



Universal Biosensors

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# Universal Biosensors, Inc.

ARBN 121 559 993

Bell Potter Life Sciences Conference

November 2012



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# UBI in summary

## Powerful technology for growing POC diagnostics markets

- Point-of-care (“POC”) diagnostics is ~\$15Bn market with ~11% growth pa
- Electro-chemical sensor technology, protected by 44 patent families...
- ...enables easy-to-use, accurate, low cost diagnostics using a handheld reader & disposable test strips, ideal for POC applications

## World-scale strip manufacturing plant in operation

- ISO13485 certified, fully automated, world-scale manufacturing in place
- Includes capacity to produce >750M glucose test strips p.a.

## 1<sup>st</sup> product, used to manage diabetes, now being sold in major world markets by LifeScan

- Blood glucose self-testing market is \$10Bn worldwide, growing ~10% pa
- LifeScan (J&J) sells 4-5Bn glucose test strips p.a. (~27% market share)...
- ...now sells glucose strips developed with UBI in >85% of world markets
- UBI earns ~US1c per Verio strip sold, and a transfer price on supply
- UBI has demonstrated feasibility of a novel glucose testing product

## 2<sup>nd</sup> product, for POC PT-INR testing, planned to launch in 2013 with Siemens

- UBI partnership with Siemens in “professional” POC coagulation testing
- PT-INR testing market estimated at ~\$700M today, growing at ~15% p.a.
- Aim to launch PT-INR test in 2013; other POC coagulation tests to follow
- UBI revenues from R&D milestones, strip manufacturing & profit share

## R&D will broaden UBI’s test menu

- UBI will apply its strip technology to immunoassay & molecular tests...
- ...while using proven strip designs to expand test “menu” cost effectively

## UBI aims to be a leader in POC diagnostics

- UBI’s capability has now been validated by 2 world-leading companies
- UBI’s early glucose business generating positive gross margins
- New products will leverage manufacturing investment and build profits
- Cash balance: \$13.9M (30/9/12), with prior 9 month cash burn of \$1.2M
- UBI is ASX-listed with market capitalisation of ~\$140M (24<sup>th</sup> Oct 2012)



# Contents

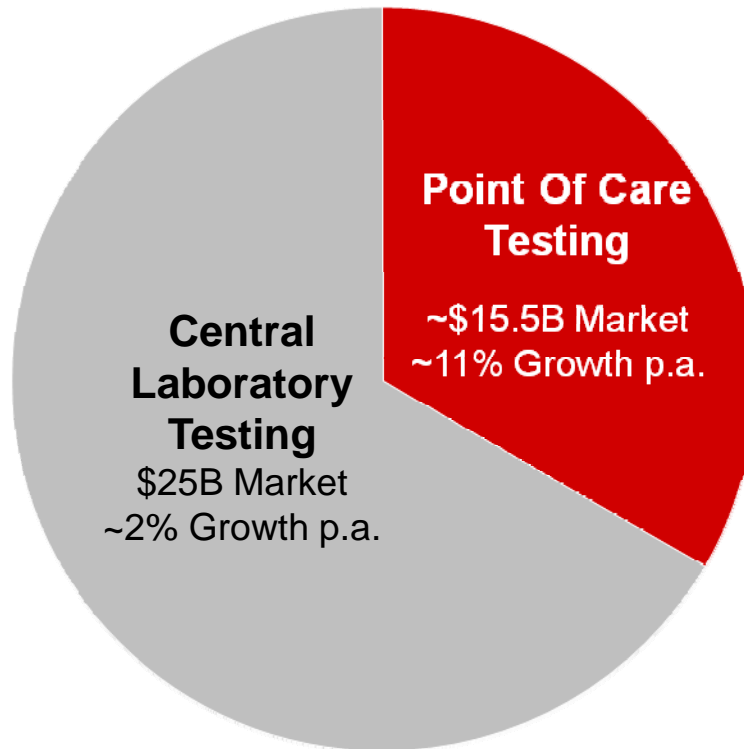
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- ➔ • **UBI Overview**
  - Blood Glucose Monitoring
  - Coagulation Testing & Beyond
  - Milestones & Financials



# UBI targets the \$15B, growing POC market

## Global In Vitro Diagnostics Market (2010 estimate)



### Point of Care Growth Drivers

- ✓ Improved Health Economics (lower cost and better outcomes)
- ✓ Supports:
  - more timely diagnosis
  - increased frequency of testing for improved health outcomes
    - Management of chronic disease
    - Monitoring the effectiveness of a therapy
  - distributed healthcare for regional & remote areas as well as emerging economies



# Using UBI's powerful diagnostic technology

- **Well suited to Point-of-Care**

- ✓ **Easy to use**

*(requires small drop of blood from finger-prick)*

- ✓ **Accurate results**

*(results that are accurate for each individual)*

- ✓ **Low cost to manufacture**

*(supports fully automated, scale manufacturing)*

- **Broad application**

- ✓ **Across analytes**

*(enzymes, immunoassay, molecular)*

- ✓ **Across geographies**

*(mature & emerging markets)*

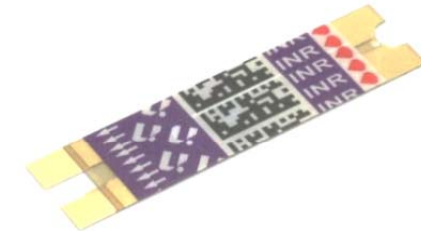
- ✓ **Across diagnostic settings**

*(hospital, clinic, physician's office, home)*

- **Patent protected**

*(44 patent families)*

## Disposable Test Strips

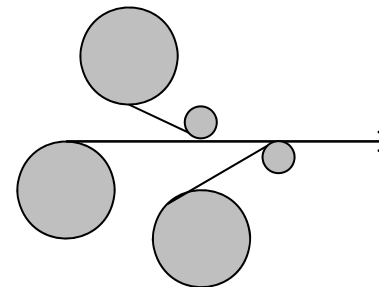
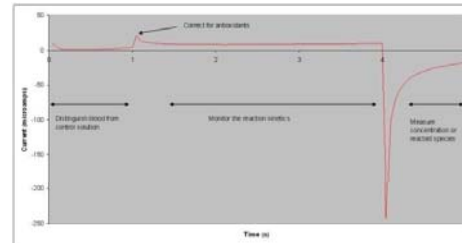
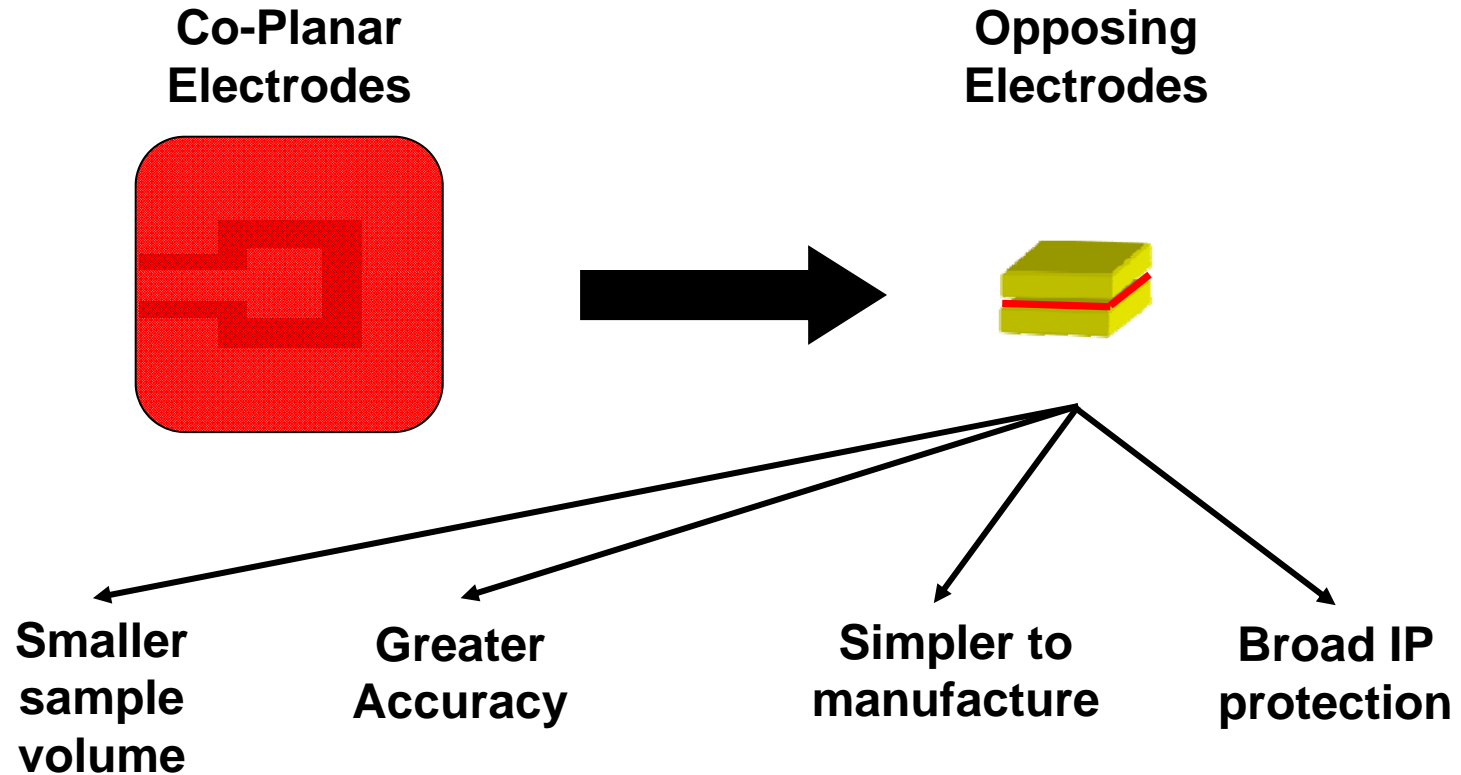


## Handheld Readers





# A paradigm shift in electrochemical sensors





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## ...and low cost, scale manufacturing



- ISO 13485
- Highly automated
- Custom designed
- Scale appropriate

- Existing capacity to produce >750M glucose strips p.a.







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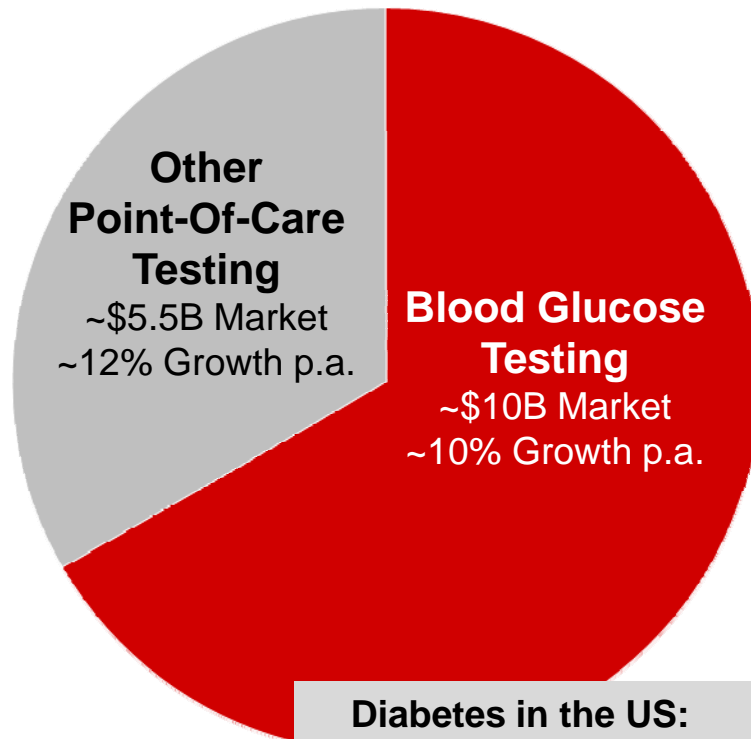
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# 1<sup>st</sup> target: the \$10B blood glucose segment

## Global Point-Of-Care Diagnostics Market (2010 estimate)



### Blood Glucose Growth Drivers

- Increased life expectancy of diabetes sufferers
- Growing incidence of diabetes in all geographies
- Technology improvements
- Increasing patient awareness

### Diabetes in the US:

- Type II prevalence doubled in US from 1990 to 2005;
- ~8.3% of US population affected;
- ~7 million people in US undiagnosed today;

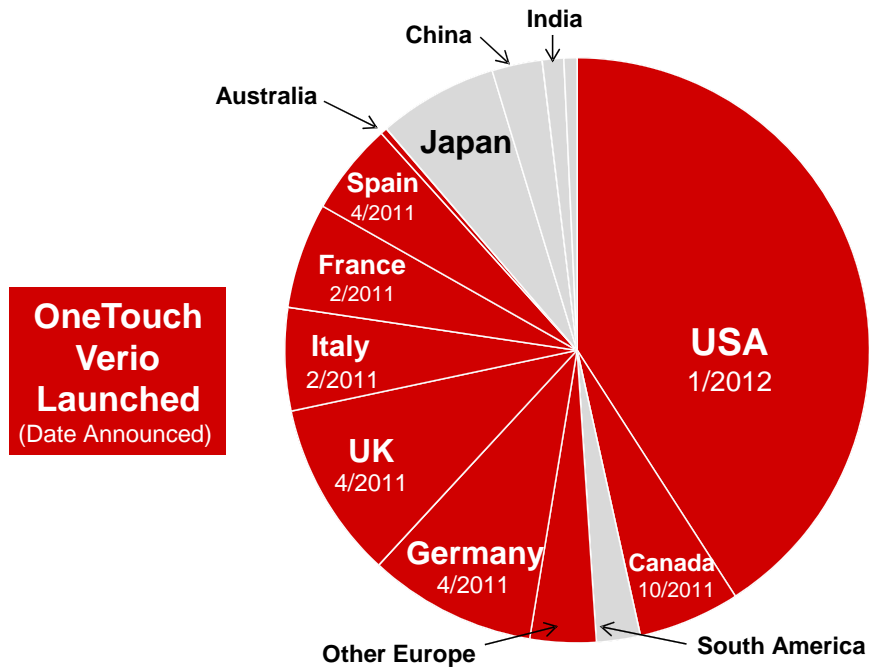


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# Global roll-out in \$10B SMBG market



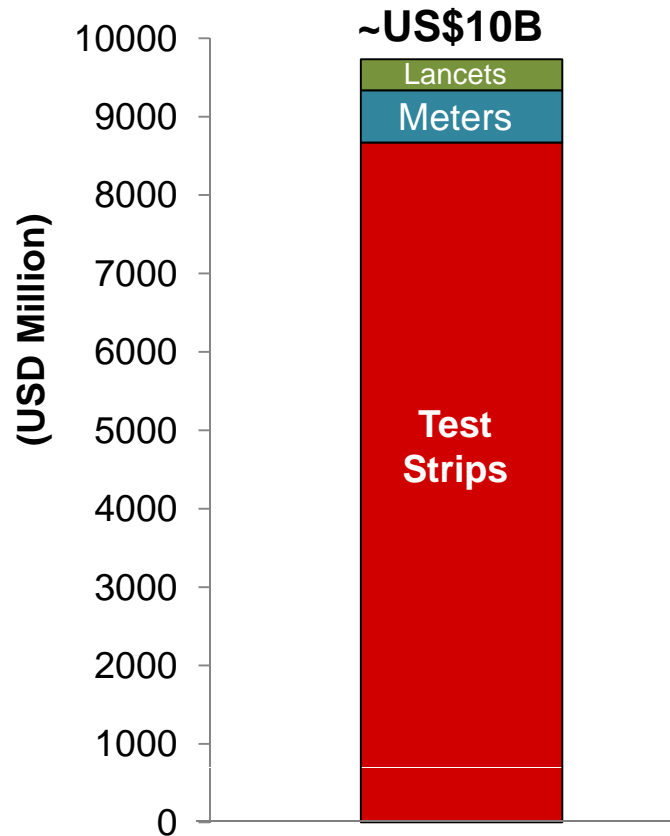
Self Monitored Blood Glucose Market  
(2015 estimate\*)



Source: Global Data, SMBG Market Study Nov 2009  
Note: images on this page are not representative of actual products approved in all markets.

# SMBG is a “consumable” driven business

**Worldwide SMBG Market**  
(2012 Est)



**OneTouch Verio**

Initial launch in The Netherlands and Australia (2010)



**OneTouch Verio Pro**

Launched in Europe (2011)



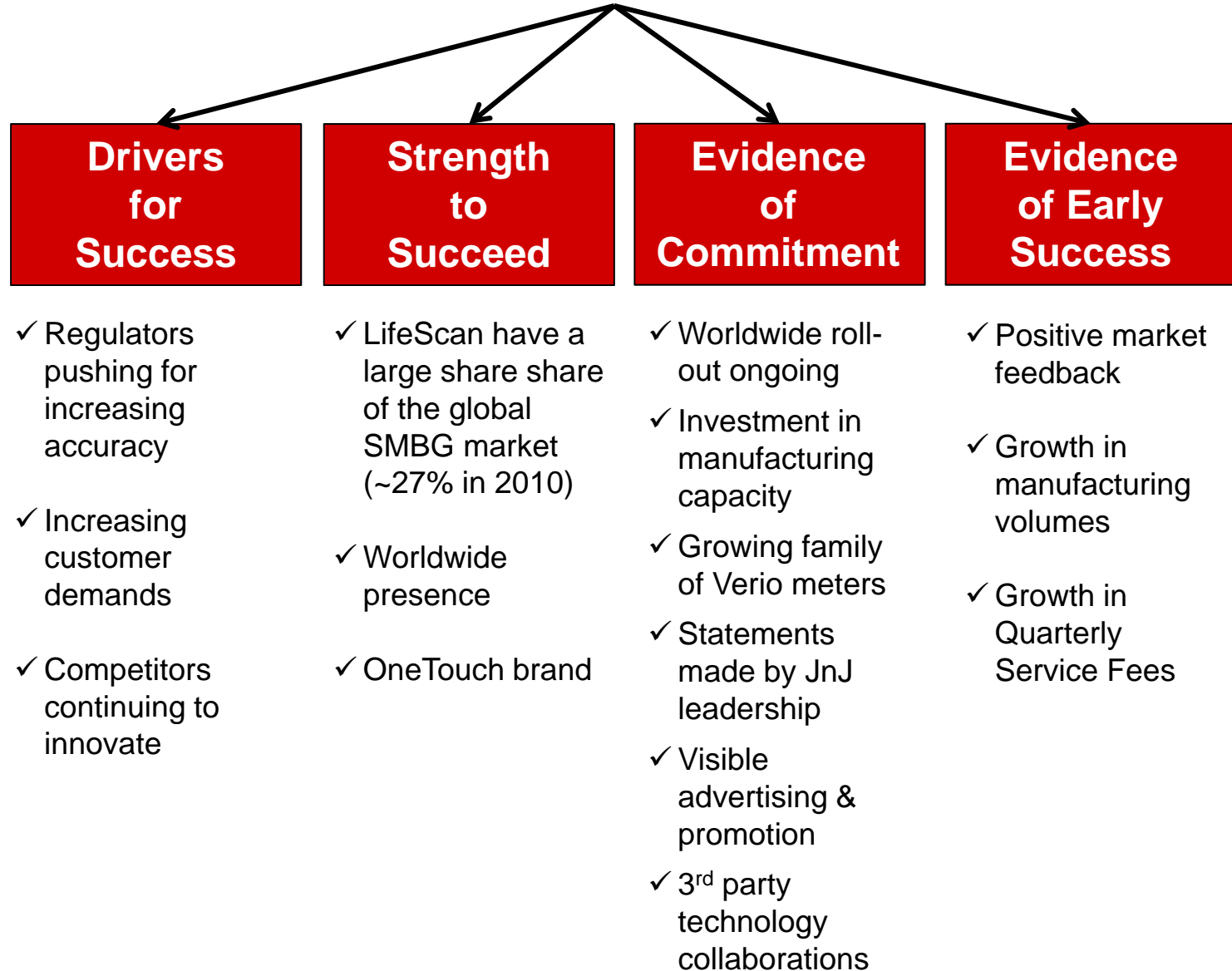
**OneTouch Verio IQ**

Launched in Canada (2011), USA, major European markets and Australia (2012)





# Reasons to believe in success...





# LifeScan / blood glucose - economics

Revenue Source	Revenue Detail
<b>Quarterly Service Fees</b> <i>(included in "Revenue from Services" in published financial statements)</i>	<b>~ US1c received for each Verio strip <u>sold</u> by LifeScan</b> <ul style="list-style-type: none"><li>• Irrespective of source of manufacture</li></ul>
<b>Manufacturing Revenues</b> <i>(included in "Revenue from Products" in published financial statements)</i>	<b>Received for all strips <u>supplied from UBI factory</u></b> <ul style="list-style-type: none"><li>i) At low volumes ("Interim Costing Period"): fixed overhead contribution</li><li>ii) At higher volumes: Standard Cost + modest margin</li></ul>
<b>R&amp;D Services</b> <i>(included in "Revenue from Services" in published financial statements)</i>	<b>Received for <u>R&amp;D / services</u> provided by UBI</b> <ul style="list-style-type: none"><li>• Typically time &amp; materials cost plus margin</li></ul>
<b>R&amp;D Milestones</b> <i>("Milestone Payments")</i>	<b>Received on hitting <u>R&amp;D or Regulatory milestones</u></b> <ul style="list-style-type: none"><li>• Typically where UBI has taken some level of technical risk</li></ul>

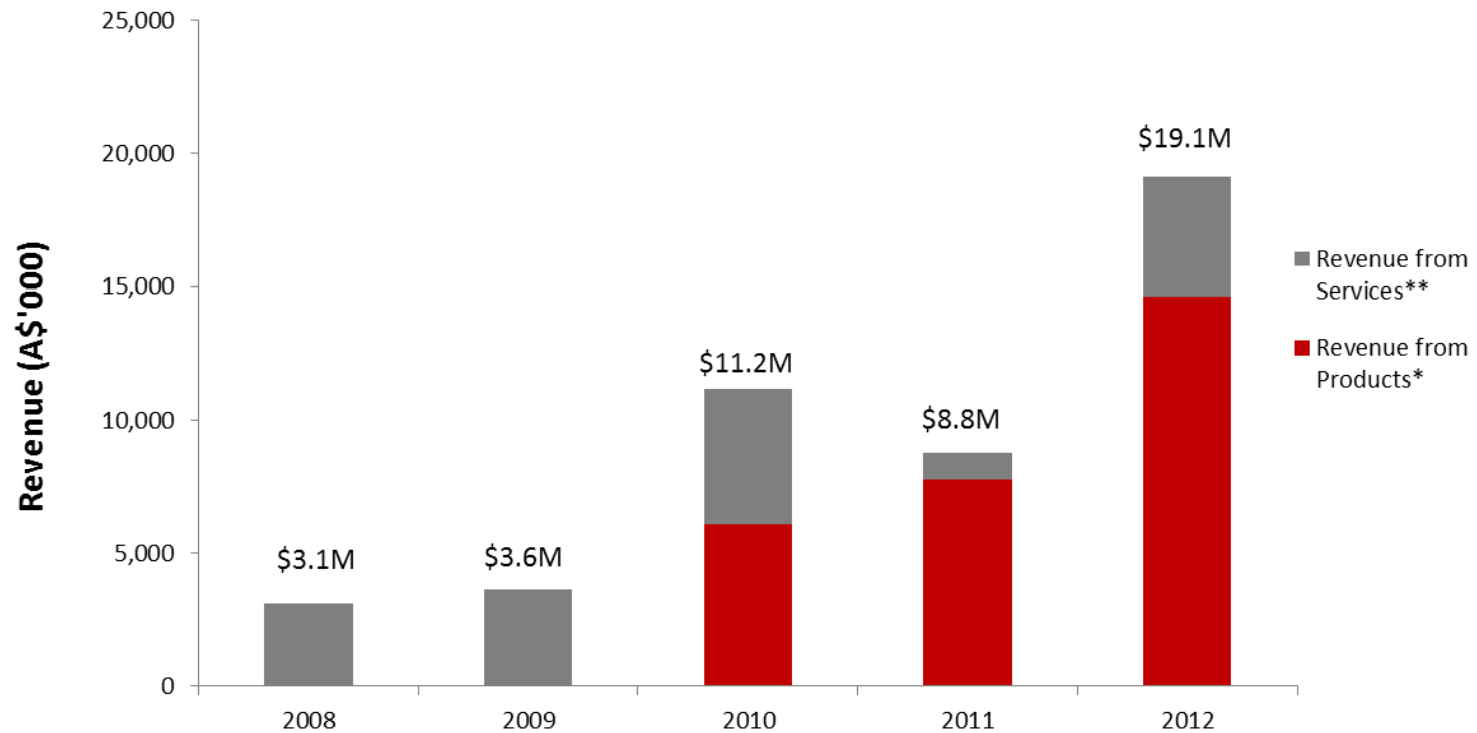
For important details relating to the terms of our commercial relationship with LifeScan, refer to our most recent form 10K and agreements filed with the SEC.



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# The “glucose business” is growing

## 9 Months YTD UBI Revenues from LifeScan (2008-2012)



\* Revenue earned from strips manufactured for LifeScan by UBI

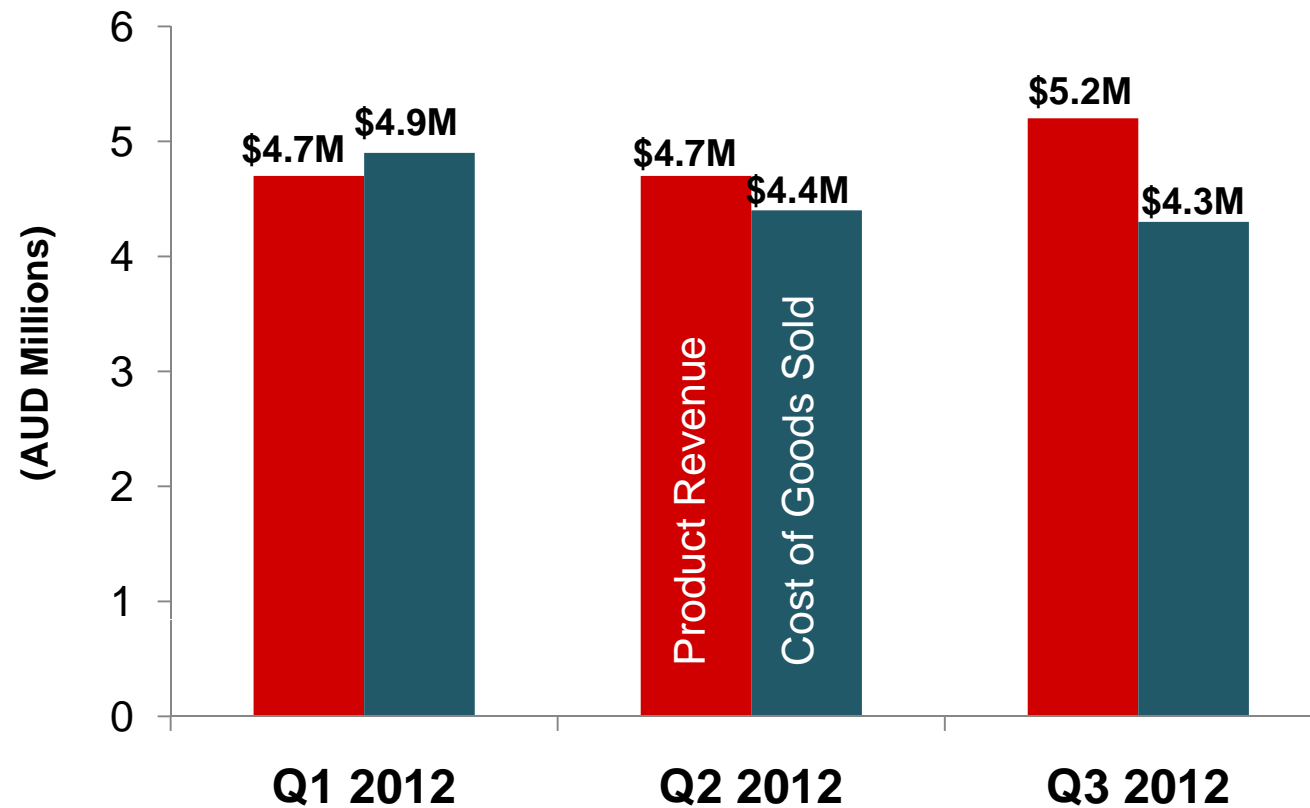
\*\* Includes U\$1c Service Fee on every Verio strip sold by LifeScan and fees earned providing R&D services to LifeScan but excludes the milestone payment received from Siemens during the 2012 period.



# Manufacturing efficiency is improving

## Quarterly Product Revenues & COGS

(AUD Millions)

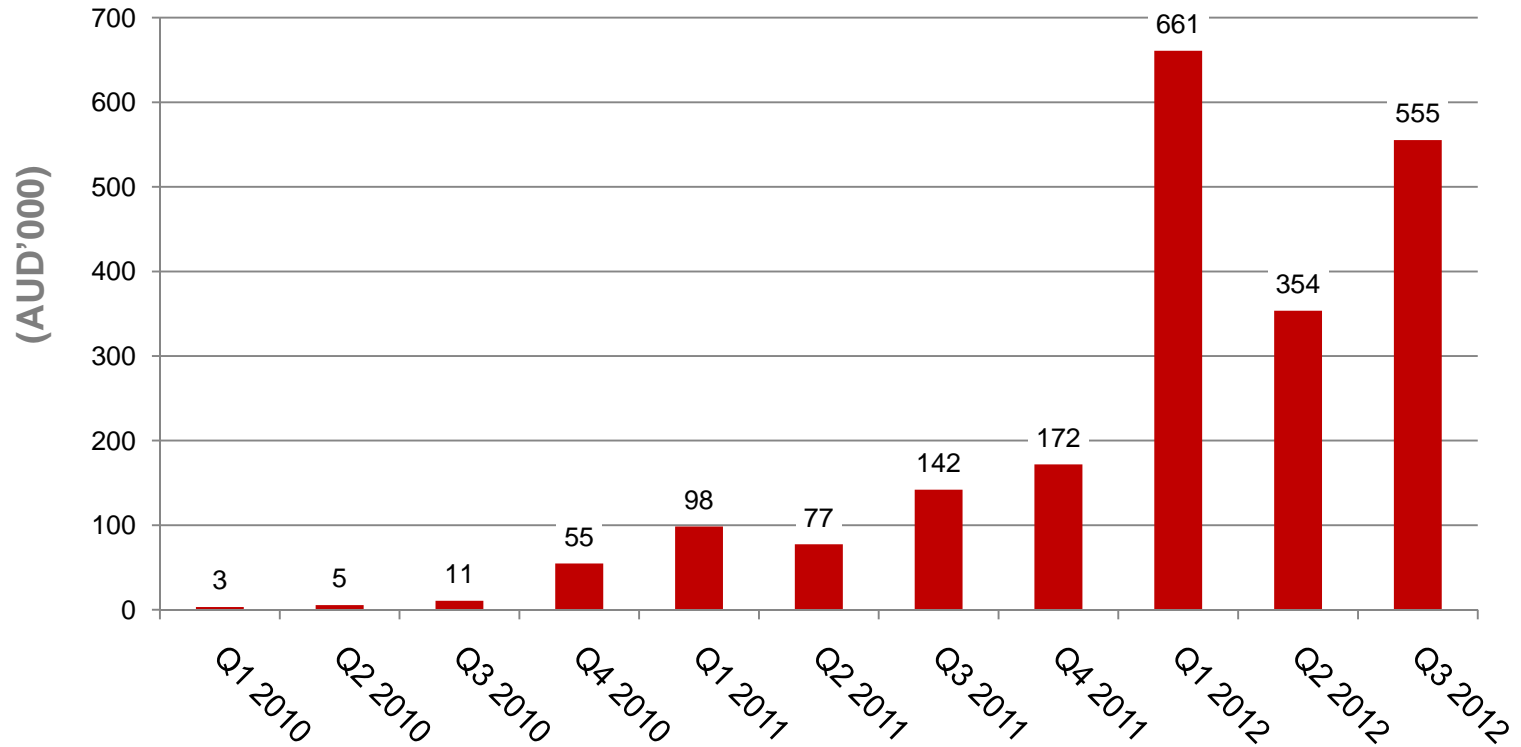






# Quarterly Service Fees are building

**Quarterly Service Fees\* (AUD'000)**  
(2010-2012)



\*Quarterly Service Fees are based on the number of Verio strips sold by LifeScan  
Source: UBI accounts (2010-12)



# The “glucose business” is profitable

## Profit & Loss - 9 Months Ended 30 Sept 2012 *LifeScan / Glucose Products only*

	<u>AUD</u>
Revenue from products*	14,615,281
Revenue from services**	4,484,671
	<u>19,099,952</u>
Cost of goods sold and services	14,244,086
Gross Margin	<u>4,855,866</u>
Gross Margin as % of Revenue	<u>25%</u>

\* Revenue earned from strips sold to LifeScan, manufactured by UBI

\*\* Includes ~US1c Service Fee earned on every Verio strip sold by LifeScan + fees earned providing R&D Services to LifeScan, but excludes the milestone payment received from Siemens during the period.



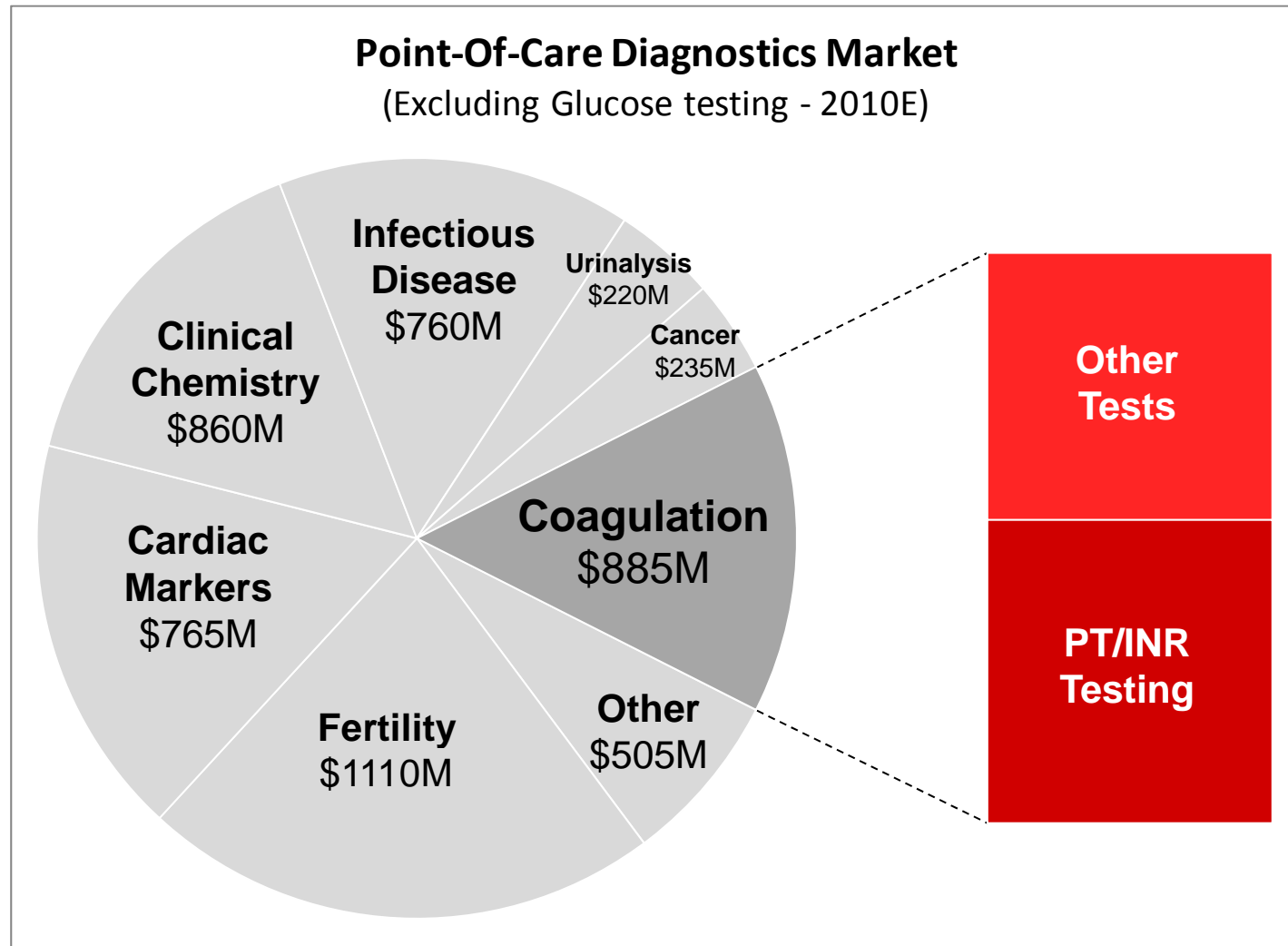
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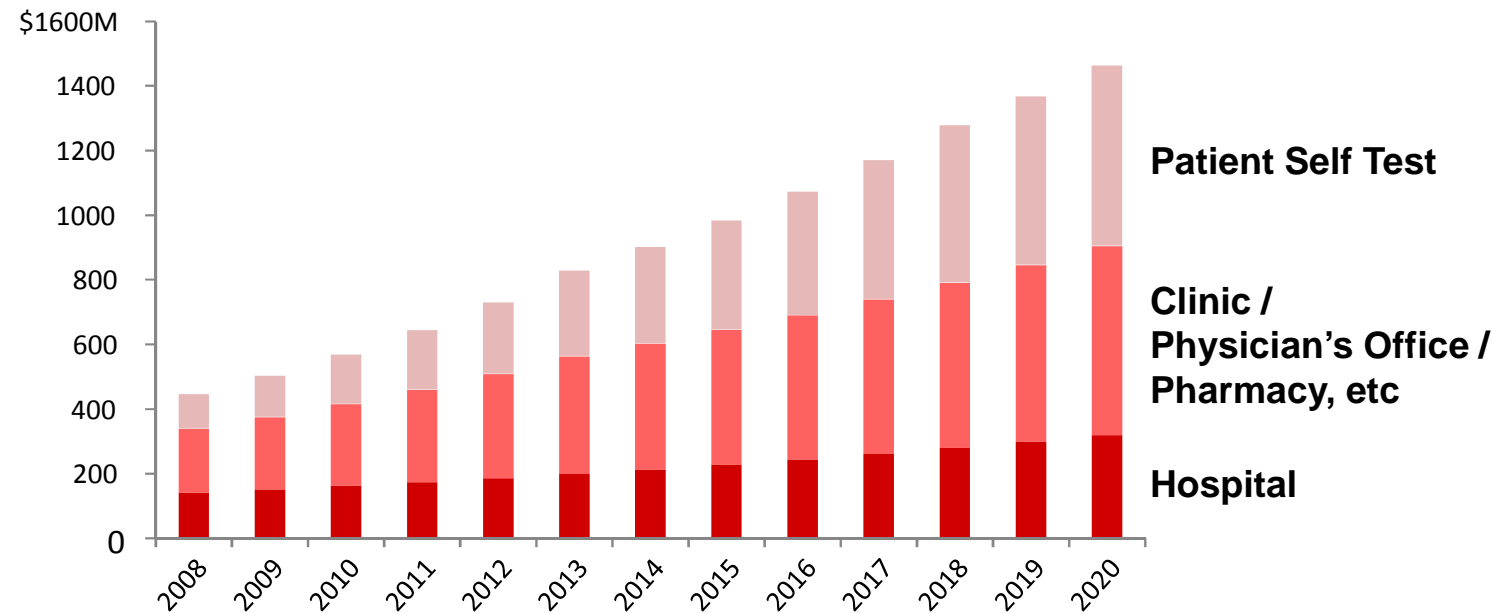
# Next opportunity: POC coagulation testing





# POC PT-INR testing will grow strongly

## Global POC PT/INR Market Projection (US\$M)



### Market growth driven by:

- ✓ growing patient population
- ✓ ongoing Warfarin use (>7 million users in 2010)
- ✓ health benefits of increasing testing frequency (towards weekly)
- ✓ US Medicare reimbursement of weekly test at ~\$5.53 / test

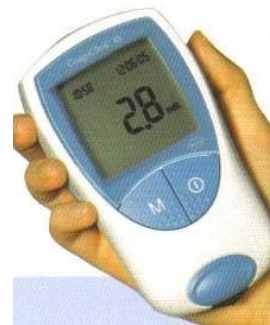


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# Roche dominates POC coagulation testing

## World POC coagulation testing market

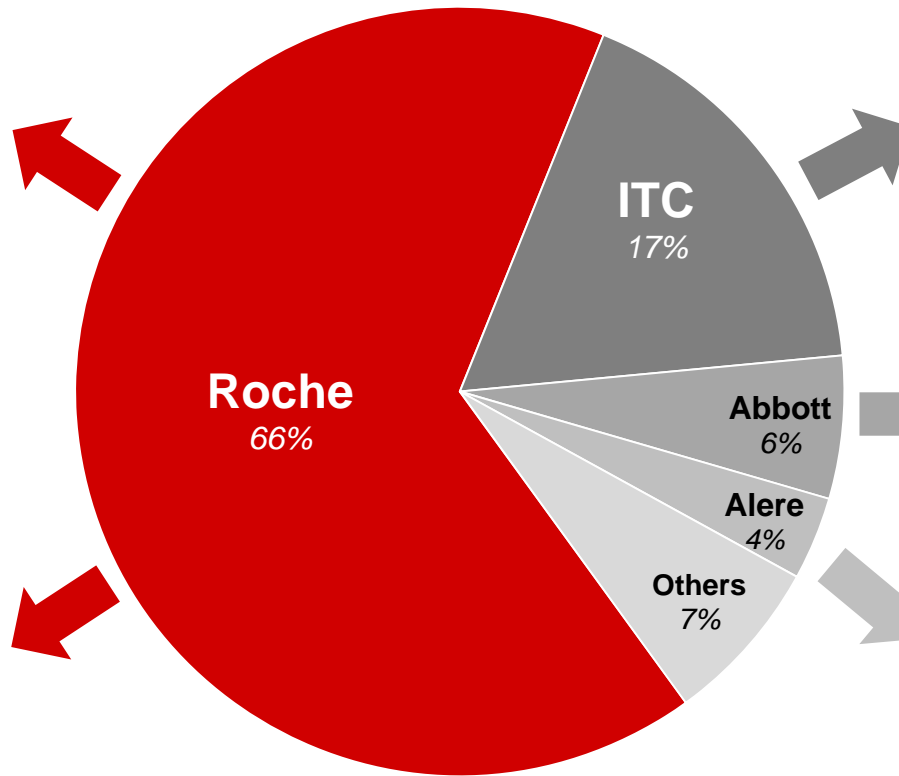
(Market share & product examples - 2012)



CoaguChek XS



CoaguChek XS Pro



ITC ProTime



Abbott i-Stat



Alere INRatio2

Source: Management estimates



# PT/INR offers good economic potential

## Maximum annual earnings opportunity (at 100% market share):

- Consider a target audience of >7 million Warfarin patients worldwide
- Assume 100% of this market
- Consider PT/INR monitoring frequency ranging from 4-weekly to weekly
- Consider earnings per test strip ranging from \$0.50 to \$1.50

Annual Earnings Opportunity <i>(at 100% market share)</i>	Indicative Earnings per Strip		
Indicative Testing Frequency	\$0.50	\$1.00	\$1.50
Once every 4 weeks (~91M tests/annum)	\$45M	\$91M	\$136M
Once every 2 weeks (~182M tests/annum)	\$91M	\$182M	\$273M
Once every week (~364M tests/annum)	\$182M	\$364M	\$546M

*Note: this analysis is intended to illustrate the scale of the opportunity within PT/INR testing across a range of input assumptions and in no way represents a forecast of likely UBI earnings.*



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# Siemens – a powerful partner for UBI

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+

SIEMENS

- **Partnership in the worldwide Coagulation market**
  - ✓ Excludes patient-self-testing segment which UBI is free to pursue separately
- **Multiple coagulation products to be developed**
  - ✓ PT/INR product first to launch (planned for 2013)
  - ✓ Further products to follow
- **Initial technology fee of \$3 million and a series of 6 payments tied to product development milestones to fund a significant portion of the R&D effort (2 out of 6 have been achieved)**
- **UBI will manufacture test strips exclusively**
- **Siemens to sell & distribute the products worldwide**

*For important details relating to the terms of our commercial relationship with Siemens, refer to our most recent form 10K and agreements filed with the SEC.*





# Emerging coagulation product portfolio

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PT-INR testing system:  
- launch expected 2013



Coagulation test #2:  
- feasibility achieved June 2012  
- now in development



Coagulation test #3:  
- feasibility achieved July 2012  
- now in development



# Strip Supply Agreement now in place

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- ✓ UBI is the exclusive manufacturer to Siemens of 3 test strips for POC coagulation testing
- ✓ Siemens has option to take over manufacturing and pay UBI a “per-strip fee”:
  - When UBI has supplied a certain (large) volume of strips
  - If UBI repeatedly fails to supply
- ✓ Transfer price of each strip is based on annual volumes
- ✓ UBI participates in upside via a profit share mechanism
  - UBI receives a percentage of any revenues received by Siemens above an agreed forecast level
- ✓ UBI will receive \$1.7M for delivering on additional reader requirements



# UBI's next opportunity: PT-INR Self Testing

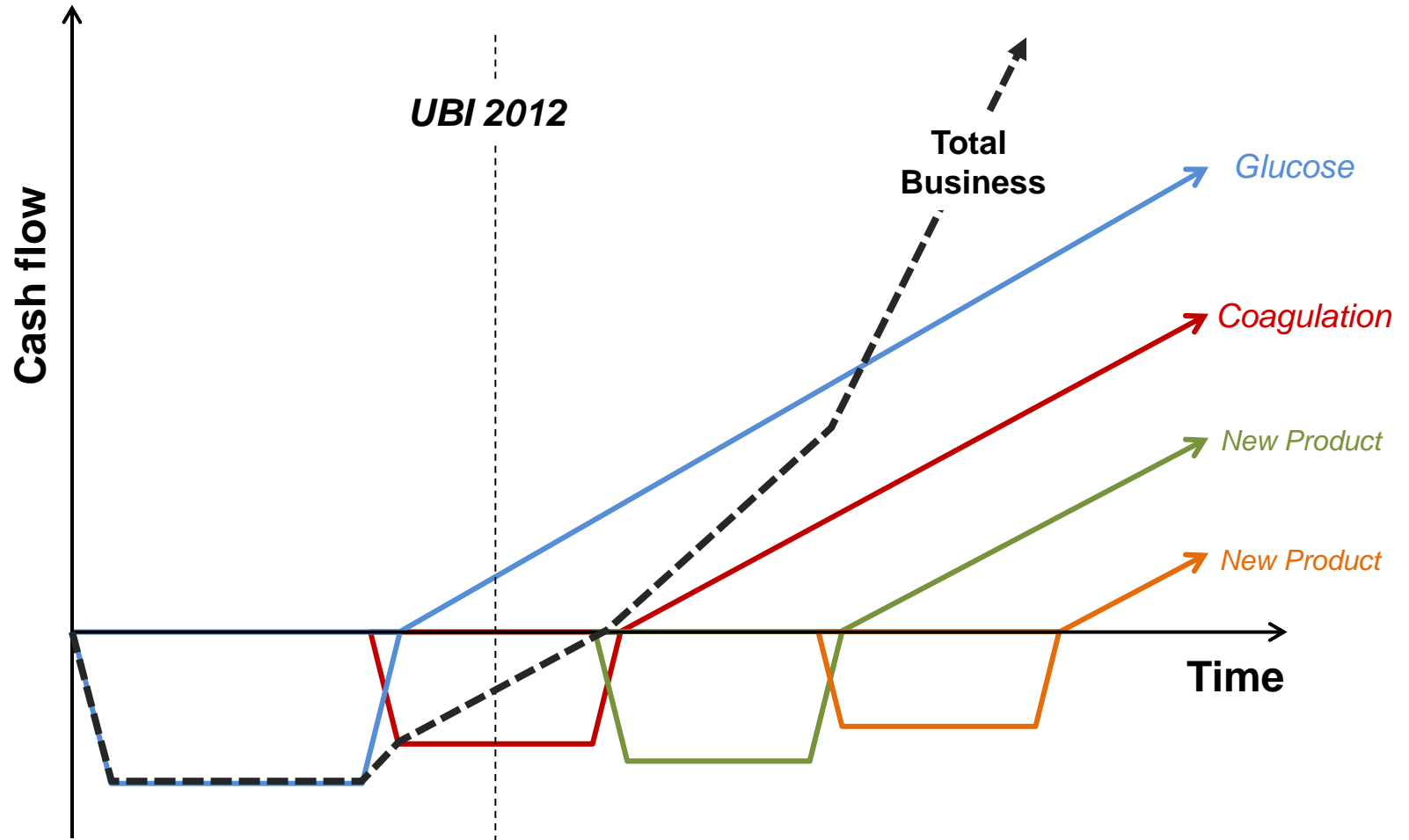
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- ✓ PT-INR growth opportunity
  - Greater convenience = more frequent testing = better health
  - Reimbursement supports move to weekly and self testing
  
- ✓ Different from the professional market
  - ✓ Typically served by different channels
  - ✓ With distinct user requirements
  
- ✓ UBI currently in discussions with channel partners / end users
  
- ✓ Further development required to meet self test needs



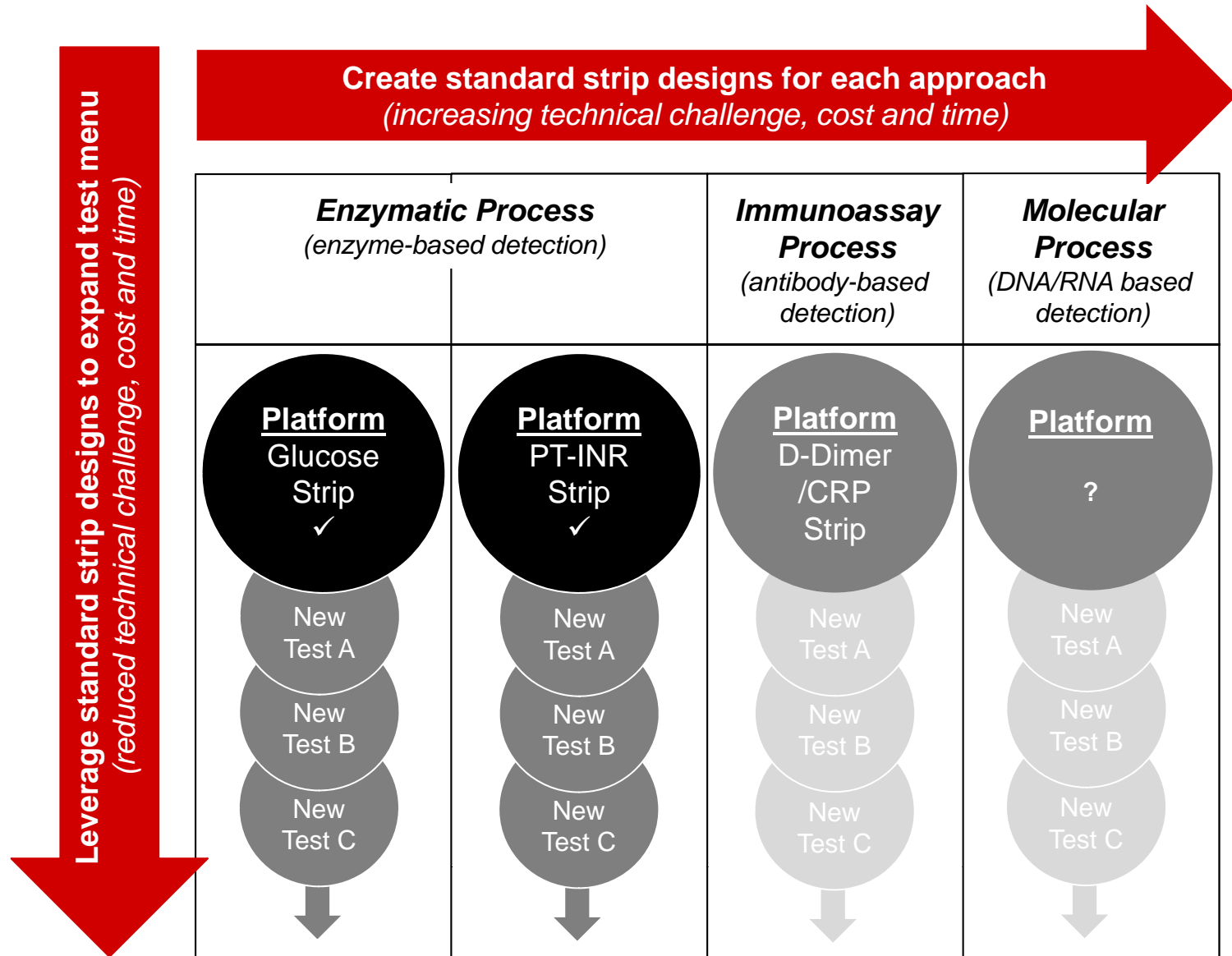
# Ongoing R&D drives earnings growth

Diagnostic Business Schematic  
(Indicative Cashflow vs Time)





# R&D balances strip design vs menu expansion





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- ➔ • **Milestones & Financials**



# Future near term milestones

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Verio (US1c) Quarterly Service Fees increasing	Quarterly	✓
Achieve feasibility of novel glucose test for LifeScan	Q4 2012	✓
Secure role in subsequent development program	Q4 2012	
First R&D milestones for Siemens completed	2012	✓
Supply Agreement signed with Siemens	Q3 2012	✓
Launch of PT-INR product with Siemens	2013	
Patient Self Test PT-INR route-to-market partner secured	2013	
Immunoassay platform feasibility demonstrated	2012	
Rapid DNA detection using UBI strip technology demonstrated	2013	



## Financial metrics (Q3 2012)

	9 months to 30 September		Change
	2012 A\$ Millions	2011 A\$ Millions	
Revenue from Products*	14.6	7.7	Up 89%
Revenue from Services**	8.8	1.0	Up 742%
Quarterly Service Fees	1.6	0.4	Up 321%
Total Revenues	23.4	8.8	Up 166%
Contribution from Products & Services	9.1	0.0	Up \$9.1M
R&D Costs	9.2	7.0	Up 30%
G&A Costs	4.7	5.2	Down 11%
Nett profit (loss) after tax	(4.7)	(11.3)	Down \$6.6M
Nett increase (decrease) in cash	(1.2)	(4.5)	Down \$3.3M

\*Sales to LifeScan of Verio strips manufactured by UBI

\*\*Includes Siemens Milestone, R&D Services & Quarterly Service Fees





# Profit & Loss: Indications for 2012 & 2013

AUD	Q3 YTD 2012	Change on 2011	Expectations for Q4 2012	Expectations for FY2013
Revenue from Products*	\$14.6M	Up 89%	<ul style="list-style-type: none"> <li>Expect similar levels of glucose strip production at UBI</li> </ul>	<ul style="list-style-type: none"> <li>Uncertain. But expect glucose strip production at UBI to be no less than FY12</li> <li>Expect first production of PT/INR strips for Siemens</li> </ul>
Revenue from R&D Services	\$7.2M	Up 1100%	<ul style="list-style-type: none"> <li>Operate final stages of Feasibility Project for LifeScan</li> </ul>	<ul style="list-style-type: none"> <li>Potential for development work on novel glucose test for LifeScan</li> </ul>
Quarterly Service Fees	\$1.6M	Up 321%	<ul style="list-style-type: none"> <li>Expect growth in Quarterly Service Fees</li> </ul>	<ul style="list-style-type: none"> <li>Uncertain. But expect growth in Quarterly Service Fees</li> </ul>
Contribution from Products & Services	\$9.1M	Up \$9.1M	<ul style="list-style-type: none"> <li>Expect to sustain manufacturing margins &amp; growth in Quarterly Service Fees</li> </ul>	<ul style="list-style-type: none"> <li>Expect an increase due to growing contribution from Quarterly Service Fees</li> </ul>
R&D Costs	\$9.2M	Up 30%	<ul style="list-style-type: none"> <li>Expect increase with Siemens products now in development</li> </ul>	<ul style="list-style-type: none"> <li>Expect similar levels to FY12</li> </ul>
G&A Costs	\$4.7M	Down 11%	<ul style="list-style-type: none"> <li>Expect little change - substantially fixed costs</li> </ul>	<ul style="list-style-type: none"> <li>Expect little change - substantially fixed costs</li> </ul>
Nett profit (loss) after tax	\$(4.7)M	Down \$6.6M		

\*Sales of strips manufactured by UBI



# UBI – ticking the boxes

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- IP protected platform technology with broad application**
- Attractive target market space**
- Powerful routes-to-market**
- Commercial product selling in the world's major markets**
- Pipeline of future product opportunities**
- Experienced, high calibre management team**
- Validation by business partners that are world leaders in their field**



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## **Attachment: Summary Financial Statements**



# Income Statement

	Years Ended December 31,			
	2011	2010	2009	2008
	A\$	A\$	A\$	A\$
<b>Revenue</b>				
Revenue from products	\$ 12,063,582	\$ 11,760,009	\$ 132,733	\$ -
Revenue from services	2,632,870	6,420,027	4,187,196	4,291,944
Milestone payment	-	-	17,722,641	-
Total revenue	14,696,452	18,180,036	22,042,570	4,291,944
<b>Operating costs &amp; expenses</b>				
Cost of goods sold and services	13,018,451	12,282,736	627,403	3,121,754
Research and development	9,812,396	6,482,150	14,898,072	11,585,258
General and administrative	7,271,488	7,185,550	5,635,569	5,510,127
Total operating costs & expenses	30,102,335	25,950,436	21,161,044	20,217,139
Profit/(loss) from operations	(15,405,883)	(7,770,400)	881,526	(15,925,195)
Other income	713,766	1,159,875	548,937	3,929,103
Net profit/(loss) before tax	(14,692,117)	(6,610,525)	1,430,463	(11,996,092)
Income tax benefit	-	-	-	206
Net profit/(loss)	(14,692,117)	(6,610,525)	1,430,463	(11,995,886)



# Balance Sheet

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## Balance Sheet as at 30<sup>th</sup> September 2012

	A\$
Current Assets (excluding cash)	8,178,561
Cash	13,935,110
Property, Plant & Equipment (net)	18,818,484
Other Non-Current Assets	<u>320,000</u>
Total Assets	<u><u>41,252,155</u></u>
Current Liabilities	6,960,780
Non-Current Liabilities	3,342,790
Stockholders' Equity	<u>30,948,585</u>
Total Liabilities & Stockholders' Equity	<u><u>41,252,155</u></u>



## Capital structure

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Number of shares on issue	159,248,538
Market capitalization (at 24 <sup>th</sup> October 2012)	A\$140 million
Number of options on issue	11.3 million
Cash (at 30 <sup>th</sup> September 2012)	A\$13.9 million
Equity raised since inception	A\$71 million



## Top 5 UBI shareholders

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<b>Shareholder</b>	<b>30<sup>th</sup> September 2012 Holding</b>
The Principals Cornerstone Fund Pty Ltd	11.4%
CM Capital Investments Pty Ltd	11.2%
National Nominees Ltd	8.6%
PFM Cornerstone Ltd	7.2%
Australian Executor Trustees SA Ltd	6.5%

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