

# Universal Biosensors, Inc.

ARBN 121 559 993

Q1 2014 Results Update

12<sup>th</sup> May 2014



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- This presentation is intended to provide a general outline only and is not intended to be a
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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.



## Q1 2014 highlights vs prior comparable period

- Continued growth in Quarterly Service Fees
  - Quarterly Service Fees up 44% to \$1.2M

#### Improved profitability of operations

- Gross Margins up by 31% to \$1.3M
- First coagulation product launch on-track for 3<sup>rd</sup> Quarter launch
  - Net R&D spend up 10% to \$2.9M

#### Operating cash burn reduced

- Operating cash burn improved 15% to \$3.4M
- Cash balance
  - \$19.4M at quarter end



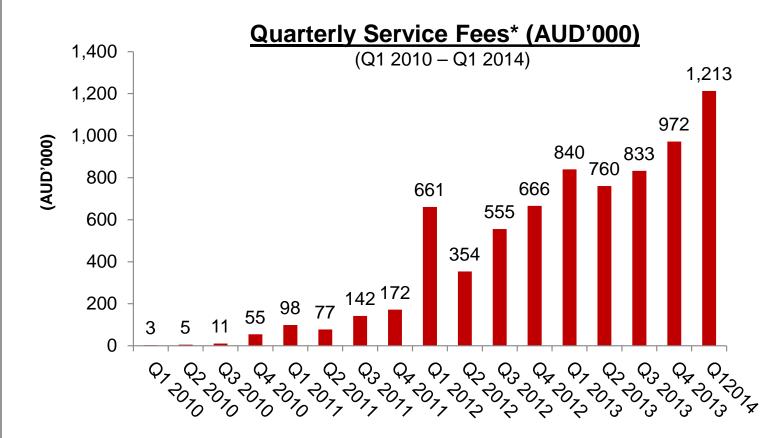
## • Business Update

#### ✓ Blood Glucose Monitoring

- ✓ Coagulation Testing
- Product Development Costs
- Financial Results Q1 2014

# **Fees from strip sales are growing rapidly**

Quarterly Service Fees (QSFs) generated from sales of OneTouch Verio test strips were \$1.21M in the first quarter of 2014. This represents an increase of 44% compared to the same period in the previous year and an increase of 25% compared to the prior quarter.



\*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.



- More evidence of tighter regulatory standards in BGM
  - ✓ FDA extended industry consultation process regarding new draft BGM performance guidelines to 7<sup>th</sup> May. Industry commentators expecting the final guidelines to reflect the initial draft.
  - ✓ European member states required under the IVD Directive to adopt new ISO standard 15197:2013 by November 2016. From this date, we expect that only product approved to the new standard can be sold in these markets
  - ✓ FDA advises patients and HCPs to stop using Shasta Technologies' generic GenStrip

"Big picture, we don't think companies making low-cost strips (generic or proprietary) have the requisite quality systems in place, a point reinforced by today's news. There is a clear need for post-market surveillance of blood glucose test strips."

Adam Brown & Kelly Close, Diabetes Industry Analysts



## More favourable indications for UBI

- Further expansion of Verio platform a positive for future strip sales
  - ✓ Launch of OneTouch VerioSync in US
  - ✓ Marketing of new OneTouch Verio system in Germany
- UBI Quarterly Service Fees (calculated on strip volumes rather than revenues) increasing rapidly in spite of pricing pressures in US BGM market.
  - ✓ JnJ report Q1 2014 US Diabetes Care\* revenues down 32% vs pcp to US\$192M, attributing this to "lower price primarily related to competitive bidding impact in the US"
  - ✓ Abbott report Q1 2014 US Diabetes Care\* revenues down 28% vs pcp to US\$97M attributed to competitive bidding and reimbursement
  - ✓ Bayer report Q1 2014 US Diabetes Care\* revenues down ~40% vs pcp to ~US\$300M as a consequence of *"tremendous price pressure"*



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## **Siemens POC coagulation on track**

#### PT-INR

- Target timetable unchanged:
  - ✓ Continue to target launch in Q3 2014
- Solid progress with Siemens on:
  - ✓ System performance validation
  - ✓ Resolving residual risks & improvements
  - ✓ Managing the logistics of launch preparations
- Product approvals based on:
  - ✓ Self-certification for CE Mark and European launch
  - ✓ FDA 510K process prior to US market launch

#### **Other POC Coagulation Tests (x2)**

• Targeting launch in 2015





## **UBI's home PT-INR test on track**

#### **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

#### **Project status:**

- ✓ 2<sup>nd</sup> generation prototype completed
- ✓ Distributor engagement accelerating
  - non-binding term sheets signed in jurisdictions which currently represent over 50% of the target market
  - inbound enquires from distributors in key markets
- ✓ Meter manufacturing establishment underway











- ✓ Blood Glucose Monitoring
- ✓ Coagulation Testing

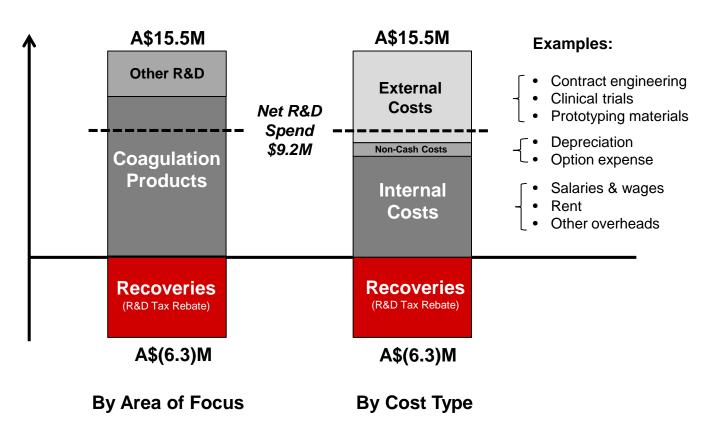
• Product Development Costs

• Financial Results – Q1 2014



UBI's FY2013 R&D Expenditure, net of recoveries was around \$9.2M. This was largely focused on 4 coagulation testing products that are all expected to be in market by the end of 2015. Of \$15.5M of expenditure, \$7.1M was made up of external costs that typically reduce following product launch. Net R&D spend in Q1 2014 was \$2.9M.

#### FY2013 R&D Expenditure Breakdown





## Growing product portfolio will drive value

#### Ongoing growth in Quarterly Service Fees

✓ Next data point expected in July

#### • Siemens POC PT-INR test

- ✓ Regulatory approvals
- ✓ Commercial production
- ✓ Launch (Q3 2014)

#### • Other Siemens POC coagulation tests

- ✓ Regulatory approvals
- ✓ Commercial production
- ✓ Launch (2015)

#### UBI-owned PT-INR test for patient self-test & decentralised settings

- ✓ Distribution agreements
- ✓ Regulatory approvals
- ✓ Commercial production
- ✓ Launch (2015)





- ✓ Blood Glucose Monitoring
- ✓ Coagulation Testing
- Product Development Costs

• Financial Results – Q1 2014

# **Financial metrics (Q1 2014)**

Despite lower Product Revenues driven by the transfer of glucose test strip production to LifeScan, the Contribution from Products & Services increased 31% versus the prior comparable period due to growth in Quarterly Service Fees that drop through to the gross margin line.

	3 months ended 31 <sup>st</sup> March			
	<b>2014</b> (A\$'M)	<b>2013</b> (A\$'M)	Change	Comments
Quarterly Service Fees	1.2	0.8	Up 44%	Increasing unit sales
Revenue from Products	0.0	3.7	Down 100%	UBI ceased low margin glucose strip manufacturing
Revenue from Services*	0.2	0.3	Down 38%	Based on partners' project requirements
Total Revenue	1.4	4.8	Down 72%	
Cost of Goods Sold & Services	0.1	3.8	Down 100%	UBI ceased low margin glucose strip manufacturing
Contribution from Products & Services	1.3	1.0	Up 31%	Quarterly Service Fees flowing straight through
R&D Expense (net)	2.9	2.7	Up 10%	4 products nearing commercialisation, offset by R&D tax rebates
G&A Expense	1.4	1.3	Up 6%	No material change
Financing costs	0.7	0.0	Up \$0.7M	Cost of debt financing
Net Loss after Tax	3.6	4.6	Improved 23%	
Operating Cash outflow	3.4	4.0	Improved 15%	

\*Excludes Quarterly Service Fees shown separately



## **Financial summary: balance sheet**

#### Balance Sheet as at 31 March 2014

Currrent Assets (excluding cash) Cash Property, Plant & Equipment (net) Other Non-Current Assets Total Assets **A\$** 12,782,655 19,464,748 15,579,609 2,920,000 50,747,012

Current Liabilities	5,745,182
Non-Current Liabilities	19,114,415
Stockholders' Equity	25,887,415
Total Liabilities & Stockholders' Equity	50,747,012

Universal Biosensors	Financial summary: capital structure				
	Number of shares on issue	175,608,938			
	Market capitalization (at 6 <sup>th</sup> May 2014)	A\$65 million			
	Number of options on issue	10.1 million			
	Cash (at 31 <sup>st</sup> March 2014)	A\$19.5 million			
	Cash (at 31 <sup>st</sup> March 2014)	A\$19.5 million			



## **Substantial shareholders**

Shareholder	31 <sup>st</sup> March 2014 Holding
National Nominees Ltd	10.3%
Talu Ventures Pty Ltd	10.1%
The Principals Cornerstone Fund Pty Ltd	9.9%
Australian Executor Trustees SA Ltd	8.0%
HSBC Custody Nominees (Aust) Ltd	5.0%
Talu Ventures Pty Ltd The Principals Cornerstone Fund Pty Ltd Australian Executor Trustees SA Ltd	10.3% 10.1% 9.9% 8.0%



- ✓ Targeting the attractive Point-of-Care diagnostics (POCD) market
- ✓ 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
- ✓ ASX-listed, SEC compliant, US Company



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