



Universal Biosensors

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# Universal Biosensors, Inc.

ARBN 121 559 993

Investor Update

13<sup>th</sup> February 2014



# Important Disclaimer

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- This presentation is intended to provide a general outline only and is not intended to be a definitive statement on the subject matter. This presentation is not financial advice and has been prepared without taking into account the objectives, financial situation or needs of a particular person.
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- The Company is subject to a number of risks. For a summary of key risks, refer to the Company's most recent Form 10-K filed with the United States Securities and Exchange Commission.
- Under applicable United States securities laws all of the shares of our common stock are "restricted securities" as that term is defined in Rule 144 under the Securities Act of 1933, as amended. Restricted securities may be resold in the public market to United States persons as defined in Regulation S only if registered for resale or if they qualify for an exemption from registration under the Securities Act. We have not agreed to register any of our common stock for resale by security holders.



# Solid progress despite challenges

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## **The investment case remains compelling**

- ✓ Targeting large, growing Point-of-Care diagnostics (POCD) markets
- ✓ With a powerful POCD technology platform
- ✓ Profitable business with world leader LifeScan (J&J) in diabetes care
- ✓ Partnered with world leader Siemens in POC coagulation testing
- ✓ Pipeline of high value future product opportunities
- ✓ Experienced, high-calibre management team
- ✓ Generating revenues from worldwide sales

## **2013 has been challenging for UBI and its shareholders...**

- ✓ Challenging blood glucose monitoring (BGM) industry dynamics
- ✓ Verio meter recall by LifeScan
- ✓ Transfer of Verio strip production to LifeScan's own facility
- ✓ Siemens launch delays

## **...but the UBI team and our partners have responded**

- ✓ New Verio products launched
- ✓ Quarterly Service Fees returned to annual growth >50%
- ✓ UBI manufacturing operations restructured
- ✓ Continued commitment to earliest possible PT-INR launch
- ✓ Additional capital accessed with minimal shareholder dilution



# Contents

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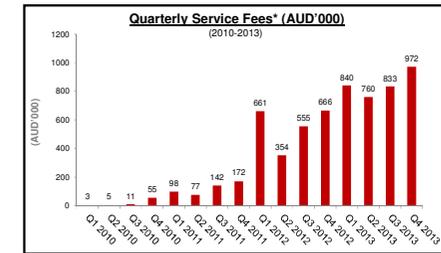
- Q4 FY2013 Update
  - ➔ ✓ **Blood Glucose Monitoring**
  - ✓ Coagulation Testing
  - ✓ Recent Financing
  - ✓ Financial Results
- Business Outlook



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# Blood glucose business has advanced

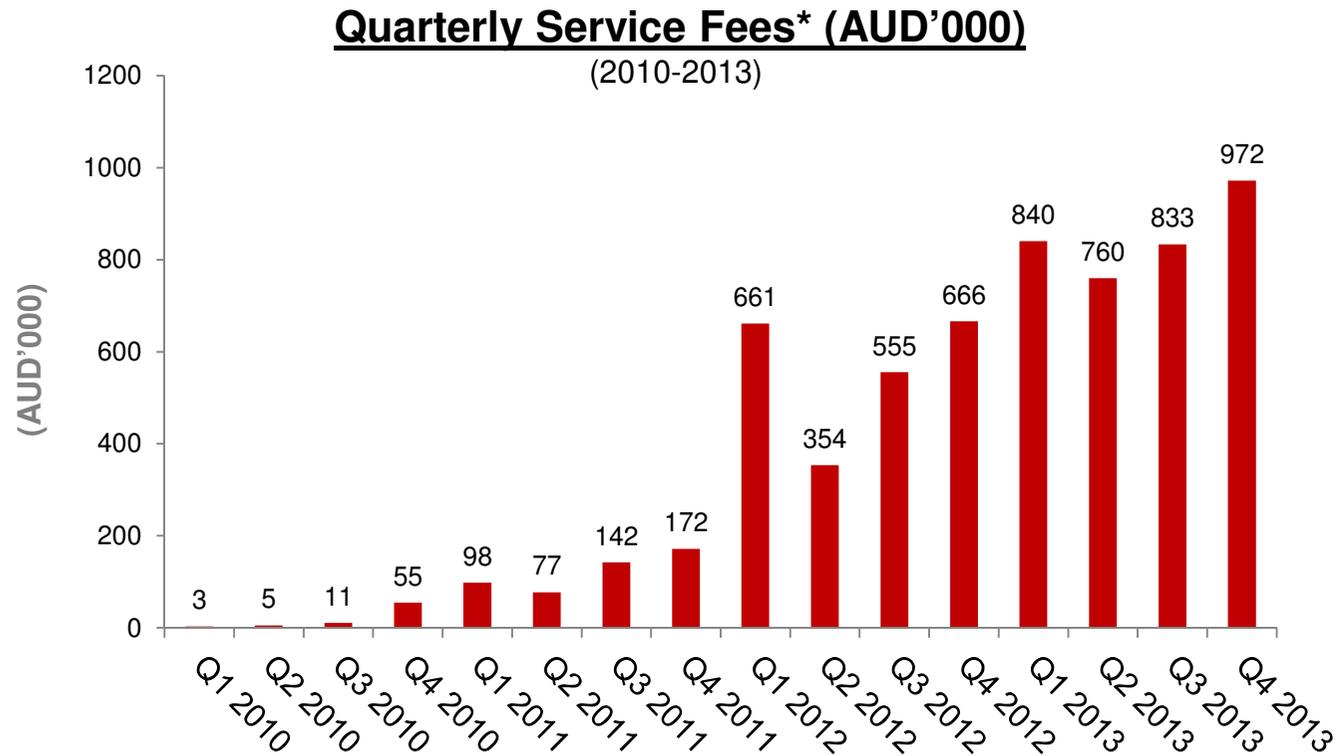
- Quarterly Service Fees growing strongly
  - ✓ \$972k in Q4 2013 is 46% higher than pcp
  - ✓ \$3.4M for FY2013 is 52% higher than pcp
- LifeScan announced the launch of the OneTouch VerioSync in January 2014
  - ✓ First system to wirelessly communicate blood glucose information to iPhone, iPad, iPod Touch
- Manufacturing on OneTouch Verio strips has been fully transitioned to LifeScan
  - ✓ Operations at UBI have been restructured (~\$400k restructuring costs in Q4 2013)
  - ✓ Business activity focused on higher margin activities





# Q4 Quarterly Service Fees up 46% on pcp

Quarterly Service Fees (QSF) represent a key value driver for UBI. Following LifeScan's worldwide meter recall at the end of March 2013 and a consequent dip in Q2, QSFs in Q4 maintained the recovery, up 46% on pcp. Full year QSFs increase by 52% over 2012 levels.



\*Quarterly Service Fees are based on the number of Verio strips sold by LifeScan

Source: UBI accounts - for important details relating to the terms of our commercial relationship with LifeScan, refer to our most recent Form 10K and agreements filed with the SEC.



# QSF growth despite BGM industry challenges

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- **Industry responds to margin pressures on BGM products in US market**

- Reduction in reimbursement in US now in effect
- Private label / “value” players competing on price
- Falls in reported US diabetes care revenues from JnJ (26% for Q4 vs pcp), Roche (27%\*) & Abbott (14%)
- Revenue decreases generally attributed to pricing, not volumes (eg Roche management referred to pricing pressures offsetting an increase in meter and strip volumes)
- Restructuring activity reported by major players in 2013



- **JnJ CEO, Alex Gorsky, comments following Q4 results:**

*“Over the course of 2013, given...some of the >70% reductions in some of the bidding here in US, we had to make necessary changes to our business model, which we did make during the year”*

*“We are committed in the diabetes space. The fact that there are over 350 million people with type 2 diabetes around the world and there is a great unmet medical need in that space, it’s important we continue to do work there.”*

\*Roche figures are for North America  
Source: [www.jnj.com](http://www.jnj.com); [www.closeconcerns.com](http://www.closeconcerns.com)

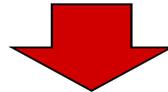


## ...while regulators demand greater accuracy

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- **Regulators demanding greater BGM performance / accuracy**

- June 2013: New ISO standard released (ISO 15197-2013)
- January 2014: FDA released new draft guidelines for BGM performance
  - more demanding than the new ISO standard
  - 90-day industry feedback process underway
- Additional focus expected on post market surveillance



- **Comments from industry:**

*“Tighter accuracy requirements clearly make the entry barrier higher for low-cost players trying to enter the arena. The big issue is ongoing, as quality control over time is where accuracy can really fall flat, especially for low cost providers”*

– CloseConcerns (Industry Analyst)

*“As far as retrospective application to devices that have already been cleared... these devices have somewhat of a lifespan... Manufacturers can only support them for so long because of availability of some of the components and just increases in technology that come along. At some point in time those would go away”*

- Courtney Lias (FDA)



# Blood glucose business profitable in 2013

## Profit & Loss – 12 Months Ended 31<sup>st</sup> December 2013

*LifeScan / Glucose Products only*

	AUD Millions
Revenue from strip manufacturing*	10.2
Revenue from R&D services**	-
Revenue from Quarterly Service Fees***	3.4
<b>Total revenue</b>	<b>13.6</b>
Cost of goods sold and services	10.4
<b>Gross margin</b>	<b>3.2</b>
<i>Gross margin as % of revenue</i>	<i>23%</i>

\* Revenue earned from strips sold to LifeScan, manufactured by UBI – “Product Revenues”

\*\* Includes fees earned providing R&D services to LifeScan, but excludes any payments received from Siemens during the period.

\*\*\* ~US1c Service Fee earned on every Verio strip sold by LifeScan



# Contents

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- Q4 FY2013 Update
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  - ➔ ✓ **Coagulation Testing**
  - ✓ Recent Financing
  - ✓ Financial Results
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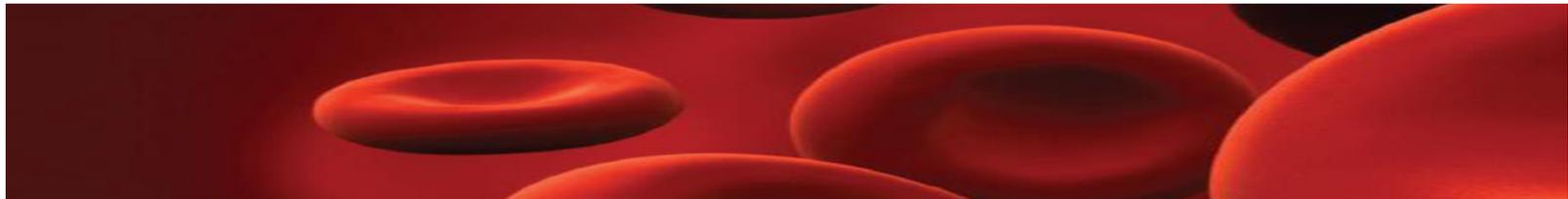


# Coagulation testing offers great potential

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## Why Coagulation is important for UBI:

- US\$1 Billion market for coagulation testing at the point of care
- Expands UBI technology to “professional” as well as “self-testing” markets
- Underpins UBI’s strip manufacturing capability
- Builds a powerful partnership with a world leader in diagnostics - Siemens
- Diversifies UBI’s business beyond
  - ✓ Blood glucose testing
  - ✓ LifeScan relationship
- UBI-owned offering in the self-testing market will build a platform for increased control and higher returns on future products
- Potential to create as much value for UBI as blood glucose testing





# Siemens POC coagulation

- **Target timetable:**

- ✓ launch of Siemens POC PT-INR testing system is expected in 2014
- ✓ revised strategy targets launch before end of Q3 2014
- ✓ Siemens & UBI focused on achieving earliest possible launch

- **Siemens demonstrating high commitment to launch:**

- ✓ high involvement in an integrated project team
- ✓ driving a high quality, competitive specification



- **Jointly working to:**

- ✓ obtain sufficient high-INR clinic data to complete system performance validation
- ✓ address residual risks and improvement opportunities
- ✓ manage the logistics of launch preparations

- **After completion of clinical trials, product approvals will be based on:**

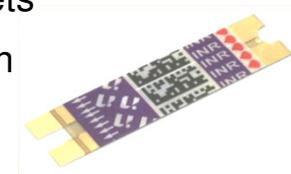
- ✓ self-certification for CE Mark and European launch
- ✓ FDA 510K process prior to US market launch



# UBI-owned coagulation test

## Opportunity:

- ✓ UBI-owned PT-INR testing system for decentralised settings including patient self-testing (PST), sold through specialist distributors in key markets
- ✓ \$200-300M market opportunity today, with potential for double-digit growth
- ✓ Opportunity for higher margin business under UBI control
- ✓ Distribution network provides channel for future UBI products



## Target timetable:

- ✓ Targeting launch in 2015



*Illustrative purposes only*

## Project status:

- ✓ 2<sup>nd</sup> generation prototype system nearing completion
- ✓ Distributor engagement accelerating
  - Lead candidates identified in key markets
  - Detailed MOUs being finalised for initial markets
- ✓ 3<sup>rd</sup> party meter manufacturing establishment underway





# Contents

---

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  - ✓ Coagulation Testing
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# Recent financing: overview

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## **Additional capital provides strength & confidence**

- push forward to launch of coagulation platform
- manage risk against external obstacles
- take UBI to profitability and cash generation

## **Using innovative structured financing (term loan + warrants)**

- cheaper than equity or royalty monetization
- greater alignment of interests than pure debt financing
- limited market appetite for equity raise

## **With an excellent and supportive business partner, Athyrium**

- international life-sciences industry specialists (US-based)
- have validated UBI future prospects
- proactive support of UBI via industry intelligence & networks



# Recent financing: deal structure

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## Deal specifics:

- \$16.0M received in December 2013, net of costs
- Further US\$10M available until 30<sup>th</sup> January 2015 under certain conditions, at UBI's option
- 5 year balloon repayment
- 10.5% interest, paid quarterly
- 4.5M warrants at \$1.00 strike price, 7 year life

*"The UBI management team's track record of creating commercial stage POC products with global partners such as LifeScan and Siemens is impressive. We are excited to invest in the Company's powerful technology platform and pipeline of high value future product opportunities, as we believe it will lead to significant innovation in both professional and consumer POC testing."*

**- Richard Pines, Athyrium Partner**



# Contents

---

- Q4 FY2013 Update
  - ✓ Blood Glucose Monitoring
  - ✓ Coagulation Testing
  - ✓ Recent Financing
  - ➔ ✓ **Financial Results**
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# Financial metrics (FY2013)

	12 months ended December 31 <sup>st</sup>			Comments
	2013 (A\$'M)	2012 (A\$'M)	Change	
<b>Quarterly Service Fees</b>	3.4	2.2	<b>Up 52%</b>	Ongoing market penetration
<b>Revenue from Products</b>	10.2	19.4	Down 47%	Transfer of glucose strip manufacturing to LifeScan's own facility
<b>Revenue from Services*</b>	1.5	8.0	Down 81%	No milestones payments or major contract R&D in 2013
<b>Total Revenue</b>	<b>15.1</b>	<b>29.6</b>	<b>Down 49%</b>	
<b>Cost of Goods Sold &amp; Services</b>	11.6	18.7	Down 38%	
<b>Contribution from Products &amp; Services</b>	<b>3.4</b>	<b>11.0</b>	<b>Down 69%</b>	
<b>R&amp;D Expense (net)</b>	9.2	13.5	Down 32%	4 products in development stage, offset by ~\$6M in R&D Tax Rebates in 2013
<b>G&amp;A Expense</b>	6.2	6.8	Down 9%	Spending restricted on non-core activities
<b>Financing costs</b>	0.8	0	Up \$0.8k	Related to structured financing
<b>Net Loss after Tax</b>	<b>11.6</b>	<b>9.1</b>	<b>Up \$2.5M</b>	
<b>Net Increase in Cash</b>	<b>0.1</b>	<b>8.6</b>	<b>Down \$8.5M</b>	Cash burn offset by additional funding received in Dec 2013

\*Excludes Quarterly Service Fees shown separately



## Financial summary: balance sheet

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### Balance Sheet as at 31 December 2013

	<b>A\$</b>
Current Assets (excluding cash)	12,047,157
Cash	23,742,422
Property, Plant & Equipment (net)	15,910,120
Other Non-Current Assets	2,920,000
Total Assets	<u>54,619,699</u>
Current Liabilities	5,422,287
Non-Current Liabilities	19,513,472
Stockholders' Equity	29,683,940
Total Liabilities & Stockholders' Equity	<u>54,619,699</u>



## Financial summary: capital structure

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Number of shares on issue	175,600,605
Market capitalization (at 3 <sup>rd</sup> February 2013)	A\$88 million
Number of options on issue	10.6 million
Cash (at 31 <sup>st</sup> December 2013)	A\$23.7 million
Equity raised since inception	A\$83.7 million



## Top 5 UBI shareholders

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Shareholder	31st December 2013	
	Holding	
<i>National Nominees Ltd</i>	10.6%	
<i>Talu Ventures Pty Ltd</i>	10.1%	
<i>The Principals Cornerstone Fund Pty Ltd</i>	9.9%	
<i>Australian Executor Trustees SA Ltd</i>	8.0%	
<i>RBC Investor Services</i>	5.3%	



# Contents

---

- Q4 FY2013 Update
  - ✓ Recent Financing
  - ✓ Blood Glucose Monitoring
  - ✓ Coagulation Testing
  - ✓ Financial Results

-  • **Business Outlook**



# UBI investment case

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- ✓ With a **powerful POCD technology** platform
- ✓ Profitable business with world leader **LifeScan (J&J)** in diabetes care
- ✓ Partnered with world leader **Siemens** in POC coagulation testing
- ✓ Pipeline of high value future product opportunities
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- ✓ **Generating revenues** from worldwide sales



# Value Drivers

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- Ongoing growth in Quarterly Service Fees (quarterly filings)
- Siemens POC PT-INR test
  - ✓ Commercial production
  - ✓ Regulatory approvals
  - ✓ Launch (2014)
- Other Siemens POC coagulation tests
  - ✓ Commercial production
  - ✓ Regulatory approvals
  - ✓ Launch (2015)
- UBI-owned PT-INR test for patient self-test & decentralised settings
  - ✓ Distribution agreements
  - ✓ Commercial production
  - ✓ Regulatory approvals
  - ✓ Launch (2015)



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