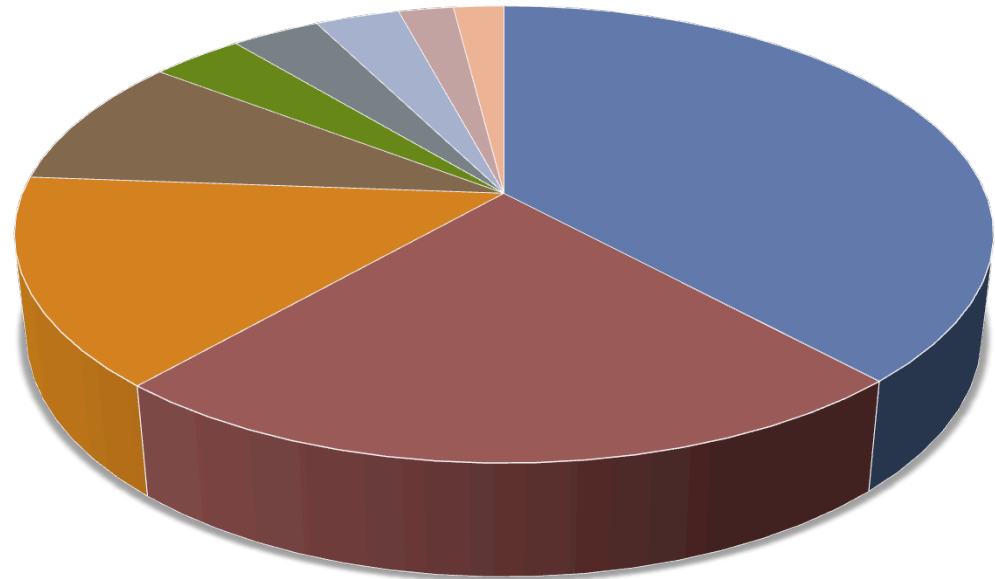
Product portfolio



SALES OF ANALYSERS

2008 – June 2014

	Units sold
Hemo Control	27,004
STAT-Site M Hgb	16,421
DiaSpect T/Tm	10,429
Lactate Scout+	6,535
Biosen C/S-Line	2,563
Quo-Test A1c	2,467
HemataSTAT II	2,348
Quo-Lab A1c	1,524
UltraCrit	1,401
Total	70,692



- Hemo Control ■ STAT-Site M Hgb ■ DiaSpect T/Tm
- Lactate Scout+ ■ Biosen C/S-Line ■ Quo-Test A1c
- HemataSTAT II ■ Quo-Lab A1c ■ UltraCrit



Diabetes	Quo-Lab	Quo-Test	Biosen A1c	Biosen
Parameter	HbA1c	HbA1c	HbA1c and glucose	Glucose and lactate
Time to results	4 minutes	4 minutes	4 minutes (A1c) 30 seconds (glucose)	20-25 seconds
Accuracy	< 3% CV	< 3% CV	<3% CV (A1c) <1.5% CV (glucose)	< 1.5% CV
Sample size	4 µl	4 µl	20 µl	20 µl
Memory	7,000 results	7,000 results	1,000 results	1,000 results
Connectivity	LIS / printer	LIS / printer	LIS / printer	LIS / printer
Manufactured	Germany	Germany	Germany	Germany
Other	Launched 2012	SFDA approval (Quo-Test)	Beta testing	SFDA approval



Anaemia	SSM Hgb	DiaSpect Tm/T	UltraCrit	Hemo Control
Parameter	Hemoglobin	Hemoglobin	Hematocrit	Hemoglobin
Time to results	30 seconds	1 – 2 seconds	30 seconds	20 seconds
Imprecision	-	-	< 0.8% CV	< 2% CV
Sample size	15 µl	10 µl	40 µl	8 µl
Memory	n/a	None	-	4,000 results
Connectivity	n/a	2.0 Bluetooth	-	LIS
Manufactured	USA	Germany	USA	Germany
Other		CLIA waived (T)	FDA 510k	CLIA waived



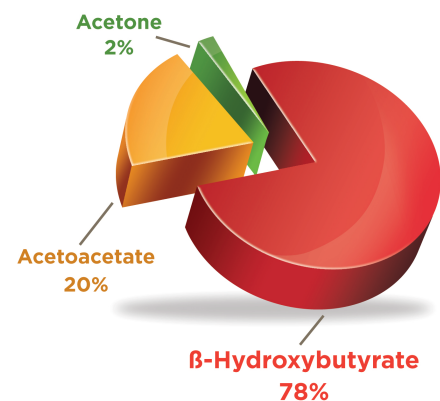
Lactate	Lactate Scout+	SensPoint	Biosen
Parameter	Lactate	Lactate	Glucose and lactate
Time to results	10 seconds	10 seconds	20-25 seconds
Accuracy	< 3.4 mmol/L +/- 0.2 mmol/L	< 3% CV	< 1.5% CV
Sample size	0.2 µl	0.2 µl	20 µl
Memory	250 results	5,000 results	1,000 results
Connectivity	PC / Bluetooth	PC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



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



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CENTRIFUGE RANGE

- **Creamatocrit™**
 - Measures the creatocrit 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 1st 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)



PRODUCTS: POINTMAN



BRAF

- 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

SERVICES: SELAH GENOMICS INC.

Company overview



- Based in Greenville, South Carolina, USA
- CLIA certified molecular 'test-as-a-service' 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 technologies e.g. sequencing
 - Synergies for the commercialisation of EKF MDx PointMan technology through fee for service testing for research and clinical trials
- Strong MDx management team with track record in commercialising innovations





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DIAGNOSTICS

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