



Financial results for the year ended 31st December 2015

Julian Baines, Chief Executive Officer
Richard Evans, Finance Director & COO

12th April 2016

Agenda

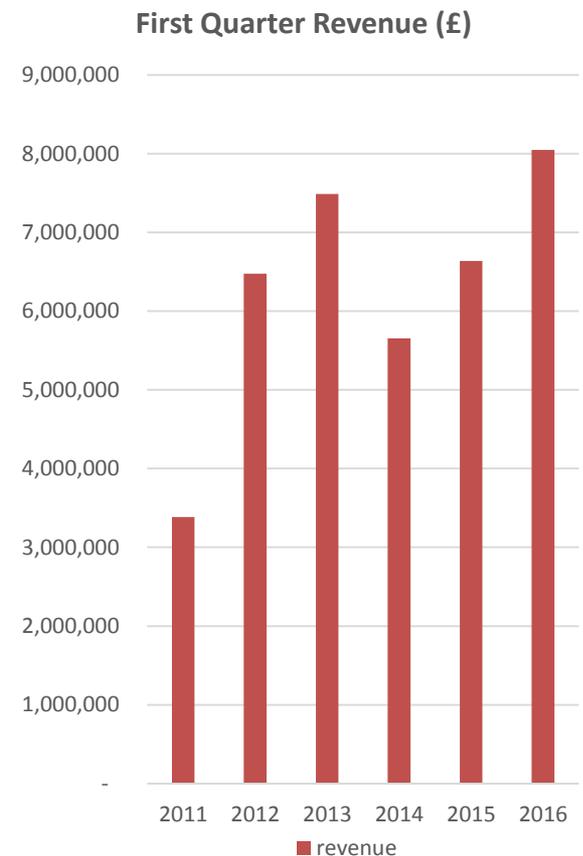
Slide no.

- 3. Introduction
- 4. Commercial and operational update
- 5. Financial performance
- 6. Point-of-Care
- 9. Central Laboratory
- 10. Pipeline
- 11. Regulatory status
- 12. 2016 Outlook
- 13. Summary

Appendices

Introduction

- Board composition:
 - Board aligned on strategy of achieving organic growth
- Company restructure:
 - Reduced headcount and sites
 - Cost savings of £6.7m p.a.
- Organic growth achievable from a variety of sources:
 - Positive start to Q1 2016 through performance of existing portfolio
 - Regulatory approval in China for Biosen provides incremental opportunities
 - US FDA for DiaSpect Tm underway
 - Significant opportunity in India and upside in Saudi Arabia
 - £30.9m revenue target and £3.0m - £4.0m AEBITDA excluding any significant new tender business



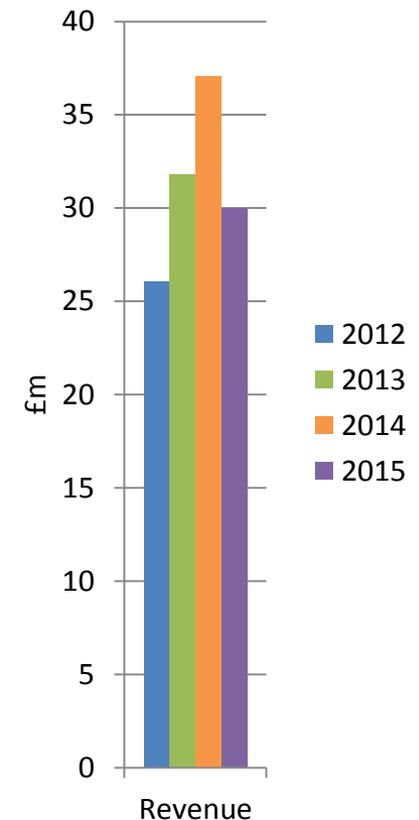
NB: Like for like revenue excluding Selah Genomics

2015: A challenging year

- Revenues down 19% to £30.0m (2014 restated: £37.1m)
- Restructuring of company:
 - Disposal of Selah Genomics
 - Decision to close Walton-on-Thames facility
 - Closure of Dublin facility and proposed disposal of RUO biomarker products
 - Moth-balled EKF Molecular Diagnostics
 - STI in Sanford, USA remains open contrary to 3rd February 2016 announcement
 - Reduced headcount by 85 (to 315)

Achievements

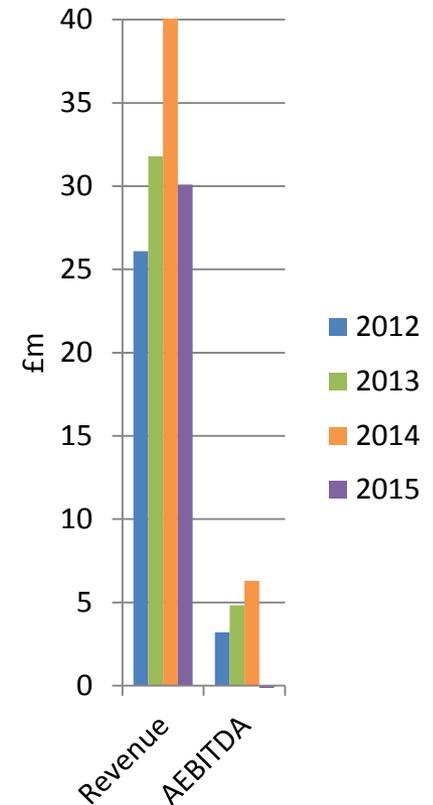
- Annual cost savings of £6.7m identified and partly implemented
- 12,879 analysers and 56m tests manufactured
- Large tenders won in Saudi Arabia (Quo-Test), Turkey (Hemo Control) and Peru (Hemo Control)
- Steady performance from core business (ex. Mexico) in 2015 despite distractions from Strategic Review, potential sale, disposal of Selah Genomics and change of Non-Executive Chairman
- Q1 2016 ahead of budget



Financial performance

Underperformance from acquisitions

- Gross profit down 23% to £14.7m (2014 restated: £19.2m)
- AEBITDA down to (£0.3m) (2014 restated: £6.7m)
- Cash used in operating activities: £2.9m (2014 £3.3m used)
- Net debt of £8.8m (2014: £2.1m net cash)
- Write-off of Selah Genomics with future annual cost saving of £2.0m
- Write-off of significant debtors in Mexico; product recovered



Point-of-Care

Hematology

- ‘Regular’ business (exc. Mexico tenders) up c. £950k
- Hemo Control up 16% YoY
- Hematastat II up 131% YoY
- DiaSpect T/Tm/CompoLab sales flat
- 2016 strategy to focus on:
 - New H2 distribution strategy in USA. Transition underway from Alere back to Stanbio and national contract sales organisation
 - Growth in Latin America with DiaSpect Tm and Hemo Control
 - Market share in India through DiaSpect Tm
 - Registration of DiaSpect Tm in USA



Hematology range

- DiaSpect Tm
- Hematastat II
- Hemo Control
- HemoPoint H2
- STAT-Site Hgb
- UltraCrit & UltraCrit+



	FY 2015 £k	FY 2014 £k	+/- £k	+/- %
Hematology analysers and tests	7,371	12,481	(5,110)	(41%)

Point-of-Care

Diabetes



- Revenues down £160k (-2%) YoY
- Sales of Biosen and Quo-Test in China impacted by regulatory issues
- 41% increase in Quo-Test revenue. Publication of positive evaluations by NGSP and KoLs. Registration of CE mark for Quo-Test and Quo-Lab following transfer of manufacturing from UK to Germany
- 2016 strategy to focus on:
 - Driving revenue from Quo-Lab OEM agreements
 - Re-establish Biosen market in China following successful re-registration
 - Attack Latin American clinical diabetes markets using relaunched Biosen C Line and S Line models

Diabetes range

- Biosen C-Line
- Biosen S-Line
- Quo-Lab A1c
- Quo-Test A1c
- STAT-Site M β-HB



	FY 2015 £k	FY 2014 £k	+/- £k	+/- %
Diabetes analysers and tests	6,463	6,623	(160)	(2%)

Point-of-Care

Maternal & Women's Health



- Revenues up £209k (+9%) YoY
- Opened market for Creatatocrit in China
- 13% increase in sales of pregnancy kits primarily in Latin America and USA
- 2016 strategy to focus on:
 - Build Chinese market with Lactate Scout+ and Creatatocrit
 - Identify other volume markets to drive incremental sales of Creatatocrit
 - Continue studies in Bristol and Rome in order to obtain CE mark for SensPoint



	FY 2015 £k	FY 2014 £k	+/- £k	+/- %
Analysers, sensors and tests	2,455	2,246	209	9%

Central Laboratory

Clinical chemistry, centrifuges and enzymes



- Total central laboratory sales +£400k (+5%):
 - 6% increase in sales of Beta-Hydroxybutyrate Liquicolor reagent
 - 8% increase in 'standard' chemistry range
 - £100k increase in sales of centrifuges and consumables
 - Includes a decrease in like for like sales of RUO biomarkers caused by closure of the department
- 2016 strategy to focus on:
 - B-HB Liquicolor and SSM B-HB. Q1 2016 sales £1.69m v £915k Q1 2015 (+80%)
 - Incremental revenue opportunities with PCT
 - Launch of Altair 240 automated chemistry analyser to drive further increases in sales of chemistry outside of USA

Central Laboratory range

- Clinical chemistry
- Contract fermentation
- Enzymes
- Liver & kidney biomarkers
- Centrifuges



	FY 2015 £k	FY 2015 £k	+/- £k	+/- %
Central Laboratory	9,101	8,701	400	5%

Pipeline

DiaSpect Tm

- Clinical trials underway. Submit for FDA 510k and CLIA waiver in 2016

sTNFR1/2

- Ongoing discussions with major pharma brands on licensing opportunities

Inborn Errors of Metabolism (PKU)

- Ongoing discussions with major food supplement brand on licensing opportunities

Regulatory

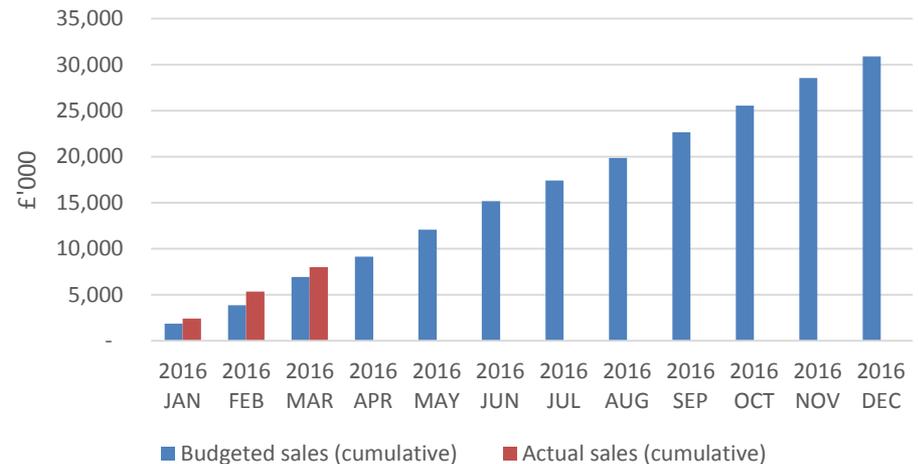
Product	Country	Status
DiaSpect Tm	USA	Clinical trials underway for FDA 510k. Trial duration will be three months. Submission for CBER (blood banks) and CDRH (all other uses)
	Russia	Clinical trials underway as part of registration
	Mexico	Registration complete
	Peru, Turkey, Malaysia, Uruguay, Paraguay	Registration submitted
Quo-Test & Quo-Lab		Transfer of manufacturing from Walton to Barleben completed. Re-registration of products progressing well
Biosen	China	Re-registration completed
PCT	Mexico	Poland site to be designated as point of manufacture
	South American countries	Product registrations underway
Corporate	USA	UDI labelling required by September 2016
	Global	New IVD regulations December 2016 require reclassification on all products (3-5 year transition period)
	Global	ISO 13485 2016 compliance

2016 Outlook

Positive start to 2016

- 115% of Q1 budget
- Sales of B-HB +80%
- Strong performances across all regions, especially USA
- Upside expected from:
 - Altair 240 analyser and reagent sales
 - Saudi Arabia HbA1c tender
 - PCT reagent sales
 - Licence agreements for PKU monitor and sTNFR biomarker

Cumulative sales against (draft) budget



Summary

- Focused on the core business
- Strategic approach is underpinned by investor feedback
- Centralised manufacturing operations to four sites
- Reduced headcount and implemented site closure programme
- Prioritisation of key markets:
 - USA: Relaunch of HemoPoint H2; FDA DiaSpect Tm
 - India: DiaSpect Tm
 - China: Re-registration of Biosen
- Revenue target £30.9m
- AEBITDA target £3.0m – £4.0m



Appendices

Consolidated income statement

	Total 2015 £'000	Total 2014 £'000	+/- £'000
Revenue	30,045	37,106	(7,061)
Gross profit	14,669	19,246	(4,577)
GP %	48.8%	51.8%	(3.0%)
Net admin. costs	(15,382)	(13,470)	(1,912)
Other income	139	371	(232)
AEBITDA	347	6,659	(6,312)
Share based payments	(226)	(512)	286
Exceptional items	(5,722)	(3,268)	(2,454)
Depreciation / amortisation	(8,052)	(4,819)	(3,233)
Finance costs / income	(1,422)	(1,491)	69
Tax	2,206	(1,440)	3,646
Loss for the year cont. operations	(13,564)	(4,871)	(8,693)

Balance Sheet / Cashflow

	2015 £'000	2014 £'000	+/- £'000
Intangible assets	42,927	93,522	(50,595)
Inventories	8,234	5,793	2,887
Trade / other receivables	7,242	16,115	(9,361)
Net (debt) / cash	(8,825)	2,100	(10,925)
Deferred considerations	485	8,493	(8,008)
Trade / other payables	8,331	7,943	388

Balance Sheet: Assets

Selected items		FY 2015 £'000	FY 2014 £'000	+/- £'000
Non-current assets	Property, plant, equipment	10,680	10,568	112
	Intangible assets	42,927	93,522	(50,595)
	Investments	402	1,152	(750)
	Deferred tax assets	340	238	102
	Total non-current assets	55,346	105,480	(49,532)
Current assets	Inventories	8,234	5,793	2,441
	Trade and other receivables	7,242	16,115	(8,873)
	Deferred tax assets	47	45	2
	Cash and cash equivalents	2,017	8,346	(6,329)
	Total current assets	17,540	30,299	(12,759)
Assets	Total assets	71,889	135,779	(63,890)

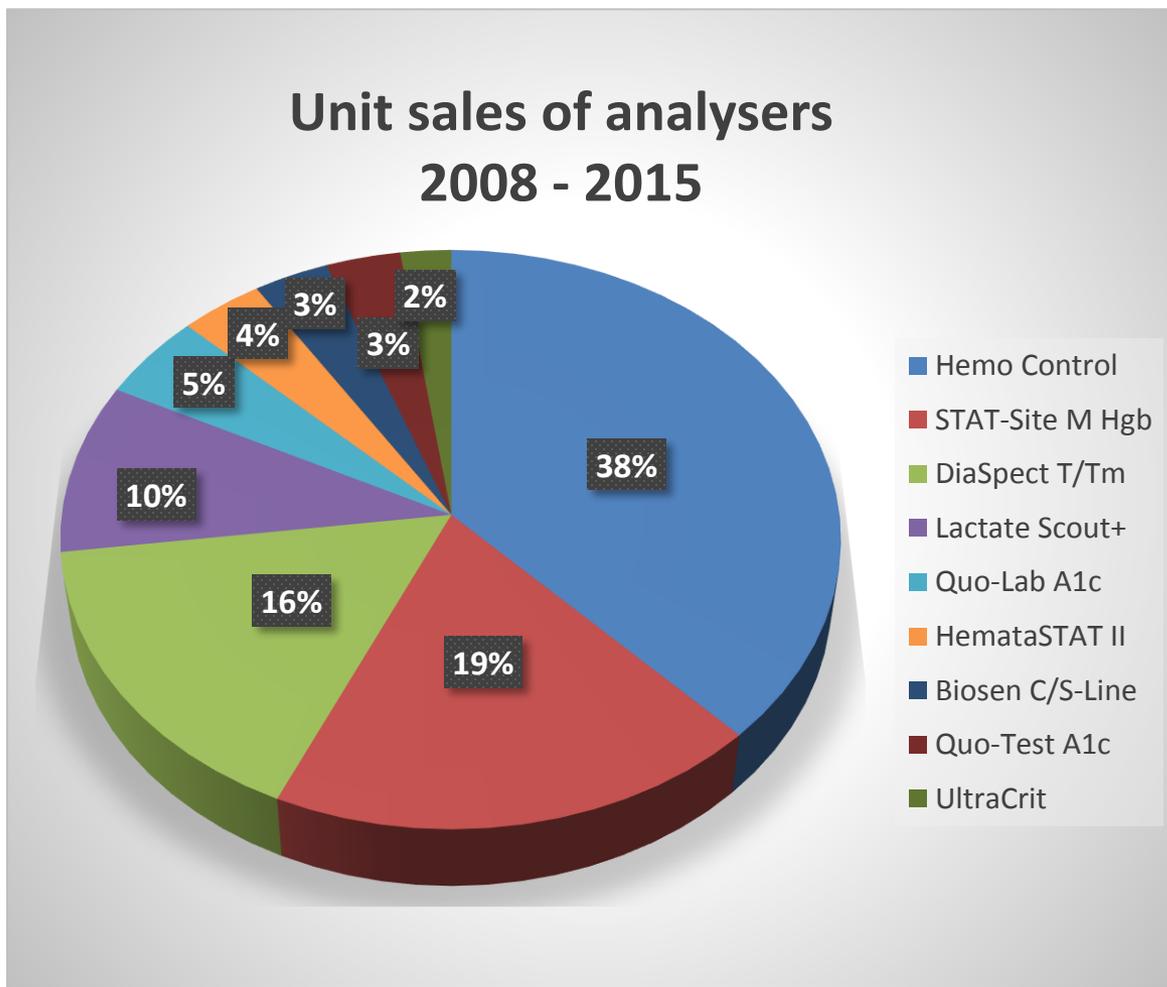
Balance sheet: Equity & liabilities

Selected items		FY 2015 £'000	FY 2014 £'000	+/- £'000
Equity attributable	Total equity	46,754	87,376	(40,622)
Non-current liabilities	Borrowings	1,167	2,492	(1,325)
	Deferred considerations	-	9,536	(9,536)
	Deferred tax liabilities	3,559	13,258	(8,106)
	Total non-current liabilities	4,726	25,286	(20,560)
Current liabilities	Trade and other payables	8,331	7,943	388
	Deferred consideration	485	8,493	(8,008)
	Current income tax liabilities	1,087	2,171	(1,084)
	Deferred tax liabilities	831	756	75
	Borrowings	9,675	3,754	5,921
	Total current liabilities	20,409	23,117	(2,708)
	Total liabilities	25,135	48,403	(23,268)
Equity and liabilities	Total equity and liabilities	71,889	135,779	(63,890)

Cashflow

	FY 2015 £'000	FY 2014 £'000	+/ - £'000
Cash at beginning of period	8,346	2,551	5,795
Cash used in operating activities	(4,285)	(4,744)	(459)
Cash used in investing activities	(5,315)	(15,874)	(10,559)
Cash used in financing activities	3,269	26,390	(23,121)
Net increase / (decrease) in cash	(6,331)	5,772	(12,103)
Exchange gains / (losses)	1	23	(22)
Cash at end of period	2,017	8,346	(6,329)

Units sold	
Hemo Control	35,579
STAT-Site M Hgb	17,874
DiaSpect T/Tm	15,249
Lactate Scout+	8,949
Quo-Lab A1c	4,522
HemataSTAT II	3,511
Biosen C-Line / S-Line	3,182
Quo-Test A1c	3,157
UltraCrit	2,146
Total	94,169



Tests sold 2015

	2014	2015	
Biosen	23,454,400	19,955,600	-17.53%
Hemo Control / HemoPoint H2	19,717,500	11,491,450	-41.72%
Hematastat II	6,634,000	10,377,000	36.07%
DiaSpect T and Tm	4,736,500	5,749,000	17.61%
UltraCrit	1,901,700	2,370,750	19.78%
STAT-Site M Hgb	1,674,200	1,097,500	-34.45%
Quo-Test A1c	641,940	876,480	26.76%
Quo-Lab A1c	637,750	869,750	26.67%
Lactate Scout+	705,768	751,824	6.13%
STAT-Site M BHB	213,600	277,500	23.03%
Total	60,317,358	53,816,854	-12.08%



Diabetes	Quo-Lab	Quo-Test	Biosen
Parameter	HbA1c	HbA1c	Glucose
Time to results	4 minutes	4 minutes	20-25 seconds
Accuracy	< 3% CV	< 3% CV	< 1.5% CV
Sample size	4 µl	4 µl	20 µl
Memory	7,000 results	7,000 results	1,000 results
Connectivity	LIS / printer	LIS / printer	LIS / printer
Manufactured	Germany	Germany	Germany
Analysers sold (2008-2015)	4,522	3,157	3,182
Tests sold (2015)	869,750	876,480	19,955,600



Diagnosics
for life



Point of
Care

Anemia	DiaSpect Tm	Hemo Control	UltraCrit	HemataSTAT
Parameter	Hemoglobin	Hemoglobin	Hematocrit	Hematocrit
Time to results	1 second	20 seconds	30 seconds	60 second spin
Accuracy	-	< 2% CV	< 0.8% CV	+/- 0.5%
Sample size	10 µl	8 µl	40 µl	-
Memory	None	4,000 results	-	None
Connectivity	2.0 Bluetooth	LIS	-	-
Manufactured	Germany	Germany	USA	USA
Analysers sold (2008-2015)	15,249	35,579	2,146	3,511
Tests sold (2015)	5,749,000	11,491,450	2,370,750	10,377,000



Diagnosics
for life



Point of
Care

Lactate	Lactate Scout+	SensPoint	Biosen
Parameter	Lactate	Lactate	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
Analysers sold (2008-2015)	8,949	-	3,182
Tests sold (2014)	751,824	-	19,955,600



Diagnostics
for life

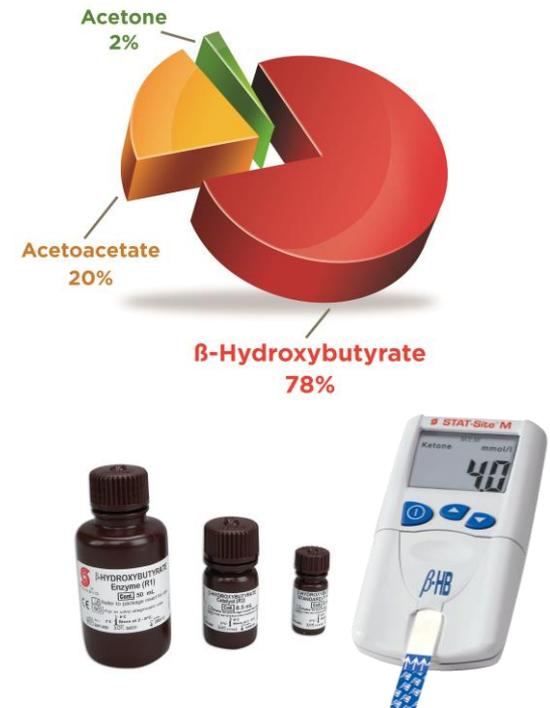


Point of
Care

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



Laboratory centrifuges

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



Diagnostics
for life



Central
Laboratory

Enzyme manufacturing

EKF Life Sciences

- Based in Elkhart, Indiana
- Certified ISO 13485: 2003 facility
- Relunched 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
- Sales up 8% 2012-2013

Contract manufacturing services

- Provides custom manufacturing, custom filling and custom packaging
- Sales doubled in 2013



Novel renal biomarkers

sTNFR1 & 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)

Thank you