

Universal Biosensors Pty Ltd  
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**Universal Biosensors**

29 October 2012

### **Blood glucose test sales underpin continued revenue growth for Universal Biosensors – Third Quarter Financial Results**

- Total revenue for the third quarter (ended September 30, 2012) is A\$8.7 million, compared to A\$2.5 million in Q3, 2011
- Year to date (to September 30, 2012) revenue is A\$23.4 million, up from A\$8.8 million at the same time last year
- Net cash outflows for year to date reduced to A\$1.2 million from A\$4.5 million at the same time last year
- Net loss year to date is A\$4.7 million, compared to a loss of A\$11.3 million in the previous year

Universal Biosensors (ASX:UBI) has reported continued revenue growth and reduced cash outgoings in its third quarter financial results for the period ended September 30, 2012, released today. A summary of the financial results is as follows:

	3 months ended September 30,			9 months ended September 30,		
	2012	2011	Change	2012	2011	Change
Revenue from products	\$5.2M	\$2.2M	Up 139%	\$14.6M	\$7.7M	Up 89%
Revenue from services	\$3.5M	\$0.3M	Up 998%	\$8.8M	\$1.0M	Up 742%
Quarterly Service Fees	\$0.6M	\$0.1M	Up 291%	\$1.6M	\$0.4M	Up 321%
Total revenue	\$8.7M	\$2.5M	Up 250%	\$23.4M	\$8.8M	Up 166%
Cost of goods sold & services	\$4.5M	\$2.4M	Up 90%	\$14.3M	\$8.8M	Up 63%
Contribution from products & services	\$4.1M	\$0.1M	Up \$4.0M	\$9.1M	-	Up \$9.1M
Research & development exp	\$3.8M	\$2.3M	Up 63%	\$9.2M	\$7.0M	Up 30%
General & administrative exp	\$1.6M	\$2.0M	Down 21%	\$4.7M	\$5.2M	Down 11%
Nett loss after tax	\$1.3M	\$3.3M	Down \$2.0M	\$4.7M	\$11.3M	Down \$6.6M
Nett increase/(decrease) in cash	\$(0.8)M	\$1.3M	Down \$2.1M	\$(1.2)M	\$(4.5)M	Up \$3.3M

The company reported revenue of A\$23.4 million for the year to date, a 166% increase compared to the same period last year.

One of the drivers is an increase in Quarterly Service Fees received from LifeScan which are based on the number of test strips sold for use in the OneTouch Verio, the blood glucose test that features a disposable testing strip developed and manufactured by Universal Biosensors. UBI earns a Quarterly Service Fee of around US1 cent for every test strip sold in addition to the product revenue it earns from the manufacture of strips. The figures show consistent growth over the past year. In the third quarter, ending September 30 2012, Universal Biosensors received Quarterly Service Fees totalling A\$0.6 million - an increase of 57% compared to the previous quarter, and up 291% on the same period last year. Quarterly Service Fees received in the year to date totalled \$1.6 million, up 321% from the same period last year.

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**Universal Biosensors**

A milestone payment of US\$1.5million received from Siemens Healthcare Diagnostics, UBI's strategic partner for the development of a range of point-of-care coagulation tests also contributed to revenue growth. During the quarter, Universal Biosensors strengthened its relationship with Siemens by entering into a long term supply and manufacturing agreement which granted UBI exclusive manufacturing rights to three coagulation tests currently in development.

Revenue from products, earned from the strips manufactured at Universal Biosensors' Rowville plant, has almost doubled increasing to A\$14.6 million for the year to date. Improved efficiency in the manufacturing process has contributed to the third consecutive quarter of improvement in gross margin to more than 15%.

Consistent with the half year financial results, net losses for the year to date has more than halved to A\$4.7 million, down from A\$11.3 million at the same time last year. The net loss for the third quarter is A\$1.3 million.

Paul Wright, CEO of Universal Biosensors said: *"Our financial results in 2012 reflect good progress on a number of fronts: the growth in blood glucose test strip sales, increased manufacturing volumes and efficiencies, and the revenues generated from UBI's world class R&D capabilities – both in glucose and coagulation testing."*

*"We are very pleased with the progress of the blood glucose test, but just as importantly the Siemens partnership has enabled us to leverage our platform technology to build an additional revenue stream from the coagulation testing market which has the potential to be just as valuable as the blood glucose business."*

Total R&D expenses for the quarter were A\$3.8 million, up from \$2.3 million compared to the previous corresponding quarter. This reflects increased investment in the coagulation testing products being developed and is expected to continue through to commercial launch with the first product expected to be launched in 2013.

Finally, we have been able to reduce G&A expenses this year as we continue to look for operating efficiencies within our overhead structure.

*Enquiries:*  
Paul Wright +61 3 9213 9000

#### **About Universal Biosensors**

For additional information in relation to Universal Biosensors, refer to  
<http://www.universalbiosensors.com/announcements.html>.

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**Universal Biosensors**

Universal Biosensors is a specialist medical diagnostics company, founded in 2001, that is focused on the development, manufacture and commercialisation of a range of in vitro diagnostic tests for point-of-care use. These tests capitalise on a technology platform which uses a novel electrochemical cell that can be adapted for multiple analytes and provide for enhanced measurements in whole blood.

### **Forward-Looking Statements**

The statements contained in this release that are not purely historical are forward-looking statements within the meaning of the Exchange Act. Forward-looking statements in this release include statements regarding our expectations, beliefs, hopes, intentions or strategies regarding the proposed offering. All forward-looking statements included in this release are based upon information available to us as of the date hereof, and we assume no obligation to update any such forward-looking statement as a result of new information, future events or otherwise. Our actual results could differ materially from our current expectations. We cannot assure you when, if at all, the proposed offering will occur, and the terms of any such offering are subject to change. Factors that could cause or contribute to such differences include, but are not limited to, factors and risks disclosed from time to time in reports filed with the SEC.



**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 10-Q**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 (d) OF  
THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2012

Commission File Number: 000-52607

**Universal Biosensors, Inc.**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**98-0424072**  
(I.R.S. Employer  
Identification Number)

**Universal Biosensors, Inc.**  
**1 Corporate Avenue,**  
**Rowville, 3178, Victoria**  
**Australia**  
(Address of principal executive offices)

**Not Applicable**  
(Zip Code)

**Telephone: +61 3 9213 9000**  
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of "accelerated filer", "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer ☐

Accelerated Filer ☒

Non-Accelerated Filer ☐ (Do not check if a smaller reporting company)

Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date:  
159,248,538 shares of Common Stock, U.S.\$0.0001 par value, outstanding as of 23 October, 2012.



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## UNIVERSAL BIOSENSORS, INC.

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Unless otherwise noted, references on this Form 10-Q to "Universal Biosensors" the "Company," "Group," "we," "our" or "us" means Universal Biosensors, Inc. a Delaware corporation and, when applicable, its wholly owned Australian operating subsidiary, Universal Biosensors Pty Ltd.



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## Universal Biosensors, Inc.

## Item 1 Financial Statements

## Consolidated Condensed Balance Sheets (Unaudited)

	September 30, 2012 A\$	December 31, 2011 A\$
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	13,935,110	15,089,209
Inventories, net	3,037,136	3,619,400
Accounts receivable	2,335,504	4,889,783
Prepayments	338,855	92,048
Financial instruments	0	83,339
Other current assets	2,467,066	827,508
Total current assets	22,113,671	24,601,287
Non-current assets:		
Property, plant and equipment	33,641,009	33,151,027
Less accumulated depreciation	(14,822,525)	(12,855,847)
Property, plant and equipment - net	18,818,484	20,295,180
Other non-current assets	320,000	320,000
Total non-current assets	19,138,484	20,615,180
Total assets	41,252,155	45,216,467
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	3,248,112	620,682
Accrued expenses	1,675,266	2,061,528
Deferred revenue	829,038	3,509,721
Borrowings	153,621	0
Employee entitlements provision	1,054,743	824,833
Total current liabilities	6,960,780	7,016,764
Non-current liabilities:		
Asset retirement obligations	2,305,271	2,166,691
Employee entitlements provision	208,480	181,367
Deferred revenue	829,039	829,039
Total non-current liabilities	3,342,790	3,177,097
Total liabilities	10,303,570	10,193,861
Commitments and contingencies	0	0
Stockholders' equity:		
Preferred stock, \$0.01 par value. Authorized 1,000,000 shares; issued and outstanding nil in 2012 (2011: nil)		
Common stock, \$0.0001 par value. Authorized 300,000,000 shares; issued and outstanding 159,240,538 shares in 2012 (2011: 159,139,965)	15,924	15,914
Additional paid-in capital	80,193,376	79,446,995
Accumulated deficit	(44,225,330)	(29,533,213)
Current year loss	(4,737,073)	(14,692,117)
Accumulated other comprehensive income	(298,312)	(214,973)
Total stockholders' equity	30,948,585	35,022,606
Total liabilities and stockholders' equity	41,252,155	45,216,467

See accompanying notes to the financial statements



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## Universal Biosensors, Inc.

## Consolidated Condensed Statements of Comprehensive Income (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	A\$	A\$	A\$	A\$
<b>Revenue</b>				
Revenue from products	5,156,432	2,153,518	14,615,281	7,740,685
Revenue from services	3,502,207	318,869	8,762,735	1,040,918
Total revenue	8,658,639	2,472,387	23,378,016	8,781,603
<b>Operating costs &amp; expenses</b>				
Cost of goods sold	4,295,066	2,314,082	13,611,253	8,500,926
Cost of services	223,760	61,257	653,739	265,763
Research and development	3,771,140	2,317,556	9,154,784	7,035,045
General and administrative	1,605,838	2,029,467	4,674,694	5,235,725
Total operating costs & expenses	9,895,804	6,722,362	28,094,470	21,037,459
Loss from operations	(1,237,165)	(4,249,975)	(4,716,454)	(12,255,856)
<b>Other income/(expense)</b>				
Interest income	90,377	145,228	335,056	549,547
Interest expense	(7,316)	0	(24,386)	0
Other	(172,011)	749,727	(331,289)	394,249
Total other income/(expense)	(88,950)	894,955	(20,619)	943,796
Net loss before tax	(1,326,115)	(3,355,020)	(4,737,073)	(11,312,060)
Income tax benefit/(expense)	0	0	0	0
Net loss	(1,326,115)	(3,355,020)	(4,737,073)	(11,312,060)
<b>Earnings per share</b>				
Basic and diluted net loss per share	(0.01)	(0.02)	(0.03)	(0.07)
<b>Other comprehensive loss, net of tax:</b>				
Unrealized gain on derivative instruments	0	0	0	0
Reclassification for losses/(gains) realized in net income	0	0	(83,339)	0
Other comprehensive loss	0	0	(83,339)	0
Comprehensive loss	(1,326,115)	(3,355,020)	(4,820,412)	(11,312,060)

See accompanying notes to the financial statements



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## Universal Biosensors, Inc.

## Consolidated Condensed Statements of Changes in Stockholders' Equity (Unaudited)

	Ordinary shares		Additional	Accumulated	Accumulated	Total
	Shares	Amount	Paid-in	Deficit	Other	Stockholders'
		A\$	Capital		Comprehensive	Equity
		A\$	A\$	A\$	A\$	A\$
<b>Balances at January 1, 2011</b>	158,871,495	15,887	77,034,717	(29,533,213)	(298,312)	47,219,079
Net loss	0	0	0	(11,312,060)	0	(11,312,060)
Other comprehensive loss	0	0	0	0	0	0
Exercise of stock options issued to employees	153,666	15	76,971	0	0	76,986
Stock option expense	0	0	1,714,052	0	0	1,714,052
<b>Balances at September 30, 2011</b>	<u>159,025,161</u>	<u>15,902</u>	<u>78,825,740</u>	<u>(40,845,273)</u>	<u>(298,312)</u>	<u>37,698,057</u>
<b>Balances at January 1, 2012</b>	159,139,965	15,914	79,446,995	(44,225,330)	(214,973)	35,022,606
Net loss	0	0	0	(4,737,073)	0	(4,737,073)
Other comprehensive loss	0	0	0	0	(83,339)	(83,339)
Exercise of stock options issued to employees	100,573	10	13,808	0	0	13,818
Stock option expense	0	0	732,573	0	0	732,573
<b>Balances at September 30, 2012</b>	<u>159,240,538</u>	<u>15,924</u>	<u>80,193,376</u>	<u>(48,962,403)</u>	<u>(298,312)</u>	<u>30,948,585</u>

See accompanying notes to the financial statements





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## Universal Biosensors, Inc.

## Consolidated Condensed Statements of Cash Flows (Unaudited)

	Nine Months Ended September 30,	
	2012	2011
	A\$	A\$
<b>Cash flows from operating activities:</b>		
Net loss	(4,737,073)	(11,312,060)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and impairment of plant & equipment	1,988,885	2,553,838
Share based payments expense	732,573	1,714,052
Loss on fixed assets disposal	8,870	17,715
Change in assets and liabilities:		
Inventory	582,264	116,581
Accounts receivables	2,554,279	2,304,606
Prepaid expenses and other current assets	(1,886,365)	(853,824)
Deferred revenue	(1,437,125)	3,055,301
Employee entitlements	257,023	261,838
Accounts payable and accrued expenses	1,158,348	(1,518,386)
Net cash used in operating activities	(778,321)	(3,660,339)
<b>Cash flows from investing activities:</b>		
Purchases of property, plant and equipment	(543,217)	(872,704)
Net cash used in investing activities	(543,217)	(872,704)
<b>Cash flows from financing activities:</b>		
Proceeds from borrowings	921,725	0
Repayment of borrowings	(768,104)	0
Proceeds from stock options exercised	13,818	76,986
Net cash provided by financing activities	167,439	76,986
Net decrease in cash and cash equivalents	(1,154,099)	(4,456,057)
Cash and cash equivalent at beginning of period	15,089,209	23,271,766
Cash and cash equivalents at end of period	13,935,110	18,815,709

See accompanying notes to the financial statements



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**Universal Biosensors, Inc.****Notes to Consolidated Condensed Financial Statements (Unaudited)****Organization of the Company**

We are a specialist medical diagnostics company focused on the research, development and manufacture of in vitro diagnostic test devices for consumer and professional point-of-care use.

We were incorporated in the State of Delaware on September 14, 2001 and our shares of common stock in the form of CHES Depositary Interests ("CDIs") have been quoted on the Australian Securities Exchange ("ASX") since December 13, 2006. Our securities are not currently traded on any other public market. Our wholly owned subsidiary and primary operating vehicle, Universal Biosensors Pty Ltd ("UBS") was incorporated as a proprietary limited company in Australia on September 21, 2001. UBS conducts our research, development and manufacturing activities in Melbourne, Australia.

We have rights to an extensive patent portfolio, with certain patents owned by UBS and a number licensed to UBS including under a license agreement between LifeScan, Inc. ("LifeScan") and UBS ("License Agreement"). Unless otherwise noted, references to "LifeScan" in this document are references collectively or individually to LifeScan, Inc., and/or LifeScan Europe, a division of Cilag GmbH International, both affiliates of Johnson and Johnson.

We are using our electrochemical cell technology platform to develop tests for a number of different markets. Our current focus is as set out below:

- Blood glucose – UBS provides services and acts as a non-exclusive manufacturer of test strips for LifeScan's "OneTouch® Verio™" blood glucose testing product, pursuant to a Master Services and Supply Agreement with LifeScan ("Master Services and Supply Agreement"). LifeScan continues its global rollout of the OneTouch® Verio™ product which is now available in countries that represent over 85% of the world self-monitoring blood glucose market including North America, major European markets and Australia. We also undertake research and development work for LifeScan pursuant to a development and research agreement ("Development and Research Agreement").
- Coagulation testing market – UBS is working with Siemens Healthcare Diagnostics, Inc. ("Siemens") to develop a range of products for the point-of-care coagulation market, pursuant to a collaboration agreement ("Collaboration Agreement") and will manufacture test strips for these products under a Supply Agreement with Siemens ("Siemens Supply Agreement").
- Other electrochemical-cell based tests – we are working to develop other point-of-care tests on our technology platform, including tests based on enzymatic, immunoassay and molecular diagnostic methods. We may seek to enter into collaborative arrangements or strategic alliances with respect to any tests arising from this work.

**Interim Financial Statements**

The accompanying unaudited consolidated condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and with the instructions to Form 10-Q and Article 10 of Regulation S-X for interim financial information. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the nine months ended September 30, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012. For further information, refer to the financial statements and footnotes thereto as of and for the year ended December 31, 2011, included in the Form 10-K of Universal Biosensors, Inc.

The year-end consolidated condensed balance sheet data as at December 31, 2011 was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP. Certain prior year amounts in the consolidated condensed financial statements have been reclassified to conform to the current presentation.

**Basis of Presentation**

These consolidated financial statements are presented in accordance with "U.S. GAAP". All amounts are expressed in Australian dollars ("AUD" or "A\$") unless otherwise stated.



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**Universal Biosensors, Inc.****Notes to Consolidated Condensed Financial Statements (Unaudited)**

The Company's consolidated financial statements have been prepared assuming the Company will continue as a going concern. We rely largely on our existing cash and cash equivalents balance and funds from our operations to provide for the working capital needs of our operations. We believe we have sufficient cash and cash equivalents to fund our operations for at least the next twelve months. However, in the event, our financing needs for the foreseeable future are not able to be met by our existing cash and cash equivalents balance and operating cash flow, we would seek to raise funds through public or private equity offerings, debt financings, and through other means to meet the financing requirements. There is no assurance that funding would be available at acceptable terms, if at all.

**Summary of Significant Accounting Policies*****Principles of Consolidation***

The consolidated financial statements include the financial statements of the Company and its wholly owned subsidiary UBS. All intercompany balances and transactions have been eliminated on consolidation.

***Use of Estimates***

The preparation of the consolidated financial statements requires management of the Company to make a number of estimates and assumptions relating to the reported amount of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the period. Significant items subject to such estimates and assumptions include the carrying amount of property, plant and equipment, deferred income taxes, asset retirement obligations and obligations related to employee benefits. Actual results could differ from those estimates.

***Reclassification***

Certain prior year amounts have been reclassified to conform to the current year presentation.

***Cash & Cash Equivalents***

The Company considers all highly liquid investments purchased with an initial maturity of three months or less to be cash equivalents. For cash and cash equivalents, the carrying amount approximates fair value due to the short maturity of those instruments.

***Short-Term Investments (Held-to-maturity)***

Short-term investments constitute all highly liquid investments with term to maturity from three months to twelve months. The carrying amount of short-term investments is equivalent to its fair value.

***Concentration of Credit Risk and Other Risks and Uncertainties***

Cash and cash equivalents and accounts receivables consists of financial instruments that potentially subject the Company to concentration of credit risk to the extent of the amount recorded on the balance sheet. The Company's cash and cash equivalents is invested with one of Australia's largest banks. The Company is exposed to credit risk in the event of default by the bank holding the cash or cash equivalents to the extent of the amount recorded on the balance sheet. The Company has not experienced any losses on its deposits of cash and cash equivalents. The Company has not identified any collectability issues with respect to receivables.

***Derivative Instruments and Hedging Activities******Derivative financial instruments***

The Company uses derivative financial instruments to hedge its exposure to foreign exchange arising from operating, investing and financing activities. The Company does not hold or issue derivative financial instruments for trading purposes. However, derivatives that do not qualify for hedge accounting are accounted for as trading instruments.



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**Universal Biosensors, Inc.****Notes to Consolidated Condensed Financial Statements (Unaudited)**

Derivative financial instruments are recognized initially at fair value. Subsequent to initial recognition, derivative financial instruments are stated at fair value. The gain or loss on remeasurement to fair value is recognized immediately in the income statement. However, where derivatives qualify for hedge accounting, recognition of any resultant gain or loss depends on the nature of the item being hedged.

*Cash flow hedges*

Exposure to foreign exchange risks arises in the normal course of the Company's business and it is the Company's policy to use forward exchange contracts to hedge anticipated sales and purchases in foreign currencies. The amount of forward cover taken is in accordance with approved policy and internal forecasts.

Where a derivative financial instrument is designated as a hedge of the variability in cash flows of a recognized asset or liability, or a highly probable forecast transaction, the effective part of any unrealized gain or loss on the derivative financial instrument is recognized directly in equity. When the forecast transaction subsequently results in the recognition of a non-financial asset or non-financial liability, the associated cumulative gain or loss is removed from equity and included in the initial cost or other carrying amount of the non-financial asset or liability.

For cash flow hedges, other than those covered by the preceding statement, the associated cumulative gain or loss is removed from equity and recognized in the consolidated statements of operations in the same period or periods during which the hedged forecast transaction affects the consolidated statements of operations and on the same line item as that hedged forecast transaction. The ineffective part of any gain or loss is recognized immediately in the consolidated statements of operations.

When a hedging instrument expires or is sold, terminated or exercised, or the Company revokes designation of the hedge relationship but the hedged forecast transaction is still probable to occur, the cumulative gain or loss at that point remains in equity and is recognized in accordance with the above policy when the transaction occurs. If the hedged transaction is no longer expected to take place, then the cumulative unrealized gain or loss recognized in equity is recognized immediately in the consolidated statements of operations.

*Derivative Instruments and Hedging Activities*

In determining fair value, we utilize valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as consider our own and counterparty credit risk. At September 30, 2012 and year ended December 31, 2011, we did not have any assets or liabilities that utilize Level 3 inputs. The valuation of our foreign exchange derivatives are based on the market approach using observable market inputs, such as forward rates and incorporate non-performance risk (the credit standing of the counterparty when the derivative is in a net asset position, and the credit standing of the Company when the derivative is in a net liability position). Our derivative assets are categorized as Level 2.

At September 30, 2012 we had outstanding contracts with a notional amount of nil (December 31, 2011: US\$4.0 million). The fair value of these contracts at September 30, 2012 was nil and an asset of A\$83,339 was recorded as 'Financial Instruments' in the consolidated condensed balance sheet as at December 31, 2011. During the three and nine months ended September 30, 2012, we recognized gains of nil and A\$83,339 recorded in earnings, respectively. No amount of ineffectiveness was recorded in earnings for these designated cash flow hedges for the period ended September 30, 2012 (December 31, 2011: nil).

*Inventory*

Inventories are stated at the lower of cost or net realizable value. Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and estimated costs necessary to dispose. Inventories are principally determined under the average cost method which approximates cost. Cost comprises direct materials, direct labour and an appropriate portion of variable and fixed overhead expenditure, the latter being allocated on the basis of normal operating capacity. Cost also includes the transfer from equity of any gains/losses on qualifying cash flow hedges relating to purchases of raw material. Costs of purchased inventory are determined after deducting rebates and discounts.



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**Universal Biosensors, Inc.****Notes to Consolidated Condensed Financial Statements (Unaudited)**

	<b>Nine Months Ended September 30, 2012</b>	<b>Year Ended December 31, 2011</b>
	<b>A\$</b>	<b>A\$</b>
Raw materials	1,955,591	3,254,675
Work in progress	205,162	102,239
Finished goods	876,383	262,486
	<u>3,037,136</u>	<u>3,619,400</u>

**Receivables**

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The allowance for doubtful accounts is the best estimate of the amount of probable credit losses in the existing accounts receivable. The allowance is determined based on a review of individual accounts for collectability, generally focusing on those accounts that are past due. The current year expense to adjust the allowance for doubtful accounts, if any, is recorded within general and administrative expenses in the consolidated statements of operations. Account balances are charged against the allowance when it is probable the receivable will not be recovered.

	<b>Nine Months Ended September 30, 2012</b>	<b>Year Ended December 31, 2011</b>
	<b>A\$</b>	<b>A\$</b>
Accounts receivable	2,335,504	4,889,783
Allowance for doubtful debts	0	0
	<u>2,335,504</u>	<u>4,889,783</u>

**Property, Plant, and Equipment**

Property, plant, and equipment are recorded at acquisition cost, less accumulated depreciation.

Depreciation on plant and equipment is calculated using the straight-line method over the estimated useful lives of the assets. The estimated useful life of machinery and equipment is 3 to 10 years. Leasehold improvements are amortized on the straight-line method over the shorter of the remaining lease term or estimated useful life of the asset. Maintenance and repairs are charged to operations as incurred and include normal services and does not include items of a capital nature.

The Company receives Victorian government grant monies under grant agreements to support our development activities, including in connection with the purchase of plant and equipment. Plant and equipment is presented net of the government grant. The grant monies are recognized against the acquisition costs of the related plant and equipment as and when the related assets are purchased.

**Research and Development**

Research and development expenses consist of costs incurred to further the Group's research and development activities and include salaries and related employee benefits, costs associated with clinical trial and preclinical



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**Universal Biosensors, Inc.****Notes to Consolidated Condensed Financial Statements (Unaudited)**

development, regulatory activities, research-related overhead expenses, costs associated with the manufacture of clinical trial material, costs associated with developing a commercial manufacturing process, costs for consultants and related contract research, facility costs and depreciation. Research and development costs are expensed as incurred.

Research and development expenses for the three and nine months ended September 30, 2012 and 2011 are as follows:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2012</u>	<u>2011</u>	<u>2012</u>	<u>2011</u>
	<u>A\$</u>	<u>A\$</u>	<u>A\$</u>	<u>A\$</u>
Research and development expenses	3,771,140	2,317,556	9,154,784	7,035,045

**Income Taxes**

The Company applies ASC 740 - Income Taxes which establishes financial accounting and reporting standards for the effects of income taxes that result from a company's activities during the current and preceding years. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

Where it is more likely than not that some portion or all of the deferred tax assets will not be realized the deferred tax assets are reduced by a valuation allowance. The valuation allowance is sufficient to reduce the deferred tax assets to the amount that is more likely than not to be realized.

We are subject to income taxes in the United States and Australia. U.S. federal income tax returns up to the 2011 financial year have been filed. Internationally, consolidated income tax returns up to the 2011 financial year have been filed.

**Asset Retirement Obligations**

Asset retirement obligations ("ARO") are legal obligations associated with the retirement and removal of long-lived assets. ASC 410 – Asset Retirement and Environmental Obligations requires entities to record the fair value of a liability for an asset retirement obligation when it is incurred. When the liability is initially recorded, the Company capitalizes the cost by increasing the carrying amounts of the related property, plant and equipment. Over time, the liability increases for the change in its present value, while the capitalized cost depreciates over the useful life of the asset. The Company derecognizes ARO liabilities when the related obligations are settled.

The ARO is in relation to our premises where in accordance with the terms of the lease, the lessee has to restore part of the building upon vacating the premises.

Our overall ARO changed as follows:

	<u>Nine Months Ended September 30,</u>	<u>Year Ended December 31,</u>
	<u>2012</u>	<u>2011</u>
	<u>A\$</u>	<u>A\$</u>
Opening balance	2,166,691	1,998,060
Accretion expense	138,580	168,631
Ending balance	2,305,271	2,166,691



## Universal Biosensors, Inc.

### Notes to Consolidated Condensed Financial Statements (Unaudited)

#### *Fair Value of Financial Instruments*

The carrying value of all current assets and current liabilities approximates fair value because of their short-term nature. The estimated fair value of all other amounts has been determined, depending on the nature and complexity of the assets or the liability, by using one or all of the following approaches:

- Market approach – based on market prices and other information from market transactions involving identical or comparable assets or liabilities.
- Cost approach – based on the cost to acquire or construct comparable assets less an allowance for functional and/or economic obsolescence.
- Income approach – based on the present value of a future stream of net cash flows

These fair value methodologies depend on the following types of inputs:

- Quoted prices for identical assets or liabilities in active markets (Level 1 inputs)
- Quoted prices for similar assets or liabilities in active markets or quoted prices for identical or similar assets or liabilities in markets that are not active or are directly or indirectly observable (Level 2 inputs)
- Unobservable inputs that reflect estimates and assumptions (Level 3 inputs)

#### *Impairment of Long-Lived Assets*

The Company reviews its capital assets, including patents and licenses, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. In performing the review, the Company estimates undiscounted cash flows from products under development that are covered by these patents and licenses. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than the carrying amount of the asset. If the evaluation indicates that the carrying value of an asset is not recoverable from its undiscounted cash flows, an impairment loss is measured by comparing the carrying value of the asset to its fair value, based on discounted cash flows.

#### *Australian Goods and Services Tax (GST)*

Revenues, expenses and assets are recognized net of the amount of associated GST, unless the GST incurred is not recoverable from the taxation authority. In this case it is recognized as part of the cost of acquisition of the asset or as part of the expense. Receivables and payables are stated inclusive of the amount of GST receivable or payable. The net amount of GST recoverable from, or payable to, the taxation authority is included with other receivables or payables in the balance sheet.

#### *Revenue Recognition*

We recognize revenue from all sources based on the provisions of the U.S. SEC's Staff Accounting Bulletin No. 104 and ASC 605 Revenue Recognition.

The Company's revenue represents revenue from sales of products, provision of services and collaborative research and development agreements.

We recognize revenue from sales of products at the time title of goods passes to the buyer and the buyer assumes the risks and rewards of ownership, assuming all other revenue recognition criteria have been met. Generally, this is at the time products are shipped to the customer.





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**Universal Biosensors, Inc.****Notes to Consolidated Condensed Financial Statements (Unaudited)**

Revenue from services are recognized when a persuasive evidence of an arrangement exists, services have been rendered, the price is fixed or determinable, and collectability is reasonably assured. Revenue recognition principles are assessed for each new contractual arrangement and the appropriate accounting is determined for each service.

Where our agreements contain multiple elements, or deliverables, such as the manufacture and sale of products, provision of services or research and development activities, they are assessed to determine whether separate delivery of the individual elements of such arrangements comprises more than one unit of accounting. Where an arrangement can be divided into separate units of accounting (each unit constituting a separate earnings process), the arrangement consideration is allocated amongst those varying units based on the relative selling price of the separate units of accounting and the applicable revenue recognition criteria applied to the separate units. Selling prices are determined using fair value, either vendor specific objective evidence or third party evidence of the selling price, when available, or the Company's best estimate of selling price when fair value is not available for a given unit of accounting.

Under ASC 605-25, which the Company adopted on January 1, 2009, the delivered item(s) are separate units of accounting, provided (i) the delivered item(s) have value to a customer on a stand-alone basis, and (ii) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in our control. Where the arrangement cannot be divided into separate units, the individual deliverables are combined as a single unit of accounting and the total arrangement consideration is recognized across other deliverables in the arrangement or over the estimated collaboration period. Payments under these arrangements typically include one or more of the following: non-refundable, upfront payments; funding of research and/or development efforts; and milestone payments.

We typically generate milestone payments from our customers pursuant to the various agreements we have with them. Non-refundable milestone payments which represent the achievement of a significant technical/regulatory hurdle in the research and development process, pursuant to collaborative agreements, and are deemed to be substantive, are recognized as revenue upon the achievement of the specified milestone. If the non-refundable milestone payment is not substantive or stand-alone value, the non-refundable milestone payment is deferred and recognized as revenue either over the estimated performance period stipulated in the agreement or across other deliverables in the arrangement.

Management has concluded that the core operations of the Company are expected to be research and development activities, commercial manufacture of approved medical or testing devices and the provision of services. The Company's ultimate goal is to utilize the underlying technology and skill base for the development of marketable products that the Company will manufacture. The Company considers revenue from the sales of products, revenue from services and the income received from milestone payments indicative of its core operating activities or revenue producing goals of the Company, and as such have accounted for this income as "revenues".

*Product and Service Agreements*

In October 2007, the Company and LifeScan entered into a Master Services and Supply Agreement, under which the Company agreed to provide certain services to LifeScan in the field of blood glucose monitoring and act as a non-exclusive manufacturer of blood glucose test strips. The Master Services and Supply Agreement was subsequently amended and restated in May 2009. The Company has concluded the Master Services and Supply Agreement should be accounted for as three separate units of accounting: 1) research and development to assist LifeScan in receiving regulatory clearance to sell the blood glucose product (milestone payment), 2) contract manufacturing of the blood glucose test strips (contract manufacturing) and 3) ongoing services and efforts to enhance the product (product enhancement).

All consideration within the Master Services and Supply agreement is contingent. The Company concluded the undelivered items were not priced at a significant incremental discount to the delivered items and revenue for each deliverable will be recognized as each contingency is met and the consideration becomes fixed and determinable. The milestone payment was considered to be a substantive payment and the entire amount has been recognized as revenue when the regulatory approval was received. Revenues for contract manufacturing and ongoing efforts to enhance the product are recognized as revenue from products or revenue from services, respectively, when the four basic criteria for revenue recognition are met.





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**Universal Biosensors, Inc.****Notes to Consolidated Condensed Financial Statements (Unaudited)**

In October 2011, the Company entered into a Statement of Work pursuant to the Development and Research Agreement with LifeScan to provide services for a feasibility study for an innovative blood glucose product. The services relating to this agreement, which commenced in September 2011, are expected to be completed by the end of the 2012 financial year.

*Research and Development Agreement*

On September 9, 2011 the Company entered into a collaboration agreement with Siemens to develop coagulation related products for hospital point-of-care and ambulatory care coagulation markets. In addition to an up-front, non-refundable payment of US\$3 million; the Company may receive up to six payments from Siemens upon the achievement of certain defined milestones relating to feasibility, regulatory submissions and the launch of the products to be developed. The Company has concluded that the up-front payment is not a separate unit of accounting and recorded the amount as deferred revenue to be recognized as revenue across other deliverables in the arrangement with Siemens based upon the Company's best estimate of selling price. The deliverables related to each milestone are considered substantive and are not priced at a significant incremental discount to the other deliverables. As the achievement of the milestones is contingent upon a future event, the revenue for each deliverable will be recognized as the contingencies are met and the consideration becomes fixed and determinable.

Of the six milestones, the Company has delivered on two as of September 30, 2012:

- In June 2012, the Company delivered on its first milestone by achieving proof of technical feasibility of a new test strip and received a payment of US\$1.5 million as consideration. A sum of US\$2,142,857 has been recognized as revenue from services in June 2012 in this regards.
- In July 2012, the Company delivered on its second milestone by achieving proof of technical feasibility of another new test strip and received a payment of US\$1.5 million as consideration. A sum of US\$2,142,857 has been recognized as revenue from services in July 2012 in this regards.

Of the total amount of US\$4,285,714 recognized as revenue, US\$3.0 million relates to the achievement of the two milestones whilst the balance relates to a portion of the deferred US\$3 million up-front payment which has been recognized as revenue.

*Interest income*

Interest income is recognized as it accrues, taking into account the effective yield on the cash and cash equivalents.

***Foreign Currency****Functional and reporting currency*

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates ("the functional currency"). The functional currency of the Company and UBS is AUD or A\$ for all years presented.

The consolidated financial statements are presented using a reporting currency of Australian dollars.

*Transactions and balances*

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the consolidated statements of operations.



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**Universal Biosensors, Inc.****Notes to Consolidated Condensed Financial Statements (Unaudited)**

The Company has recorded foreign currency transaction (losses)/gains of (A\$177,011) and A\$852,183 for the three month period ended September 30, 2012 and 2011, respectively and (A\$307,249) and A\$484,504 for the nine month period ended September 30, 2012 and 2011, respectively.

The results and financial position of all the Group entities that have a functional currency different from the reporting currency are translated into the reporting currency as follows:

- assets and liabilities for each balance sheet item reported are translated at the closing rate at the date of that balance sheet;
- income and expenses for each income statement are translated at average exchange rates (unless this is not a reasonable approximation of the effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the dates of the transactions); and
- all resulting exchange differences are recognized as a separate component of equity.

On consolidation, exchange differences arising from the translation of any net investment in foreign entities are taken to the Accumulated Other Comprehensive Income.

***Commitments and Contingencies***

Liabilities for loss contingencies, arising from claims, assessments, litigation, fines, and penalties and other sources are recorded when it is probable that a liability has been incurred and the amount of the assessment can be reasonably estimated. Our contingent liabilities as at September 30, 2012 are as follows:

- we have an obligation to pay 50% of the patent fees paid by LifeScan on the licensed patents prior to the date of the first commercial sale of a non-glucose product and 50% of the patent fees incurred by LifeScan thereafter. The amount to be paid by us initially upon the first commercial sale of a non-glucose product is likely to be between US\$1.3 million to US\$1.6 million. We have the right to make this payment either as a lump sum within 45 days of receipt of the supporting documentation from LifeScan or in equally monthly installment payments during the 24 months subsequent to the date of receipt of the supporting documentation.
- during 2009, LifeScan chose not to proceed with the registration of the then current product but to proceed with an enhanced product, called OneTouch® Verio™, and acknowledged that there would be a delay as a result. As a result of this change, LifeScan agreed to pay additional amounts per strip manufactured by us in 2010 and 2011 up to a specified volume limit ("manufacturing initiation payments"). At the same time, we agreed to pay LifeScan a marketing support payment in each of the two years following the first year in which 1 billion strips are sold by LifeScan in each such year equal to 40% of the total manufacturing initiation payments made. The total amount of marketing support payments expected to be paid to LifeScan is approximately US\$2 million.

***Patent and License Costs***

Legal and maintenance fees incurred for patent application costs have been charged to expense and reported in research and development expense. Legal and maintenance fees incurred for patents relating to commercialized products are capitalized and amortized over the life of the patents.

***Clinical Trial Expenses***

Clinical trial costs are a component of research and development expenses. These expenses include fees paid to participating hospitals and other service providers, which conduct certain testing activities on behalf of the Company. Depending on the timing of payments to the service providers and the level of service provided, the Company records prepaid or accrued expenses relating to these costs.

These prepaid or accrued expenses are based on estimates of the work performed under service agreements.



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**Universal Biosensors, Inc.****Notes to Consolidated Condensed Financial Statements (Unaudited)*****Leased Assets***

All of the Company's leases are considered operating leases. The costs of operating leases are charged to the statement of operations on a straight-line basis over the lease term.

***Stock-based Compensation***

We measure stock-based compensation at grant date, based on the estimated fair value of the award, and recognize the cost as an expense on a straight-line basis over the vesting period of the award. We estimate the fair value of stock options using the Trinomial Lattice model. We also grant our employees Restricted Stock Units ("RSUs") and Zero Priced Employee Options ("ZEPOs"). RSUs are stock awards granted to employees that entitle the holder to shares of common stock as the award vests. ZEPOs are stock options granted to employees that entitle the holder to shares of common stock as the award vests. The value of RSUs and ZEPOs are determined and fixed on the grant date based on the Company's stock price.

We record deferred tax assets for awards that will result in deductions on our income tax returns, based on the amount of compensation cost recognized and our statutory tax rate in the jurisdiction in which we will receive a deduction. Differences between the deferred tax assets recognized for financial reporting purposes and the actual tax deduction reported in our income tax return are recorded in expense or in capital in excess of par value if the tax deduction exceeds the deferred tax assets or to the extent that previously recognized credits to paid-in-capital are still available if the tax deduction is less than the deferred tax asset.

**(a) Stock Option Plan**

In 2004, the Company adopted an employee option plan ("Plan"). Options may be granted pursuant to the Plan to any person considered by the board to be employed by the Group on a permanent basis (whether full time, part time or on a long term casual basis). Each option gives the holder the right to subscribe for one share of common stock. The total number of options that may be issued under the Plan is such maximum amount permitted by law and the Listing Rules of the Australian Securities Exchange ("ASX"). The exercise price and any exercise conditions are determined by the board at the time of grant of the options. Any exercise conditions must be satisfied before the options vest and become capable of exercise. The options lapse on such date determined by the board at the time of grant or earlier in accordance with the Plan. Options granted to date have had a term up to 10 years and generally vest in equal tranches over three years.

An option holder is not permitted to participate in a bonus issue or new issue of securities in respect of an option held prior to the issue of shares to the option holder pursuant to the exercise of an option. If the Company changes the number of issued shares through or as a result of any consolidation, subdivision, or similar reconstruction of the issued capital of the Company, the total number of options and the exercise price of the options (as applicable) will likewise be adjusted.

In accordance with ASC 718, the fair value of the option grants was estimated on the date of each grant using the Trinomial Lattice model. The assumptions for these grants were:

	Grant Date						
	Sep-12	Mar-12	Nov-11	Nov-11	Sep-11	Mar-11	Feb-11
Exercise Price (A\$)	0.73	0.75	Nil	0.89	1.00	1.37	1.38
Share Price at Grant Date (A\$)	0.73	0.75	0.89	0.89	1.00	1.37	1.38
Volatility	67%	67%	68%	68%	69%	70%	71%
Expected Life (years)	7	7	7	7	7	7	7
Risk Free Interest Rate	3.00%	3.78%	3.72%	3.72%	3.89%	5.36%	5.45%
Fair Value of Option (A\$)	0.42	0.44	0.89	0.52	0.59	0.83	0.83



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**Universal Biosensors, Inc.****Notes to Consolidated Condensed Financial Statements (Unaudited)**

Stock option activity during the current period is as follows:

	Number of shares	Weighted average exercise price A\$
Balance at December 31, 2011	11,417,536	1.02
Granted	262,000	0.74
Exercised	(100,573)	0.19
Lapsed	(292,498)	1.14
Balance at September 30, 2012	11,286,465	1.02

The number of options exercisable as at September 30, 2012 and December 31, 2011 was 7,677,785 and 8,011,691, respectively. The total stock compensation expense recognized in income statement is A\$257,229 and A\$689,588 for the three month period ended September 30, 2012 and 2011, respectively and A\$732,573 and A\$1,714,052 for the nine month period ended September 30, 2012 and 2011, respectively.

As of September 30, 2012, there was A\$1,049,018 of unrecognized compensation expense related to unvested share-based compensation arrangements under the Employee Option Plan. This expense is expected to be recognized as follows:

Fiscal Year	A\$
2012	524,518
2013	450,131
2014	69,867
2015	4,502
	<u>1,049,018</u>

The aggregate intrinsic value for all options outstanding as at September 30, 2012 and December 31, 2011 was zero.

**(b) Restricted Share Plan**

Our Employee Share Plan was adopted by the Board of Directors in 2009. The Employee Share Plan permits our Board to grant shares of our common stock to our employees and directors (although our Board has determined not to issue equity to non-executive directors). The number of shares able to be granted is limited to the amount permitted to be granted at law, the ASX Listing Rules and by the limits on our authorized share capital in our certificate of incorporation. All our employees are eligible for shares under the Employee Share Plan. The Company currently proposes to continue to issue A\$1,000 worth of RSUs to employees of the Company on a recurring basis, but no more frequently than annually. The restricted shares have the same terms of issue as our existing shares of common stock but are not able to be traded until the earlier of three years from the date on which the shares are issued or the date the relevant employee ceases to be an employee of the Company or any of its associated group of companies.

The table below sets forth the RSUs issued by the Company since January 1, 2011:

	Number of Restricted Shares Issued	Market Value of Restricted Shares Issued A\$
November, 2011	86,471	76,959



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**Universal Biosensors, Inc.****Notes to Consolidated Condensed Financial Statements (Unaudited)**

Restricted stock awards activity during the current period is as follows:

	Number of shares	Weighted average issue price A\$
Balance at December 31, 2011	157,763	1.23
Release of restricted shares	(12,312)	1.30
Balance at September 30, 2012	<u>145,451</u>	<u>1.22</u>

**Employee Benefit Costs**

The Company contributes to standard defined contribution superannuation funds on behalf of all employees at nine percent of each such employee's salary. Superannuation is a compulsory savings program whereby employers are required to pay a portion of an employee's remuneration to an approved superannuation fund that the employee is typically not able to access until they are retired. The Company permits employees to choose an approved and registered superannuation fund into which the contributions are paid. Contributions are charged to the statement of operations as they become payable.

**Borrowings**

In January 2012, UBS entered into an arrangement with BMW Australia Finance Pty Ltd to fund the Group's insurance premium. The total amount financed is A\$921,725 at inception. Interest is charged at a fixed rate of 3.2% per annum and the short-term borrowing is repayable over a 12 month period. The short-term borrowing is secured by the insurance premium refund. The carrying value for borrowings approximates fair value because of the short maturity of the loan.

**Net Loss per Share and Anti-dilutive Securities**

Basic and diluted net loss per share is presented in conformity with ASC 260 – Earnings per Share. Basic and diluted net loss per share has been computed using the weighted-average number of common shares outstanding during the period. Other than in a profit making year, the potentially dilutive options issued under the Universal Biosensors Employee Option Plan were not considered in the computation of diluted net loss per share because they would be anti-dilutive given the Company's loss making position.

**Total Comprehensive Income**

The Company follows ASC 220 – Comprehensive Income. Comprehensive income is defined as the total change in shareholders' equity during the period other than from transactions with shareholders, and for the Company, includes net income and cumulative translation adjustments.

The tax effects allocated to each component of other comprehensive income is as follows:

	Before-Tax Amount A\$	Tax (Expense)/ Benefit A\$	Net-of-Tax Amount A\$
<b>Nine months ended September 30, 2012</b>			
Unrealized loss on derivative instruments	0	0	0
Reclassification for gains realised in net income	<u>83,339</u>	<u>0</u>	<u>83,339</u>
Other comprehensive loss	<u>83,339</u>	<u>0</u>	<u>83,339</u>
<b>Nine months ended September 30, 2011</b>			
Unrealized gain on derivative instruments	0	0	0
Other comprehensive income	<u>0</u>	<u>0</u>	<u>0</u>



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**Universal Biosensors, Inc.****Notes to Consolidated Condensed Financial Statements (Unaudited)****Recent Accounting Pronouncements**

In December 2011, the FASB issued ASU 2011-11 which amended the disclosure requirements regarding offsetting assets and liabilities of derivatives, sale and repurchase agreements, reverse sale and repurchase agreements, and securities borrowing and securities lending arrangements. The enhanced disclosures will require entities to provide both net and gross information for these assets and liabilities. The amendment is effective for fiscal years beginning on or after January 1, 2013. The Company does not anticipate that this amendment will have a material impact on its financial statements.

In July 2012, the FASB issued ASU 2012-02 which intends to simplify how entities test indefinite-lived intangible assets other than goodwill for impairment. After an assessment of certain qualitative factors, if it is determined to be more likely than not that an indefinite-lived asset is impaired, entities must perform the quantitative impairment test. Otherwise, the quantitative test is optional. The amended guidance is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012, with early adoption permitted. The adoption of this guidance is not expected to have a material impact on the company's financial results.

**Related Party Transactions**

Details of related party transactions material to the operations of the Group other than compensation arrangements, expense allowances, and other similar items in the ordinary course of business, are set out below:

In September 2011, we entered into a license agreement with Speedx Pty Ltd ("Speedx") pursuant to which Speedx granted us a license in the field of molecular diagnostics. Under the agreement we make milestone payments totaling A\$500,000 if certain specified targets are achieved and payments ranging from 5% to 15% of our sales and licensing revenues to Speedx. Messrs Denver and Jane are directors of the Company and Speedx Pty Ltd. Certain of our substantial shareholders also hold substantial shareholdings in Speedx. CM Capital Pty Ltd, which holds approximately 11% of our shares and of which Mr Jane is a director, holds approximately 34% of the issued shares in Speedx. PFM Cornerstone Limited, which holds approximately 7% of our shares and of which Messrs Denver and Hanley and Dr Adam are directors, holds approximately 34% of the issued shares in Speedx.

Based on the latest Amendment to Schedule 13G filed on January 25, 2012, Johnson and Johnson Development Corporation (a venture capital wholly owned subsidiary of Johnson & Johnson) beneficially held 14,915,400 shares in the Company as at December 31, 2011 which represents approximately 9.4% of the Company's shares. The latest available Thomson Reuters report, a third party independent analyst, indicates that as of September 30, 2012, Johnson and Johnson Development Corporation did not own any shares in the Company.

The following transactions occurred with LifeScan, an affiliate of Johnson and Johnson:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2012</b>	<b>2011</b>	<b>2012</b>	<b>2011</b>
	<b>A\$</b>	<b>A\$</b>	<b>A\$</b>	<b>A\$</b>
<i>Current Receivables - Owing by LifeScan</i>				
Sale of goods			2,170,236	1,183,281
Sale of services			128,703	96,246
			<u>2,298,939</u>	<u>1,279,527</u>
<i>Revenue from LifeScan</i>				
Revenue from products	5,156,432	2,153,518	14,615,281	7,740,685
Revenue from services	1,414,811	318,869	4,484,671	1,040,918
	<u>6,571,243</u>	<u>2,472,387</u>	<u>19,099,952</u>	<u>8,781,603</u>





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**Universal Biosensors, Inc.****Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations**

*The following discussion and analysis provides information that we believe is relevant to an assessment and understanding of our results of operations and financial condition. You should read this analysis in conjunction with our audited consolidated financial statements and related footnotes and Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Form 10-K filed with the United States Securities and Exchange Commission ("SEC"). This Form 10-Q contains, including this discussion and analysis, certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, which are intended to be covered by the safe harbors created by such acts. For this purpose, any statements that are not statements of historical fact may be deemed to be forward looking statements, including statements relating to future events and our future financial performance. Those statements in this Form 10-Q containing the words "believes", "anticipates", "plans", "expects", and similar expressions constitute forward looking statements, although not all forward looking statements contain such identifying words.*

*The forward looking statements contained in this Form 10-Q are based on our current expectations, assumptions, estimates and projections about the Company and its businesses. All such forward looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results to be materially different from those results expressed or implied by these forward-looking statements, including those set forth in this Quarterly Report on Form 10-Q.*

**Our Business**

We are a specialist medical diagnostics company focused on the research, development and manufacture of in vitro diagnostic test devices for consumer and professional point-of-care use.

We were incorporated in the State of Delaware on September 14, 2001 and our shares of common stock in the form of CHES Depositary Interests ("CDIs") have been quoted on the Australian Securities Exchange ("ASX") since December 13, 2006. Our securities are not currently traded on any other public market. Our wholly owned subsidiary and primary operating vehicle, Universal Biosensors Pty Ltd ("UBS") was incorporated as a proprietary limited company in Australia on September 21, 2001. UBS conducts our research, development and manufacturing activities in Melbourne, Australia.

We have rights to an extensive patent portfolio, with certain patents owned by UBS and a number licensed to UBS including under a license agreement between LifeScan, Inc. ("LifeScan") and UBS ("License Agreement"). Unless otherwise noted, references to "LifeScan" in this document are references collectively or individually to LifeScan, Inc., and/or LifeScan Europe, a division of Cilag GmbH International, both affiliates of Johnson and Johnson.

We are using our electrochemical cell technology platform to develop tests for a number of different markets. Our current focus is as set out below:

- Blood glucose – UBS provides services and acts as a non-exclusive manufacturer of test strips for LifeScan's "OneTouch® Verio™" blood glucose testing product, pursuant to a Master Services and Supply Agreement with LifeScan ("Master Services and Supply Agreement"). LifeScan continues its global rollout of the OneTouch® Verio™ product which is now available in countries that represent over 85% of the world self-monitoring blood glucose market including North America, major European markets and Australia. We also undertake research and development work for LifeScan pursuant to a development and research agreement ("Development and Research Agreement").
- Coagulation testing market – UBS is working with Siemens Healthcare Diagnostics, Inc. ("Siemens") to develop a range of products for the point-of-care coagulation market, pursuant to a collaboration agreement ("Collaboration Agreement") and will manufacture test strips for these products under a Supply Agreement with Siemens ("Siemens Supply Agreement").
- Other electrochemical-cell based tests – we are working to develop other point-of-care tests on our technology platform, including tests based on enzymatic, immunoassay and molecular diagnostic methods. We may seek to enter into collaborative arrangements or strategic alliances with respect to any tests arising from this work.



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**Universal Biosensors, Inc.****Results of Operations***Revenue from Products*

OneTouch® Verio™ was first launched in the Netherlands in January 2010 and is now available in countries that represent over 85% of the world self-monitoring blood glucose market. The manufacturing results of the blood glucose test strips during the respective periods are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	A\$	A\$	A\$	A\$
Revenue from products	5,156,432	2,153,518	14,615,281	7,740,685
Cost of goods sold	(4,295,066)	(2,314,082)	(13,611,253)	(8,500,926)
	861,366	(160,564)	1,004,028	(760,241)

Pursuant to the agreement we have with LifeScan, one of two pricing methodologies will apply depending on whether we received purchase orders above or below a specified quantity of blood glucose test strips in a quarter. If purchase orders of less than the specified quantity of test strips are received within a quarter, we are considered to be in the “interim costing period”. In the interim costing period, the Company is not expected to generate any profit from the manufacture of test strips, but is expected to recover most of its glucose manufacturing costs. If purchase orders increase beyond the specified quantity of blood glucose test strips per quarter, the interim costing period will cease to apply and a different pricing methodology will apply, at which time we expect our blood glucose manufacturing operations to be profitable. Revenue from product sales varies every quarter and is dependent upon LifeScan’s requirements.

During 2009, LifeScan chose not to proceed with the registration of the then current product but to proceed with an enhanced product, called OneTouch® Verio™, and acknowledged that there would be a delay as a result. As a result of this change, LifeScan agreed to pay us additional amounts per strip manufactured by us in 2010 and 2011 up to a specified volume limit. These additional payments ceased during the third quarter of 2011.

Whilst we received the additional amount per strip during the first three quarters of 2011, we still sustained a manufacturing loss as we were in the interim costing period and the total revenue was not sufficient to recover our manufacturing costs.

For the three and nine months ended September 30, 2012, we generated profits from our blood glucose manufacturing operations as we ceased to be in the interim costing period in the fourth quarter of 2011 and remained outside the interim costing period during the first three quarters of 2012. Although the manufacturing volumes during the first three quarters of 2012 were similar, we sustained a minor loss in the first quarter due to increased manufacturing costs. The increased manufacturing costs reflected lower yields and manufacturing transition as volumes grew. During the last two quarters, management efforts to improve manufacturing efficiency have resulted in lower costs and improved margins.

We will remain outside the interim costing period in the last quarter of 2012.

*Revenue from Services*

We provide various services to our customers and partners. The revenue is grouped into the following categories:

- Contract research and development – we undertake contract research and development on behalf of our customers and partners;
- Product enhancement – a service fee based on the number of strips sold by our customers and partners is payable to us as an ongoing reward for our services and efforts to enhance the product;
- Other services – ad-hoc services provided on an agreed basis based on our customers and partners requirements.





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**Universal Biosensors, Inc.**

There are different arrangements for each service being provided. The net margin during the respective periods in relation to the provision of services is as follows:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2012</u>	<u>2011</u>	<u>2012</u>	<u>2011</u>
	<u>A\$</u>	<u>A\$</u>	<u>A\$</u>	<u>A\$</u>
Revenue from services	3,502,207	318,869	8,762,735	1,040,918
Cost of services	(223,760)	(61,257)	(653,739)	(265,763)
	<u>3,278,447</u>	<u>257,612</u>	<u>8,108,996</u>	<u>775,155</u>

Contract research and development and the product enhancement service fee makes up the major portion of revenue from services.

Contract research and development - the nature and scope of contract research and development is determined by our customers and partners based upon their requirements and therefore our revenues and margins tend to fluctuate. There was an increase in the contract research and development revenue during the three and nine months ended September 30, 2012 compared to the same periods of the previous fiscal year. The increase reflects the commencement of a new research and development project for LifeScan in September 2011. The project is to determine the feasibility of an innovative blood glucose product. The US\$4.5 million feasibility project awarded to us by LifeScan is expected to be completed by the end of this fiscal year. Revenue is recognized for the feasibility project when services have been performed, the amount of the payment can be reliably measured and collectability is reasonably assured. We recognize revenue for accounting purposes ratably over the feasibility period. The increase in research and development revenue during the three and nine months ended September 30, 2012 compared to the same periods of the previous fiscal year also reflects revenue of US\$2,142,857 and US\$4,285,714, respectively recognized pursuant to our collaboration agreement with Siemens. Of the total amount recognized as revenue, US\$3.0 million relates to the achievement of the first two milestones and the balance relates to a portion of the deferred US\$3 million up-front payment under the collaboration agreement.

Service fee – this is as follows for the respective periods:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2012</u>	<u>2011</u>	<u>2012</u>	<u>2011</u>
	<u>A\$</u>	<u>A\$</u>	<u>A\$</u>	<u>A\$</u>
Service fees	<u>555,339</u>	<u>141,983</u>	<u>1,569,861</u>	<u>372,487</u>

The service fee increased by 291% and 321% during the three and nine months ended September 30, 2012 as compared to the same period in the previous financial year due primarily to the fact that the OneTouch® Verio™ is now sold in over 85% of the world self-monitoring blood glucose market. LifeScan launched the OneTouch® Verio™ IQ System in the United States in January 2012. The service fee increased by 57% during the three months ended September 30, 2012 as compared to the previous quarter and reflects increased demand for the product.

**Research and Development Expenses**

Research and development expenses are related to developing electrochemical cell platform technologies. Research and development expenses consist of costs associated with research activities, as well as costs associated with our product development efforts, including pilot manufacturing costs. Research and development expenses include:

- consultant and employee related expenses, which include consulting fees, salary and benefits;
- materials and consumables acquired for the research and development activities;
- external research and development expenses incurred under agreements with third party organizations and universities; and



## Universal Biosensors, Inc.

- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation of leasehold improvements and equipment and laboratory and other supplies.

Our principal research and development activities can be described as follows:

### (a) Blood coagulation

Since 2005, we have undertaken development work on a Prothrombin Time test for monitoring the therapeutic range of the anticoagulant, warfarin, based on measuring activity of the enzyme thrombin. In September 2011 we entered into a Collaboration Agreement with Siemens pursuant to which we will develop a range of test strips and reader products for the point-of-care coagulation market. The first test currently being developed by UBS is a modified version of a Prothrombin Time International Normalized Ratio test. We are also in the process of developing two other tests in the point-of-care coagulation market. We have also entered into a Supply Agreement with Siemens under which we will supply these tests.

### (b) Immunoassay

We are continuing to develop our immunoassay platform. We are developing a D-dimer test for the detection and monitoring of several conditions associated with thrombotic disease, particularly deep venous thrombosis (clots in the leg) and pulmonary embolism (clots in the lung). We are also working on a C-reactive protein test to assist in the diagnosis and management of inflammatory conditions.

This work will allow the electrochemical cell platform technology to be expanded to a range of immunoassay tests.

### (c) DNA/RNA

We have undertaken some early stage work assessing the possibility of using DNA binding chemistries to build a strip test for DNA, RNA and as a possible alternative method for improving the sensitivity of protein assays. This concept work is at an early stage and may not yield any positive results. To enable us to access certain molecular diagnostic technology, we entered into a license with SpeedX Pty Ltd. SpeedX Pty Ltd is an Australian technology focused on the development of catalytic nucleic acid enzymes for medical diagnostics and other applications.

Research and development expenses for the respective periods are as follows:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2012</u>	<u>2011</u>	<u>2012</u>	<u>2011</u>
	<u>A\$</u>	<u>A\$</u>	<u>A\$</u>	<u>A\$</u>
Research and development expenses	<u>3,771,140</u>	<u>2,317,556</u>	<u>9,154,784</u>	<u>7,035,045</u>

Depending on the number of research and development activities we undertake and the development phase of the research and development, our research and development expenditure will fluctuate.

In taking an idea or a concept and converting it into a product there are several phases involved. The closer the idea or the concept to a product, the lower the technical risk but the greater the effort and cost expended. In our research and development program, the first phase is exploratory research. In this phase the idea is investigated by a small focused team to establish the viability of the concept as the base for a product. Once this hurdle has been passed, the project enters the development phases, which include building prototype strips and instruments, finalizing the product design, doing extensive testing and documentation and developing or validating the product production processes. This requires a larger group of people and a much higher use of materials compared to the research phase, so is typically more expensive, but necessary to be able to commercialize a product.

Research and development expenditure increased by 63% and 30% during the three and nine months ended September 30, 2012 compared to the same period of the previous fiscal year. During 2011, with the exception of the Prothrombin Time test project, all our other projects were in the exploratory research phase. Since July 2012, in addition to the



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**Universal Biosensors, Inc.**

Prothrombin Time test project which is in the final stages of the development phase and is targeted for launch in 2013, we have two other tests which are in the development phase of product development. These two additional tests are part of our collaboration with Siemens and are within the point-of-care coagulation market. We received two milestone payments of US\$1.5 million each from Siemens in June and July 2012 which subsidized research and development expenses attributable to Siemens related projects. This amount has been recorded as "Revenue from services". If other pre-agreed milestones set by Siemens are achieved, a portion of the research and development expenditure will be subsidized by milestone payments from Siemens.

The non-cash components of depreciation and share based payments expense included in the research and development expenditure are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	A\$	A\$	A\$	A\$
Depreciation	149,562	292,383	508,232	801,518
Share based payments	111,358	301,842	318,014	746,019
	<u>260,920</u>	<u>594,225</u>	<u>826,246</u>	<u>1,547,537</u>

While we have a degree of control as to how much we spend on research and development activities in the future, we cannot predict what it will cost to complete our individual research and development programs successfully or when or if they will be commercialized. The timing and cost of any program is dependent upon achieving technical objectives, which are inherently uncertain.

In addition, our business strategy contemplates that we may enter into collaborative arrangements with third parties for one or more of our non-blood glucose programs. In the event that we are successful in securing such third party collaborative arrangements, the third party will direct the research and development activities which will influence our research and development expenditure and these parties may contribute towards all or part of the cost of these activities.

*General and Administrative Expenses*

General and administrative expenses currently consist principally of salaries and related costs, including stock option expense, for personnel in executive, business development, finance, accounting, information technology and human resources functions. Other general and administrative expenses include depreciation, repairs and maintenance, insurance, facility costs not otherwise included in research and development expenses, consultancy fees and professional fees for legal, audit and accounting services. General and administrative expenses are generally fixed in nature.

General and administrative expenses for the respective periods are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	A\$	A\$	A\$	A\$
General and administrative expenses	<u>1,605,838</u>	<u>2,029,467</u>	<u>4,674,694</u>	<u>5,235,725</u>

General and administrative expenses decreased by 21% and 11% during the three and nine months ended September 30, 2012 compared to the same period previous financial year and reflect management's intent of restricting spending on non-core activities. The non-cash components of depreciation and share based payments expense included in the general and administrative expenditure are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	A\$	A\$	A\$	A\$
Depreciation	25,559	42,388	71,650	145,306
Share based payments	123,195	327,015	350,917	815,760
	<u>148,754</u>	<u>369,403</u>	<u>422,567</u>	<u>961,066</u>



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**Universal Biosensors, Inc.***Interest Income*

Interest income decreased by 38% and 39% during the three and nine months ended September 30, 2012 compared to the same period in the previous financial year. The decrease in interest income is attributable to lower interest rates and the lower amount of funds available for investment.

*Interest Expense*

Interest expense of A\$7,316 and A\$24,386 for the three and nine months ended September 30, 2012 relates to a 3.2% interest being charged on a short-term borrowing initiated in January 2012.

*Other*

Other is primarily represented by foreign exchange movements arising from the settlement of foreign denominated transactions and from the translation at period-end exchange rates of monetary assets and liabilities denominated in foreign currencies.

**Critical Accounting Estimates and Judgments**

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, income, costs and expenses, and related disclosures. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates.

We believe that of our significant accounting policies, which are described in the notes to our consolidated financial statements, the following accounting policies involve a greater degree of judgment and complexity. Accordingly, we believe that the following accounting policies are the most critical to aid in fully understanding and evaluating our consolidated financial condition and results of operations.

**(a) Revenue Recognition**

The Company recognizes revenue when persuasive evidence of an arrangement exists, delivery has occurred, the sales price is fixed or determinable, and collection is probable. Product is considered delivered to the customer once it has been shipped and title and risk of loss have been transferred.

In addition, the Company enters into arrangements, which contain multiple revenue generating activities. The revenue for these arrangements is recognized as each activity is performed or delivered, based on the relative fair value and the allocation of revenue to all deliverables based on their relative selling price. In such circumstances, the Company uses a hierarchy to determine the selling price to be used for allocation of revenue to deliverables, vendor-specific objective evidence, third-party evidence of selling price and the Company's best estimate of selling price. The Company's process for determining its best estimate of selling price for deliverables without vendor-specific objective evidence or third-party evidence of selling price involves management's judgment. The Company's process considers multiple factors that may vary depending upon the unique facts and circumstances related to each deliverable.



## Universal Biosensors, Inc.

### (b) Stock-Based Compensation

We account for stock-based employee compensation arrangements using the modified prospective method as prescribed in accordance with the provisions of ASC 718 – Compensation – Stock Compensation.

Each of the inputs to the Trinomial Lattice model is discussed below.

#### *Share Price at Valuation Date*

The value of the options granted in 2012 and 2011 has been determined using the closing price of our common stock trading in the form of CDIs on ASX at the time of grant of the options. The ASX is the only exchange upon which our securities are quoted.

#### *Volatility*

We applied volatility having regard to the historical price change of our shares in the form of CDIs available from the ASX.

#### *Time to Expiry*

All options granted under our share option plan have a maximum 10 year term and are non-transferable.

#### *Risk Free Rate*

The risk free rate which we applied is equivalent to the yield on an Australian government bond with a time to expiry approximately equal to the expected time to expiry on the options being valued.

### (c) Income Taxes

We apply ASC 740 – Income Taxes which establishes financial accounting and reporting standards for the effects of income taxes that result from a company's activities during the current and preceding years. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

Where it is more likely than not that some portion or all of the deferred tax assets will not be realized the deferred tax assets are reduced by a valuation allowance. The valuation allowance is sufficient to reduce the deferred tax assets to the amount that is more likely than not to be realized.

### (d) Impairment of Long-Lived Assets

We review our capital assets, including patents and licenses, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. In performing the review, we estimate undiscounted cash flows from products under development that are covered by these patents and licenses. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than the carrying amount of the asset. If the evaluation indicates that the carrying value of an asset is not recoverable from its undiscounted cash flows, an impairment loss is measured by comparing the carrying value of the asset to its fair value, based on discounted cash flows.



## Universal Biosensors, Inc.

### Financial Condition, Liquidity and Capital Resources

#### Net Financial Assets

Our net financial assets position is shown below:

	Nine Months Ended September 30, 2012 A\$	Year Ended December 31, 2011 A\$
Financial assets:		
Cash and cash equivalents	13,935,110	15,089,209
Accounts receivables	2,335,504	4,889,783
Financial instruments	0	83,339
Total financial assets	16,270,614	20,062,331
Debt:		
Short term borrowings	153,621	0
Total debt	153,621	0
Net financial assets	16,116,993	20,062,331

We rely largely on our existing cash and cash equivalents and funds from our operations to provide for the working capital needs of our operations. We believe we have sufficient cash and cash equivalents to fund our operations for at least the next twelve months.

The carrying value of the cash and cash equivalents and the accounts receivables approximates fair value because of their short-term nature.

We regularly review all our financial assets for impairment. There were no impairments recognized for the three and nine months ended September 30, 2012 and 2011.

#### Derivative Instruments and Hedging Activities

In determining fair value, we utilize valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as consider our own and counterparty credit risk. At September 30, 2012 and year ended December 31, 2011, we did not have any assets or liabilities that utilize Level 3 inputs. The valuation of our foreign exchange derivatives are based on the market approach using observable market inputs, such as forward rates and incorporate non-performance risk (the credit standing of the counterparty when the derivative is in a net asset position, and the credit standing of the Company when the derivative is in a net liability position). Our derivative assets are categorized as Level 2.

We had outstanding contracts with a notional amount of nil and US\$4.0 million as at September 30, 2012 and December 31, 2011, respectively. The fair value of these contracts at September 30, 2012 was nil and an asset of A\$83,339 at December 31, 2011 recorded as 'Financial Instruments' in the consolidated condensed balance sheet. During the three and nine months ended September 30, 2012, we recognized gains of nil and gains of A\$83,339 recorded in earnings, respectively. No amount of ineffectiveness was recorded in earnings for these designated cash flow hedges for the period ended September 30, 2012 (2011: nil). For further details, see Notes to Consolidated Financial Statements – *Summary of Significant Accounting Policies*.

**Universal Biosensors, Inc.***Measures of Liquidity and Capital Resources*

The following table provides certain relevant measures of liquidity and capital resources:

	Nine Months Ended September 30, 2012 A\$	Year Ended December 31, 2011 A\$
Cash and cash equivalents	13,935,110	15,089,209
Working capital	15,152,891	17,584,523
Ratio of current assets to current liabilities	3.18 : 1	3.51 : 1
Shareholders' equity per common share	0.19	0.22

The movement in cash and cash equivalents and working capital in each of the years was primarily due to reductions to outflows of cash and to the timing of cash receipts, payments, sales and accruals in the ordinary course of business. We have not identified any collection issues with respect to receivables.

*Summary of Cash Flows*

	Nine Months Ended September 30, 2012 A\$	2011 A\$
Cash provided by/(used in):		
Operating activities	(778,321)	(3,660,339)
Investing activities	(543,217)	(872,704)
Financing activities	167,439	76,986
Net increase/(decrease) in cash and cash equivalents	(1,154,099)	(4,456,057)

The major drivers of the operating cash outflows during the nine month period ended September 30, 2012 were:

- An increase in the Company's production volumes from the OneTouch® Verio™ requiring additional resources (both materials and labour); and
- An increase in our research and development activities, primarily relating to our collaboration with Siemens.

The operating cash outflows during this period were to a large extent offset by receipts from our customers and partners including the US\$3.0 million milestone payment from Siemens.

Our net cash used in operating activities during the nine month period ended September 30, 2011 was primarily for our research and development projects including efforts involved in establishing our manufacturing. The outflow during this period has been partially offset by receipts from our customers and partners.

Our net cash used in investing activities for all periods is primarily for the purchase of various plant and equipment, and fit out of our facilities based on our needs. Additionally, this financial year, we have invested in disaster recovery.

During 2012 we also took advantage of a favorable borrowing opportunity to prepay our annual insurances. The borrowings will be repaid within this financial year. This is reflected as a financing activity. A minor portion of the financing activities disclosed in our financial statements is attributable to the exercise of employee stock options.

Our net cash provided by financing activities during the nine month period ended September 30, 2011 is primarily represented by proceeds received from employees exercising their options.

**Off-Balance Sheet Arrangement**

The future minimum lease payments under non-cancelable operating leases (with initial or remaining lease terms in excess of one year) as of September 30, 2012 are:

	A\$
Less than 1 year	564,906
1 – 3 years	282,729
More than 3 years	0
Total minimum lease payments	847,635





## Universal Biosensors, Inc.

The above relates to our operating lease obligations in relation to the lease of our premises and certain office equipment.

### Contractual Obligations

Our future contractual obligations at September 30, 2012 were as follows:

	Payments Due By Period				
	Total A\$	Less than 1 year A\$	1 – 3 years A\$	3 – 5 years A\$	More than 5 years A\$
Asset Retirement Obligations (1)	2,305,271	0	2,305,271	0	0
Operating Lease Obligations (2)	847,635	564,906	282,729	0	0
Purchase Obligations (3)	5,604,202	5,604,202	0	0	0
Other Long-Term Liabilities on Balance Sheet (4)	208,480	0	177,876	24,999	5,605
Total	<u>8,965,588</u>	<u>6,169,108</u>	<u>2,765,876</u>	<u>24,999</u>	<u>5,605</u>

- (1) Represents legal obligations associated with the retirement and removal of long-lived assets
- (2) Our operating lease obligations relate primarily to the lease of our premises
- (3) Represents outstanding purchase orders
- (4) Represents long service leave owing to the employees

### Segments

We operate in one segment. Our principal activities are research and development, commercial manufacture of approved medical or testing devices and the provision of services including contract research work. We operate predominantly in one geographical area, Australia.





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**Universal Biosensors, Inc.****Item 3 Quantitative and Qualitative Disclosures About Market Risk****Financial Risk Management**

The overall objective of our financial risk management program is to seek to minimize the impact of foreign exchange rate movements and interest rate movements on our earnings. We manage these financial exposures through operational means and by using financial instruments. These practices may change as economic conditions change.

*Foreign Currency Market Risk*

We transact business in various foreign currencies, including U.S. dollars and Euros. We have established a foreign currency hedging program using forward contracts to hedge the net projected exposure for each currency and the anticipated sales and purchases in U.S. dollars and Euros. The goal of this hedging program is to economically guarantee or lock-in the exchange rates on our foreign exchange exposures. The Company does not hold or issue derivative financial instruments for trading purposes. However, derivatives that do not qualify for hedge accounting are accounted for as trading instruments.

Although the Company has a hedging program, as at balance sheet date there were no open derivatives that would need to be disclosed.

*Interest Rate Risk*

Since the majority of our investments are in cash and cash equivalents in AUD, our interest income is affected by changes in the general level of Australian interest rates. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. Our investment portfolio is subject to interest rate risk but due to the short duration of our investment portfolio, we believe an immediate 10% change in interest rates would not be material to our financial condition or results of operations.

*Inflation*

Our business is subject to the general risks of inflation. Our results of operations depend on our ability to anticipate and react to changes in the price of raw materials and other related costs over which we may have little control. Our inability to anticipate and respond effectively to an adverse change in the price could have a significant adverse effect on our results of operations. In the face of increasing costs, the Company strives to maintain its profit margins through cost reduction programs, productivity improvements and periodic price increases.



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**Universal Biosensors, Inc.****Item 4 Controls and Procedures**

*Disclosure Controls and Procedures.* At the end of the period covered by this report, the Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Paul Wright, Chief Executive Officer, and Sales Balak, Chief Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Messrs. Wright and Balak concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures were effective.

*Changes in Internal Control Over Financial Reporting.* During the fiscal quarter ended September 30, 2012, there were no changes in the Company's internal control over financial reporting identified in connection with the evaluation referred to above in this Item 4 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.



Universal Biosensors, Inc.

## PART II OTHER INFORMATION

### Item 1 Legal Proceedings

None.

### Item 1A Risk Factors

None.

### Item 2 Unregistered Sales of Equity Securities and Use of Proceeds

With the exception of the issuance of shares of Common Stock upon the exercise of stock options issued to employees, there has been no sale of new equity securities by the Company since December 31, 2011. The table below sets forth the number of employee stock options exercised and the number of shares issued in the nine month period ended September 30, 2012. The Company issued these shares in reliance upon exemptions from registration under Regulation S under the Securities Act of 1933, as amended.

Exercise Date	Number of Options Exercised and Corresponding Number of Shares Issued	Option Exercise Price	Proceeds Received (A\$)
February, 2012	6,248	US\$ 0.26	1,518
June, 2012	55,993	US\$ 0.22	12,300
August, 2012	38,332	A\$ 0.00	0
	<u>100,573</u>		<u>13,818</u>

The funds raised will be used for working capital requirements including the continued development of our existing pipeline and point-of-care tests and to identify and develop additional tests.

### Item 3 Defaults Upon Senior Securities

None.

### Item 4 Mine Safety Disclosures

Not applicable.

### Item 5 Other Information

None.

### Item 6 Exhibits

<u>Exhibit No</u>	<u>Description</u>	<u>Location</u>
10.1	Amendment to Collaboration Agreement between Universal Biosensors Pty Ltd and Siemens Healthcare Diagnostics, Inc. dated September 20, 2012	Filed herewith – confidential treatment requested
10.2	Supply Agreement between Universal Biosensors Pty Ltd and Siemens Healthcare Diagnostics, Inc. dated September 20, 2012	Filed herewith – confidential treatment requested
10.3	Supplemental Agreement – Reader Product Support Obligations and Responsibilities between Universal Biosensors Pty Ltd and Siemens Healthcare Diagnostics, Inc. dated September 20, 2012	Filed herewith – confidential treatment requested



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**Universal Biosensors, Inc.**

31.1	Rule 13a-14(a)/15d-14(a) Certification (Principal Executive Officer)	Filed herewith
31.2	Rule 13a-14(a)/15d-14(a) Certification (Principal Financial Officer)	Filed herewith
32	Section 1350 Certificate	Furnished herewith
101	The following materials from the Universal Biosensors, Inc. Quarterly Report on Form 10-Q for the quarter ended September 30, 2012 formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Condensed Balance Sheets, (ii) the Consolidated Condensed Statements of Comprehensive Income, (iii) the Consolidated Condensed Statements of Changes in Stockholder's Equity, (iv) the Consolidated Condensed Statements of Cash Flows and (v) the Notes to Consolidated Condensed Financial Statements	As provided in Rule 406T of Regulation S-T, this information is furnished herewith and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934



Universal Biosensors, Inc.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

UNIVERSAL BIOSENSORS, INC.  
(Registrant)

Date: October 29, 2012

By: /s/  
Paul Wright  
Principal Executive Officer

Date: October 29, 2012

By: /s/  
Salesh Balak  
Principal Financial Officer



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**INDEX TO EXHIBITS**  
**Quarterly Report on Form 10-Q**  
**Dated October 29, 2012**

<u>Exhibit No</u>	<u>Description</u>	<u>Location</u>
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## Exhibit 10.1

AMENDMENT TO  
COLLABORATION AGREEMENT

THIS AMENDMENT TO COLLABORATION AGREEMENT (the “*Amendment*”) is made and entered into as of September 20, 2012 (the “*Amendment Date*”), by and between UNIVERSAL BIOSENSORS PTY LTD., having a place of business at 1 Corporate Avenue, Rowville, Victoria 3178, Australia (“*UBI*”), and SIEMENS HEALTHCARE DIAGNOSTICS INC., having a place of business at 511 Benedict Avenue, Tarrytown, NY 10591, USA (“*Siemens*”).

WHEREAS, UBI and Siemens are parties to that certain Collaboration Agreement dated September 9, 2011 (the “*Collaboration Agreement*”), and now wish to amend the Collaboration Agreement as set forth in this Amendment. Capitalized terms used but not otherwise defined in this Amendment shall have the meanings provided in the Collaboration Agreement.

NOW, THEREFORE, in consideration of the covenants and promises herein contained, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, agree as follows:

**1. Amendment to Section 7.3.** The first paragraph of Section 7.3 of the Collaboration Agreement is hereby amended and restated to read in its entirety as follows:

“**Profit-Sharing. Annex 7.3** hereto sets forth Siemens’ annual forecasts (expressed in Euro) for gross revenues from sales of each Strip Product for calendar years 2013 through 2024 (in each case, an “*Annual Forecast*”). On a Strip Product-by-Strip Product basis, if, in any year, gross sales of a Strip Product exceed \*[REDACTED]% of the Annual Forecast for such Strip Product for such year (the “*Bonus Threshold*”), then, within 60 days after the end of such year, Siemens shall pay to UBI a bonus equal to \*[REDACTED]% of the Deemed Profit (defined below) from the Incremental Revenues (defined below). Said gross sales expressly includes revenues increased by the effect of the commercial practice commonly known in the in vitro diagnostic industry as “reagent rental”. For purposes of this Section 7.3:”

**2. Amendment to Section 17.2.** Section 17.2 of the Collaboration Agreement is hereby amended and restated to read in its entirety as follows:

“**17.2 Indemnification by UBI.** UBI hereby agrees to save, defend, indemnify and hold harmless Siemens, its Affiliates and their respective officers, directors, employees, consultants and agents (the “*Siemens Indemnitees*”), from and against any and all Losses to which any Siemens Indemnatee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise directly or indirectly out of: (a) the development, manufacture, use, handling, storage, sale or other disposition of Strip Products by or on behalf of UBI or any of its Affiliates or Third Party licensees; (b) the gross negligence or willful misconduct of any UBI Indemnatee; or (c) the breach by UBI of any warranty, representation, covenant or agreement made by it in this Agreement; except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any Siemens Indemnatee or the breach by Siemens of any warranty, representation, covenant or agreement made by it in this Agreement; *provided, however*, that, \*[REDACTED].”

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



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**3. Amended Annex 7.3.** Annex 7.3 to the Collaboration Agreement is hereby amended and restated in its entirety as set forth in Exhibit I attached to this Amendment.

**4. Effect of Amendment.** Except as specifically amended by this Amendment and supplemented by that certain letter agreement between Siemens and UBI dated as of the Amendment Date and titled “Supplemental Agreement – Reader Product Support Obligations and Responsibilities,” the terms and conditions of the Collaboration Agreement shall remain in full force and effect.

**5. Counterparts.** This Amendment may be executed in counterparts, including by transmission of facsimile or PDF copies of signature pages to the parties, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument.

[Remainder of this page intentionally left blank.]





IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment as of the Amendment Date.

**UNIVERSAL BIOSENSORS PTY LTD.**

**SIEMENS HEALTHCARE DIAGNOSTICS INC.**

By: /s/ PAUL WRIGHT  
Name: Paul Wright  
Title: CEO

By: /s/ DAVID STEIN 9/19/12  
Name: David Stein  
Title: CEO POC

By: /s/ WOLFGANG WRUMNIG 9/18/12  
Name: Wolfgang Wrumnig  
Title: CFO



EXHIBIT I

Annex 7.3

**Annual Forecasts of Strip Product Sales**  
(in thousands of Euro)

2013   2014   2015   2016   2017   2018   2019   2020   2021   2022   2023   2024

\*[REDACTED]  
\*[REDACTED]  
\*[REDACTED]  
\*[REDACTED]

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



**Exhibit 10.2**

**SUPPLY AGREEMENT**

**This Supply Agreement** (“**Supply Agreement**”) is effective as of September 20, 2012 (“**Effective Date**”) by and between **SIEMENS HEALTHCARE DIAGNOSTICS INC.** (“**Siemens**”), having a place of business at 511 Benedict Avenue, Tarrytown, NY 10591, USA, and **UNIVERSAL BIOSENSORS PTY LTD.**, a company incorporated in Victoria, Australia (“**UBI**”), having an address at 1 Corporate Avenue, Rowville, Victoria 3178, Australia.

**WHEREAS**, UBI is engaged in the business of researching, developing, manufacturing and selling medical devices and materials and components suitable for use in medical devices;

**WHEREAS**, UBI and Siemens have engaged in joint development efforts, pursuant to that certain Collaboration Agreement, effective as of September 9, 2011, as amended (“**Collaboration Agreement**”), to develop the Products (as defined herein) for exclusive sale by Siemens worldwide in the Field; and

**WHEREAS**, Siemens and UBI wish to establish terms and conditions for Siemens’ purchase of Products from UBI for sale by Siemens worldwide in the Field.

Now, therefore, in consideration of the above premises and the mutual covenants herein set forth, the parties hereto agree as follows:

**1. DEFINITIONS.**

All capitalized terms in this Supply Agreement that are not expressly defined herein are to be interpreted as they are defined in the Collaboration Agreement. For purposes of this Supply Agreement:

**1.1\*[REDACTED].**

**1.2 “Associated Materials”** shall have the meaning provided in Section 1.17.

**1.3 “Business Day”** shall mean a day other than a Saturday, Sunday or any day on which commercial banks located in Rowville, Victoria, Australia, and/or Tarrytown, New York, USA, are authorized or obligated by law to be closed.

**1.4 “Control”** means the direct or indirect beneficial ownership of at least fifty (50%) percent of the voting stock or other ownership interest of a corporation or other business entity, or the power to elect at least fifty (50%) percent of the directors or trustees of a corporation or other business entity, or such other relationship which in fact constitutes actual control.

**1.5 “Change Order”** shall mean a document which records or authorizes a Major Change, including identification of what needs to be changed, the reason(s) for such change, a description and drawings of the change, a list of documents and departments affected by the change, formal approval of the change, and instruction regarding the timing of implementation of the change.

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



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1.6 “CRM” shall have the meaning provided in Section 3.13.

1.7 “Delivery” shall mean delivery FCA (Incoterms 2010) UBI’s facility in Rowville, Victoria, Australia.

1.8 “Delivery Date” shall mean the date on which a shipment of Product(s) ordered by Siemens is to be available to Siemens or its designee at UBI’s loading dock and ready for shipment.

1.9\*[REDACTED] shall have the meaning provided in Section 3.6.

1.10\*[REDACTED] shall have the meaning provided in Section 3.6.

1.11\*[REDACTED] shall mean the occurrence of any of the following:

(a) UBI files a petition in bankruptcy or makes a general assignment for the benefit of creditors or otherwise acknowledges in writing insolvency, or is adjudged insolvent or bankrupt, and UBI (i) fails to assume this Supply Agreement in any such bankruptcy proceeding within 30 days after filing or (ii) assumes and assigns this Supply Agreement to a Third Party;

(b) UBI is placed in a process of complete liquidation;

(c) an administrator, trustee or receiver is appointed for any substantial portion of UBI’s business and such administrator, trustee or receiver is not discharged within 60 days after appointment;

(d) any case or proceeding shall have been commenced or other action taken against UBI in bankruptcy or seeking liquidation, reorganization, dissolution, a winding-up arrangement, composition or readjustment of its debts or any other relief under any bankruptcy, insolvency, reorganization or similar act or law of any jurisdiction and is not dismissed or converted into a voluntary proceeding governed by clause (a) above within 60 days after filing;

(e) UBI loses all or a fundamental part of its test-strip manufacturing capabilities as a result of a Force Majeure event and either: (i) \*[REDACTED]; or (ii) \*[REDACTED];

(f) \*[REDACTED];

(g) Siemens terminates this Agreement for UBI’s uncured material breach in accordance with Section 8.3(b); or

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



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(h) \*[REDACTED];

1.12 “Failure to Supply” shall mean, on a Product-by-Product basis, with respect to a particular Product:

(a) during the \*[REDACTED] period beginning on the first day of the Initial Shipment Month of such Product, \*[REDACTED] in which UBI (i) fails to deliver to Siemens at least \*[REDACTED]% of the quantity of such Product requested by Siemens under accepted Purchase Orders for Product to be delivered in \*[REDACTED], or (ii) is more than \*[REDACTED] late in delivering the quantity of such Product ordered by Siemens in \*[REDACTED]; or

(b) after such \*[REDACTED] period, one month in which UBI (i) fails to deliver to Siemens at least \*[REDACTED]% of the quantity of such Product requested by Siemens under accepted Purchase Orders for that Product to be delivered in \*[REDACTED], or (ii) is more than \*[REDACTED] late in delivering the quantity of such Product ordered by Siemens in \*[REDACTED], until the volume of such Product supplied to Siemens in \*[REDACTED] exceeds \*[REDACTED] after which event “Failure to Supply” shall mean \*[REDACTED] in which UBI (i) fails to deliver to Siemens at least \*[REDACTED]% of the quantity of such Product requested by Siemens under accepted Purchase Orders for such Product to be delivered in \*[REDACTED], or (ii) is more than \*[REDACTED] late in delivering the quantity of such Product ordered by Siemens in \*[REDACTED];

in each case to the extent such Purchase Order is submitted by Siemens with sufficient lead-time as set forth in Section 4.1, is consistent with Siemens’ forecasts, and does not exceed UBI’s supply commitment; and except, in each case, to the extent such failure or delay is caused by Force Majeure or by Siemens’ failure or delay in delivering any applicable HHS-Supplied Materials conforming to the HHS Warranty in sufficient quantity necessary to produce the quantity of such Product ordered.

1.13 “Force Majeure” shall have the meaning provided in Article 6.

1.14 “HHS Invention” shall mean any invention, portion of an invention, improvement or other development (whether or not protected, patentable and/or copyrightable or capable of being protected in any other way) made by \*[REDACTED]; *provided, however,* that “HHS Inventions” shall exclude any invention, portion of an invention, improvement or other development (whether or not protected, patentable and/or copyrightable or capable of being protected in any other way) made by \*[REDACTED] (each, a “Test Strip Invention”). By way of example only, \*[REDACTED]. Test Strip Inventions shall be deemed to constitute \*[REDACTED] for all purposes under the Collaboration Agreement, and the respective provisions of the Collaboration Agreement relating to \*[REDACTED] are incorporated by reference herein and shall apply to the Test Strip Inventions, including Proprietary Rights therein.

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



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**1.15 “HHS Letter”** shall mean that certain letter agreement among Siemens, Siemens GmbH and UBI, dated as of the Effective Date.

**1.16 “HHS-Supplied Materials”** shall mean, with respect to a particular Product, any \*[REDACTED] (as applicable) that, in each case, is, or is to be, supplied by Siemens or Siemens GmbH for use in the manufacture of such Product.

**1.17 “HHS Technology”** shall mean: (i) \*[REDACTED]; (ii) any associated proprietary materials that Siemens GmbH (either directly or through Siemens or another Siemens Affiliate) provides or has provided to UBI, including, without limitation, \*[REDACTED]; (iii) all current or future information and know-how (such as, by way of example only and without limitation, copyrightable material, trade secrets, techniques, algorithms, software, source code, designs, drawings, blueprints, materials, parts lists, listing of ingredients, specifications, test data, charts and graphs, manufacturing procedures, operation sheets, bills of material, and vendor lists) that, in each case, (A) \*[REDACTED], (B) are or were disclosed or provided to UBI by Siemens GmbH (either directly or through Siemens or another Siemens Affiliate) pursuant to this Supply Agreement, the Collaboration Agreement or the MTA, and (C) constitute Confidential Information of Siemens or of Siemens GmbH for purposes of Article 9 of this Supply Agreement \*[REDACTED]; and (iv) all Proprietary Rights in the items described in the preceding clauses (i), (ii) and (iii).

**1.18 “HHS Warranty”** shall have the meaning provided in Section 5.5.

**1.19 “Initial Shipment Month”** shall have the meaning provided in Section 4.5(a).

**1.20 “Major Change”** shall mean, with respect to a particular Product:

(a) a change to the validated manufacturing process for such Product \*[REDACTED] that, in each case, would: (i) require revalidation of the manufacturing process; (ii) affect the Regulatory Approvals for such Product (*e.g.*, by necessitating an amendment thereto or requiring Siemens to seek new Regulatory Approvals); or (iii) impact Product quality; or

(b) an amendment to the Specifications.

**1.21 “Manufacturing Know-How”** shall mean, with respect to a particular Product, all proprietary information and know-how that is necessary to make such Product, whether in the possession of UBI or Third Parties involved in the supply of raw materials or tooling (except, in the case of Third Party proprietary information and know-how, to the extent UBI does not have the right to access the same and/or to provide the same to Siemens), including but not limited to those items identified in **Exhibit A**, and all regulatory documents (other than regulatory documents and approvals held by Siemens), manufacturing documentation, process sheets, Specifications, product, tooling and equipment design documents, bills of materials and other documents as reasonably requested; but excluding, in each case, HHS Technology, HHS Inventions, and Proprietary Rights in HHS Inventions.

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



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**1.22 “Materials”** shall mean the raw materials and components necessary to manufacture a Product, excluding HHS-Supplied Materials.

**1.23 “MTA”** shall mean that certain Material Transfer Agreement between UBI and Siemens GmbH, dated January 15, 2011, as amended.

**1.24 “Persistent Supply Failure”** shall mean:

(a) during the \*[REDACTED] period beginning on the first day of the Initial Shipment Month of a Product (the “**New Product Phase**”), either: (i) \*[REDACTED] Failures to Supply said Product; or (ii) \*[REDACTED] Failures to Supply said Product in any period of \*[REDACTED]; and

(b) after expiration of the period specified in the preceding paragraph (a): (i) \*[REDACTED] Failures to Supply any Product that is beyond the New Product Phase in any period of \*[REDACTED]; or (ii) \*[REDACTED] Recall incidents in any period of \*[REDACTED] resulting from any Product that is beyond the New Product Phase supplied by UBI that does not conform to the Product Warranty (other than as a result of failure of any HHS-Supplied Material delivered to UBI that does not conform to the HHS Warranty);

except, in each case, in the event that a remedial action plan to address the issue pursuant to Section 3.15 has been approved and UBI is complying with such remedial action plan.

For purposes of the foregoing, \*[REDACTED]. In addition, \*[REDACTED] for purposes of Section 1.24(b).

**1.25 “Process Validation”** shall mean validation of the final manufacturing processes to be used for the initial shipment of each Product hereunder in accordance with the terms of the Collaboration Agreement.

**1.26 “Product”** shall mean any of the following:

(a) the test strip developed pursuant to the Collaboration Agreement for measuring Prothrombin Time and International Normalized Ratio (PT/INR) that uses rTF (“**PT/INR Product**”);

(b) the test strip developed pursuant to the Collaboration Agreement for measuring \*[REDACTED]; and

(c) the test strip developed pursuant to the Collaboration Agreement for measuring \*[REDACTED].

**1.27 “Product Warranty”** shall have the meaning provided in Section 5.1.

**1.28** \*[REDACTED].

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.





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**1.29 “Purchase Order”** shall mean a written purchase order for Product(s) issued by the Siemens purchasing department or by the purchasing department of Siemens’ designee to UBI, which specifies the quantity of each Product ordered and the desired Delivery Date(s) for such Product(s). A Purchase Order submitted by Siemens shall be deemed to be “accepted” as expressly set forth in Section 4.1(b).

**1.30 “Quality Assurance Agreement” or “QAA”** shall mean that Quality Assurance Agreement by and between Siemens and UBI and effective as of the Effective Date in connection herewith, substantially in the form attached hereto as **Exhibit C**.

**1.31 “Regulatory Approval”** shall mean any registration submission or regulatory approval for a Product held by Siemens, its Affiliate or its Third Party designee.

**1.32 \*[REDACTED].**

**1.33 “SOPs”** shall mean UBI’s standard operating procedures for the manufacture and release of test strips, as in effect from time to time.

**1.34 “Siemens GmbH”** shall mean Siemens’ Affiliate Siemens Healthcare Diagnostics Products GmbH, Emil-von-Behring-Str. 76, 35041 Marburg, Germany.

**1.35 “Specifications”** shall mean the functional specifications for each Product initially established by mutual written agreement of the parties at the completion of Product development activities for such Product under Articles 2, 3 and 4 of the Collaboration Agreement, subject to amendment from time to time as mutually agreed by the parties in writing.

**1.36 “Supply Year”** shall have the meaning provided in Section 4.6(a).

**1.37 “Term”** shall have the meaning provided in Section 8.1.

**1.38 “Test Strip Invention”** shall have the meaning provided in Section 1.14.

**1.39 “Validation”** shall have the meaning provided in Section 3.7(a).

**1.40 “Warranty Period”** shall have the meaning provided in Section 5.1.

## 2. SCOPE—PURCHASES.

**2.1 Scope of Supply Agreement.** Unless otherwise agreed by both parties in writing, this Supply Agreement applies to all Purchase Orders which Siemens may place with UBI for any Product after the date of this Supply Agreement and after completion of development activities for such Product under the Collaboration Agreement.

**2.2 No Inconsistent or Additional Terms.** Unless otherwise agreed by both parties in a separate writing signed by authorized representatives of both parties for a specific transaction, no inconsistent or additional term or condition in any Purchase Order,

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



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acknowledgement of Purchase Order or other document delivered by either party to the other party related to any Product ordered or delivered hereunder shall be applicable to a transaction within the scope of this Supply Agreement. Terms set forth in any Purchase Order, acknowledgement thereof, or other document delivered by either party to the other party related to any Product ordered or delivered hereunder that are in addition to, inconsistent with or different from the terms set forth in this Supply Agreement shall be of no effect, and the agreed upon terms of this Supply Agreement shall govern.

**2.3 Purchase Obligation.** Except as explicitly stated to the contrary in Sections 3.21 and 7.1 and in Article 4 or in the Collaboration Agreement, this Supply Agreement shall impose no obligation on Siemens to purchase any Product from UBI, nor convey to Siemens any right to manufacture or have manufactured any Product. Except as provided in Sections 3.21 and 7.1 or in the Collaboration Agreement, should Siemens desire to purchase any Product, UBI shall sell exclusively to Siemens, and Siemens shall purchase exclusively from UBI, the quantities of such Product contained in Siemens' Purchase Orders which will be issued from time to time during the Term, subject to the terms and conditions of this Supply Agreement; *provided, however*, that Siemens acknowledges that UBI retains the right, subject to the terms and conditions of the Collaboration Agreement:

(a) to make, have made, use, sell, have sold, offer for sale, and import PT/INR \*[REDACTED] test strips solely in Field 2 and/or outside of the Field that (i) \*[REDACTED] and (ii) \*[REDACTED]; and

(b) to grant any UBI Affiliate or Third Party a license to engage in any of the activities described in the preceding subparagraph (a).

### 3. AGREEMENT TO MANUFACTURE; MANUFACTURING RESPONSIBILITIES.

**3.1 Siemens-Authorized Supplier.** A pre-condition of this Supply Agreement is that UBI must become a Siemens-authorized supplier, which means meeting and maintaining specific quality, supplier, manufacturing and service standards required of all Siemens suppliers as outlined in the QAA, attached as **Exhibit C** and Siemens' "Click-4-Suppliers" tool. In the event of any conflict between the terms of this Supply Agreement and the terms of the QAA, the terms of this Supply Agreement shall prevail.

#### 3.2 Specifications; Labeling.

(a) UBI will manufacture each Product to the applicable Specifications using the manufacturing processes as they exist as of Process Validation for such Product, with such subsequent changes thereto as may be made in compliance with Section 3.7 hereof (the "**Process**"). UBI also agrees to comply with the QAA. Prior to commencing manufacture of each Product, the Parties shall review and mutually approve the final manufacturing process to be used for the initial shipment of that Product hereunder.

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



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(b) UBI shall be responsible for calibration of each lot of Product using the calibration process forming part of the Process. Calibration parameters for each lot will be converted by UBI into a barcode that is incorporated into vial labeling and provided with the lot along with the batch release certificate and/or sent to Siemens electronically. Calibration will be conducted by UBI at UBI's sole expense in accordance with the process set forth in **Exhibit G**.

(c) UBI shall be responsible for labeling and packaging Products and shall supply Products to Siemens in final packaging ready to be shipped to customer. UBI will supply Product in sealed vials, each containing 25 strips, packed in cartons. UBI shall be responsible for labeling the strips, vials, and cartons (including strip and vial barcodes and printed cartons) and packaging vials into cartons with instructions for use and any other inserts agreed between the parties. The cartons shall be packed in appropriate shipping containers in accordance with Section 4.8 hereunder. All labeling and packaging of each Product shall be done by UBI in accordance with the packaging and labeling specifications for such Product established by mutual written agreement of the parties at the completion of development activities for such Product under Articles 2, 3 and 4 of the Collaboration Agreement, subject to amendment from time to time as mutually agreed by the parties in writing.

(d) To assist UBI with establishing a vial labeling and packaging capability in Rowville, Siemens shall, by October 30, 2012:

(i) \*[REDACTED]; and

(ii) \*[REDACTED].

UBI shall be solely responsible for \*[REDACTED]. Personal injury or property loss arising from the \*[REDACTED]. Upon expiration or termination of this Agreement, UBI shall \*[REDACTED].

**3.3 Batch Release.** UBI will provide to Siemens, or to an agreed upon notified body for products designated as Annex II by Directive 98/79/EC, copies of batch release documents, in English, for the initial shipment of each Product manufactured hereunder, or samples from such initial batch(es) to be tested by the notified body if required under the CE mark, prior to releasing the first shipment of each Product to Siemens hereunder.

**3.4 Regulatory Matters.** Siemens shall be solely responsible for obtaining and maintaining all regulatory approvals required for marketing, sale and distribution of Products in all countries in which Siemens engages in such activities. UBI shall provide Siemens all reasonable and necessary documentary and advisory assistance to Siemens in its efforts to obtain and maintain such regulatory approvals at no charge.

**3.5 Siemens Raw Material.** Siemens will supply, directly or through an Affiliate, HHS-Supplied Materials to UBI for UBI to use exclusively in the development (pursuant to the Collaboration Agreement) and manufacture of Products for Siemens hereunder. UBI shall give Siemens a \*[REDACTED] lead time to supply HHS-Supplied Materials. \*[REDACTED].

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



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UBI shall use HHS-Supplied Materials only for the development and production of Products, unless Siemens specifically and previously authorizes UBI in writing that a different source of these materials may be used in the manufacture of Products for Siemens. UBI shall not use HHS-Supplied Materials for any purposes other than the development and production of Products for Siemens. No other rights, by implication, estoppel or otherwise, are granted under the HHS Technology to UBI under this Supply Agreement or the Collaboration Agreement. The HHS Technology shall remain the exclusive property of Siemens GmbH. \***[REDACTED]**. UBI shall not transfer, disclose or otherwise make available the HHS Technology or parts of it or any HHS Invention to any Third Party without the prior express written consent of Siemens GmbH. \***[REDACTED]**. Notwithstanding anything to the contrary in this Supply Agreement or in the Collaboration Agreement, HHS Inventions (including all Proprietary Rights therein) shall be deemed to constitute \***[REDACTED]** for all purposes under the Collaboration Agreement, and the respective provisions in the Collaboration Agreement relating to \***[REDACTED]** are incorporated by reference herein and shall apply to HHS Inventions. Without limiting the generality of the foregoing, \***[REDACTED]**. Upon termination or expiration of this Supply Agreement, UBI shall promptly cease using the HHS Technology and HHS Inventions, and any and all Proprietary Rights in such HHS Inventions, and shall return to Siemens or, upon Siemens' written request, destroy any remaining HHS-Supplied Materials in UBI's possession.

The respective rights and obligations of Siemens, Siemens GmbH and UBI with respect to inventions and improvements arising from UBI's use of HHS Technology, whether before or after the Effective Date, including all Proprietary Rights therein, are exclusively those set forth in this Supply Agreement (including, without limitation, the provisions of the Collaboration Agreement that are incorporated by reference in this Supply Agreement) and the HHS Letter.

### 3.6 \***[REDACTED]**

(a) \***[REDACTED]**

(b) \***[REDACTED]**

(c) \***[REDACTED]**. Upon \***[REDACTED]**, Siemens shall have the right to use the Manufacturing Know-How solely for the purpose of exercising the licenses granted to Siemens pursuant to Section 8.1.1(c) of the Collaboration Agreement as applicable to Products only, subject to the terms and conditions of the Collaboration Agreement, including, without limitation, the obligation to pay Per-Strip Fees and bonus payments to UBI in accordance with Sections 7.2 and 7.3, respectively, of the Collaboration Agreement. All Manufacturing Know-How shall be deemed the Confidential Information of UBI, and shall be deemed to have been disclosed to Siemens by UBI (and not by a Third Party), for purposes of Article 9 of this Supply Agreement.

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



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**3.7 Changes to Manufacturing or Product Design.**

(a) **Major Changes.** Subject to Section 3.7(c) below, after Process Validation or approval of the Specifications for the initial shipment of each Product hereunder in accordance with the terms of the Collaboration Agreement, as applicable (individually and collectively, “**Validation**”), no Major Change shall be made except upon mutual written agreement of the parties. Either party may propose a Major Change by delivering a Change Order with respect thereto to the other party, and the parties shall promptly discuss such proposed Major Change in good faith, giving reasonable consideration to the proposing party’s reasons for proposing the Major Change and, if applicable, the other party’s reasons for objecting to such Major Change. A Change Order with all Siemens and UBI signature boxes approved is the only recognized authorization of a Major Change. UBI shall involve and cooperate with Siemens manufacturing and quality personnel in implementing any approved Major Change. The parties shall negotiate in good faith as to \*[REDACTED]; *provided, however*, that \*[REDACTED]. The parties acknowledge that a Major Change may \*[REDACTED]. Subject to the foregoing, neither party shall unreasonably withhold its approval of any Major Change.

(b) **Other Changes.** After Validation, in addition to the requirements for Major Changes set forth in Section 3.7(a), and subject to Section 3.7(c) below, UBI agrees not to make any other change of any Product manufacturing facility (other than manufacturing location changes, which shall be governed by Section 3.7(c)) or Third Party supplier, component, or raw material which differs from those processes, facilities, suppliers, components or materials being used or contemplated for use to produce Products at the time of Validation (“**Other Changes**”), without Siemens’ prior written approval, not to be unreasonably withheld or delayed. Without limiting the generality of the foregoing, after Validation, Siemens’ prior written approval (not to be unreasonably withheld or delayed) will be required for UBI to (i) \*[REDACTED], and (ii) \*[REDACTED]. However, the parties acknowledge that requiring Siemens’ prior written approval for each individual Other Change, regardless of its significance or insignificance, is inefficient and could result in Failures to Supply. Accordingly, no later than initiation of production of the initial shipment of each Product hereunder, the parties shall use commercially reasonable efforts to identify and in good faith reach mutual written agreement regarding specific Other Changes, or categories thereof, that may be made without Siemens’ prior written approval but with written notice to Siemens (“**Non-Major Changes**”), including (i) \*[REDACTED], (ii) \*[REDACTED], and (iii) \*[REDACTED].

**(c) Manufacturing Location Changes.**

(i) Should UBI decide that it wishes to change the location of its Product manufacturing facilities, UBI shall provide Siemens with as much prior written notice thereof as practicable, and, at Siemens’ request, the parties shall discuss in good faith UBI’s reasons for such location change and the potential impact of such location change. Siemens acknowledges that UBI has the right to change the location of its Product manufacturing facilities without Siemens’ approval; *provided, however*, that (A) under no circumstances may UBI change the location of its Product manufacturing facilities to a country that is subject to embargoes, sanctions or similar trade restrictions imposed by foreign governments that would

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prohibit or restrict Siemens from importing Products manufactured in such country or from selling Products imported from such country, and (B) UBI shall involve and cooperate with Siemens manufacturing and quality personnel in implementing such change in location of UBI's Product manufacturing facilities.

(ii) \*[REDACTED]

(iii) If UBI chooses to change the location of its Product manufacturing facilities, \*[REDACTED]:

(1) \*[REDACTED];

(2) \*[REDACTED]; or

(3) \*[REDACTED].

(iv) \*[REDACTED].

(v) In the event of any such manufacturing location change, Siemens shall have the right to inspect the new site to verify that UBI has replicated the manufacturing process for all process-critical functions.

(vi) Notwithstanding the foregoing provisions of this Section 3.7(c), \*[REDACTED].

**(d) Manufacturing Readiness.**

(i) During the validation phase and before M290 of Siemens' product development process for each Product, UBI will provide a manufacturing validation and readiness report in a format acceptable to Siemens.

(ii) Before commencing manufacturing of each Product, the parties shall conduct a joint manufacturing readiness review at UBI's Product manufacturing facility. During such review, the parties shall review all documents and information necessary for UBI to deliver such Product conforming to its Specifications.

**3.8 Testing.** UBI shall test, or have a Third Party test, Product in accordance with SOPs. As of the Effective Date, the parties do not anticipate that Siemens will supply any test equipment to UBI, or have UBI design and fabricate any test equipment that, in each case, is to be used for testing Product. However, if Siemens does supply any such test equipment to UBI, or have UBI design and fabricate any such test equipment, the requirements and schedule for maintaining and calibrating such equipment, and responsibility for the costs thereof, shall be mutually agreed by the parties in writing. UBI shall modify such test equipment as any Change Order may require or as mutually agreed upon process changes require. Siemens and UBI shall mutually agree how UBI shall be compensated for making such modification.

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**3.9 Traceability.** UBI agrees that the Material content of each Product delivered to Siemens will have clear traceability to the original Material manufacturer, except in the case of common laboratory reagents and other chemicals. UBI shall not \* [REDACTED], without the prior written approval of Siemens.

**3.10 Retention Samples and Lot Numbers.** UBI will hold reference and/or retention samples from each batch of Product and from each delivery of a batch of starting material (other than solvents, gases or water used in the manufacturing process) for each lot of Product manufactured under this Supply Agreement in accordance with UBI's Quality Management System. UBI shall also assign lot numbers to Product manufactured hereunder in accordance with UBI's Quality Management System.

**3.11 Material Purchases and Supply Chain Management.** UBI is responsible for planning, purchasing, quality assurance and payment for all Materials in accordance with this Supply Agreement, including the QAA. UBI agrees to take primary responsibility to resolve all material, technical and quality issues related to its suppliers of Materials and to use commercially reasonable efforts to resolve these issues in a timely manner and in accordance with this Supply Agreement. UBI shall use commercially reasonable efforts to manage component obsolescence to prevent disruption of supply. UBI shall promptly notify Siemens of any anticipated material or component shortages. Siemens acknowledges that, in ordering Materials, UBI will rely on the binding portions of the forecasts submitted pursuant to Section 4.5(a) and on Purchase Orders submitted by Siemens and accepted by UBI under Section 4.1.

**3.12 Inventory Requirements.** UBI will maintain sufficient supply of Products in work-in-process and/or finished goods inventory and of raw material inventory, based on Siemens' Purchase Orders and forecasts, to support UBI's commitments set forth in Section 4.5(a) and the service obligations set forth in Section 4.13 and a unit forecast and commitment provision.

**3.13 Supply of Critical Raw Materials.** Critical Raw Materials ("CRM") are irreplaceable Materials necessary to manufacture a Product. The CRM shall be stored in controlled conditions at UBI in accordance with SOPs. Prior to the date at which validation of the final manufacturing process for a Product is achieved, UBI and Siemens shall mutually agree in good faith to a list of CRMs \* [REDACTED], and UBI agrees to \*[REDACTED]. Once the list of CRMs and \*[REDACTED] is mutually agreed by the parties, if Siemens \*[REDACTED]. Once a plan is agreed to and implemented by Siemens and UBI, UBI will \*[REDACTED]. If the \* [REDACTED], at such time as Siemens (or its Affiliate or Third Party designee) assumes sole responsibility for the manufacture of Product pursuant to Section 3.21, or in the event of Persistent Supply Failure, then, in each case, UBI shall make such safety stock available to Siemens as required to produce Product, subject to reimbursement by Siemens to UBI of the cost of such safety stock plus shipping costs.

**3.14 Disaster Recovery Plan; Risk Management Plan.** Within 30 days after validation of the final manufacturing process to be used for the initial batch of a Product hereunder, UBI shall make available to Siemens for review a disaster recovery/contingency

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manufacturing plan and a risk management plan to support Siemens' Product requirements in the event of a Force Majeure event. Siemens may propose commercially reasonable changes to such plans, and UBI shall consider in good faith incorporating such proposed changes.

**3.15 Supply Interruption.** UBI shall pursue commercially reasonable efforts to manufacture and supply each Product and, under a Failure to Supply condition, to take all commercially reasonable steps to mitigate interruption of supply of such Product to Siemens, and Siemens shall provide reasonable cooperation and consultation to UBI in connection therewith. Without limiting the generality of the foregoing:

(a) If \*[REDACTED] and at either party's request, UBI and Siemens shall promptly (and in any event within 30 days after the \*[REDACTED]) convene a meeting of their respective quality and other representatives to discuss the causes of such Failures to Supply and potential steps to be taken to address the causes of such Failures of Supply or otherwise to reduce the risk of future Failures to Supply.

(b) Subject to Section 3.15(c):

(i) if at any time UBI anticipates a future condition or event which for any reason (including an end of life condition for any Product material) is likely to result in a Failure To Supply situation or prevent the timely supply of Product in accordance with this Supply Agreement, UBI shall give written notice to Siemens promptly after UBI first anticipates such future condition or event and as far in advance of the anticipated occurrence thereof as practicable; and

(ii) if at any time UBI experiences a condition or event which for any reason (including an end of life condition for any Product material) is likely to result in a Failure To Supply situation or prevent the timely supply of Product in accordance with this Supply Agreement, UBI shall give written notice to Siemens of the occurrence of such condition or event \*[REDACTED] as promptly as practicable, after the occurrence thereof.

In either case, UBI will promptly advise Siemens of the nature and probable duration of such condition or event and the nature, timing and anticipated effect of remedial actions being undertaken or planned by UBI to prevent, mitigate, reverse, eliminate and/or otherwise address such condition or event. Siemens shall provide reasonable cooperation and consultation to UBI in connection therewith.

(c) In the case of a Force Majeure event that results or is likely to result in a Failure to Supply situation or other failure to timely supply Products (including, without limitation, in the circumstances described in Section 1.11(e) hereof), UBI shall, as promptly as reasonably practicable under the circumstances, provide written notice of such Force Majeure event to Siemens, including the nature of such event or condition, and, to the extent known to UBI at such time, the probable duration of such event or condition, remedial actions being undertaken, planned or evaluated by UBI, and the timing and anticipated effect of such remedial actions. As promptly as practicable after UBI delivers any such notice, appropriate

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representatives of the parties (including, but not limited to, their quality representatives) shall consult with each other regarding the foregoing matters in good faith. In addition, except as set forth in Section 3.15(c)(ii) below, as promptly as practicable, and in any event within \*[REDACTED] after delivery of such notice, UBI shall deliver to Siemens a plan and timeline for remedial actions to be taken by UBI (a “**Remediation Plan**”), \*[REDACTED].

(i) \*[REDACTED].

(ii) \*[REDACTED].

(iii) \*[REDACTED].

**3.16 Code of Conduct and Corporate Responsibility.** The provisions of Article 15 and Annex 15.1 of the Collaboration Agreement are hereby incorporated by reference in this Supply Agreement.

**3.17 Supply Chain Security.** Siemens supports internationally recognized initiatives to secure the commercial supply chain (*e.g.*, C-TPAT, WCO SAFE Framework of Standards) so as to assure freight and or merchandise is not compromised contrary to law. Therefore, UBI must implement reasonable security control standards to ensure integrity and correctness of merchandise and accompanying commercial documentation relative to Siemens’ transaction. UBI must reasonably address the following disciplines when delivering merchandise to Siemens:

**(a) Procedural Security:** Procedures should be in place to protect against unmanifested material being introduced into the supply chain.

**(b) Physical and Access Security:** UBI’s facilities should be safeguarded to resist unlawful entry and protect against outside intrusion. Adequate measures should be considered for positively identifying employees, visitors, and vendors and to prevent unauthorized access to information technology systems.

**(c) Education and Training Awareness:** A security awareness program should be provided to employees covering cargo integrity, determining and addressing unauthorized access and communication protocols for notifying policing agencies when suspected or known illegal activities are present.

**(d) Conveyance Security:** UBI should implement reasonable steps to protect against the introduction of unauthorized personnel and material in conveyance (*e.g.*, containers, trucks, drums, etc.) destined to Siemens.

**(e) Notification:** If as a result of facilitating a shipment to Siemens, UBI suspects a supply chain security breach or concern after the dispatch from its facility, the UBI is obligated to notify Siemens immediately.

**3.18 Requirements For Country Of Manufacture Marking And Other Documentation.** Siemens shall be solely responsible for any required marking of Product with the country of manufacture, in accordance with U.S. Customs regulations and other applicable laws.

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**3.19 Environmental Protection; Duties to Declare.** Should UBI deliver legally permissible products, which are, however, subject to statutorily-imposed substance restrictions and/or information requirements (*e.g.*, REACH, RoHS), UBI shall declare such substances in the web database BOMcheck ([www.BOMcheck.net](http://www.BOMcheck.net)) or in a reasonable format provided by Siemens no later than the date of first delivery of Product. The foregoing shall only apply with respect to laws which are applicable at the registered seat of UBI. Furthermore, UBI shall also declare all substances which are set out in the list of “**Siemens Declarable Substances**”, attached as **Exhibit E**, applicable at the time of delivery in the manner described above.

**3.20 Supply Chain Logistics.** UBI agrees to establish cross functional teams with Siemens to work out logistics and implementation plan for supply chain optimization. Siemens shall be responsible for determining logistics for shipment of Products.

**3.21 Rights To Manufacture Product.** UBI grants Siemens an option, exercisable as set forth below, to manufacture Products. Siemens may exercise this option: (a) in the event of Persistent Supply Failure with respect to any Product; or (b) at any time after Siemens has purchased an aggregate of \*[REDACTED] of Product under this Supply Agreement (for the sake of clarity, \*[REDACTED]) (i) for any reason or no reason upon at least 12 months’ notice to UBI, or (ii) in the event that Control of UBI passes to any Listed Company (defined below), effective immediately upon written notice to UBI given no later than 30 days after the first public announcement of such Listed Company’s acquisition of Control of UBI. For purposes of this Section 3.21, “**Listed Company**” shall mean any of the companies identified in **Exhibit F** hereto. \*[REDACTED].

Should Siemens exercise the option, the parties shall negotiate in good faith a separate written transition agreement setting forth the parties’ respective rights and obligations with respect to Manufacturing Know-How and technology transfer for the Products and Siemens’ reimbursement and payment obligations in connection therewith. UBI will assist Siemens in the transfer of Manufacturing Know-How necessary to enable Siemens to make, sell, have made and have sold, the Products. Siemens will reimburse UBI’s reasonable costs associated with the know-how transfer, and \*[REDACTED]. Siemens shall have the right to use the Manufacturing Know-How solely for the purpose of exercising the licenses granted to Siemens pursuant to Section 8.1.1(c) of the Collaboration Agreement as applicable to the Products only for so long as such licenses remain in effect, subject to the terms and conditions of the Collaboration Agreement, including, without limitation, the obligation to pay Per-Strip Fees and bonus payments to UBI in accordance with Sections 7.2 and 7.3, respectively, of the Collaboration Agreement.

**3.22 \*[REDACTED]**

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#### 4. COMMERCIAL TERMS AND PRICING.

**4.1 Purchase Orders.** Siemens may order Products by issuing Purchase Orders to UBI at least \*[REDACTED] prior to the desired Delivery Date, and UBI shall sell Products to Siemens pursuant to such Purchase Orders, subject, in each case, to the terms of this Supply Agreement.

(a) Purchase Orders may be delivered to UBI by any reasonable means, including, but not limited to, postal delivery, courier delivery, facsimile transmission, and electronic mail, provided that Siemens shall first have confirmed with UBI the applicable mailing address, facsimile number, and/or electronic mail address to which Purchase Orders are to be submitted. Each Purchase Order shall set forth the Siemens facsimile number and/or electronic mail address to which UBI shall direct any questions, confirmations or other communications regarding such Purchase Order contemplated by Sections 4.1, 4.2 and 4.3.

(b) UBI will confirm receipt and acceptance of each Purchase Order submitted by Siemens that meets the conditions specified in this Supply Agreement within five (5) Business Days of receipt. If Siemens wishes to submit a Purchase Order that departs in any respect from the conditions specified in this Agreement (a “Non-Standard Order”) (by way of example only, a Purchase Order for a quantity of a Product that exceeds UBI’s commitments for such Product under Section 4.5(a)), Siemens shall first notify UBI of the details of Siemens’ proposed Non-Standard Order, and the parties shall promptly discuss the same in good faith. Siemens shall not submit any Non-Standard Order unless and until such time as the parties have mutually agreed to the conditions of such Non-Standard Order. UBI is under no obligation to accept any Non-Standard Order.

**4.2 Information in Purchase Orders.** Purchase Orders issued under this Supply Agreement shall contain the following information:

(a) The quantity of each Product to be shipped.

(b) The then-applicable Supply Price(s) for such Product(s).

(c) The desired Delivery Date, which shall be at least \*[REDACTED] after the date such Purchase Order is submitted to UBI.

(d) Purchase Order number.

(e) The Siemens facsimile number and/or email address to which UBI shall direct any questions, confirmations or other communications.

In addition, the parties agree to use reasonable efforts to reference this Supply Agreement in Purchase Orders issued pursuant hereto; however, this Supply Agreement shall apply to any Purchase Order for any Product regardless of whether such reference shall have been placed on the Purchase Order.

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**4.3 Discrepancy in Quantity.** Purchase Orders and forecasts for each Product will be expressed in multiples of \* [REDACTED]. For PT/INR Product, until such time as the total volume of PT/INR Product purchased by Siemens from UBI exceeds \*[REDACTED], each Purchase Order submitted by Siemens for PT/INR Product shall be for a minimum of \* [REDACTED]. Within 30 days after validation of the final manufacturing process to be used for the initial shipment of each Product hereunder, UBI shall notify Siemens of the approximate lot size, expressed as a number of strips. Siemens acknowledges that actual lot sizes will vary from run to run and that, while UBI shall use commercially reasonable efforts to ship the quantity of Product ordered by Siemens and will ship at least the quantity of Product ordered by Siemens, the actual number of strips in any lot may exceed the approximate lot size notified by UBI to Siemens as set forth above. For clarity, UBI shall have no obligation to deliver to Siemens, and Siemens shall have no obligation to accept or pay for, any such excess strips. Should UBI be unable to ship at least the quantity of Product ordered, UBI shall so notify Siemens in writing within three (3) Business Days of becoming aware of such discrepancy.

**4.4 Purchase Orders Accepted Prior to Expiration or Termination.** After this Supply Agreement otherwise terminates or expires, the provisions of this Supply Agreement shall continue to apply to any Purchase Orders issued and accepted during the Term.

#### 4.5 Supply.

(a) **Rolling Forecasts.** Siemens will provide a rolling twelve-month forecast to UBI by the end of each month. The \* [REDACTED] of each forecast shall be a non-cancelable, legally binding commitment on the part of UBI to manufacture and supply, and on the part of Siemens to purchase, the quantity of each Product set forth therein. Unless otherwise mutually agreed by the parties in writing, the \*[REDACTED] of each forecast shall be a non-cancelable, legally binding commitment on the part of UBI to manufacture and supply, and on the part of Siemens to purchase, the quantity of each Product set forth therein. The \* [REDACTED] of each forecast shall be a non-cancelable, legally binding commitment on the part of UBI to manufacture and supply up to \*[REDACTED]% of the quantity of each Product set forth therein, and on the part of Siemens to purchase at least \* [REDACTED]% the quantity of each Product set forth therein. The \*[REDACTED] of each forecast shall be non-binding on either party. To illustrate:

- \*[REDACTED]
- \*[REDACTED]
- \*[REDACTED]
- \*[REDACTED]

For the month in which Siemens wishes to receive the initial shipment of each Product (“**Initial Shipment Month**”), Siemens will provide \*[REDACTED] before the Initial Shipment Month. The \*[REDACTED] forecast will include forecasted volumes for \*[REDACTED]. The first of the rolling twelve-month forecasts described above will be submitted by the end of the month preceding the Initial Shipment Month.

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



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(b) **Delivery Times.** UBI shall use all commercially reasonable efforts to deliver Product on the Delivery Date set forth in each accepted Purchase Order, subject to Siemens' compliance with its forecasting obligations and provided that such Delivery Date is at least \*[REDACTED] after the date such Purchase Order is submitted to UBI. In the event that UBI believes it will not meet any such specified Delivery Date, UBI shall notify Siemens as soon as reasonably possible of the delay and the reasons therefor and use commercially reasonable efforts to minimize such delay.

#### 4.6 Pricing.

(a) The prices for each Product shall be based on annual volume of such Product ordered (*i.e.*, covered by Purchase Orders) during each Supply Year (defined below) as set forth in **Exhibit B**, subject to adjustment in accordance with this Section 4.6. For each 12-month period beginning on October 1 (each, a "**Supply Year**") during the Term (except in the case of the period from and including the Initial Shipment Month to September 30 of the calendar year in which the Initial Shipment Month occurs (the "**Initial Stub Period**")), the price to be charged by UBI for a Product purchased during each calendar quarter of such Supply Year shall be based on \*[REDACTED]. For purposes of this Section 4.6(a), Product will be deemed to have been "purchased" upon submission of an invoice for such Product in accordance with Section 4.12. Except as expressly set forth in this Supply Agreement or as otherwise agreed to between the parties, the purchase prices set forth in **Exhibit B** are firm and fixed and applicable to the Purchase Orders issued by Siemens during the Term. UBI shall pay all taxes, assessments, permits and fees, however designated, associated with the manufacture or sale of the Products which are levied on Product purchased by Siemens hereunder and the Product prices set forth herein are inclusive of such amounts. Siemens shall pay all taxes, assessments, permits and fees, however designated, associated with exporting the Products which are levied on Product purchased by Siemens hereunder, and the Product prices set forth herein are exclusive of such amounts. Product prices are FCA (INCOTERMS 2010) UBI's facility in Rowville, Victoria, Australia and include labeling and final packaging into vials, cartons, and shipper boxes.

(b) Prices are expressed in US Dollars and all credits, payments and refunds shall be in US Dollars.

(c) Except as expressly set forth herein, Siemens shall bear all costs of storage and insurance of Product released to Siemens hereunder.

**4.7 Performance Expectation.** Siemens and UBI will conduct quarterly business reviews at a time and date agreed upon by both parties. The purpose of these reviews is to review performance metrics and define projects to propagate continuous improvement of the products and processes covered within this Supply Agreement with long term goals to jointly reduce UBI's and Siemens' internal costs during the term. Performance metrics may include:

- Third Party supplier performance metrics
- Quality of delivered goods
- Discrepancies in quantities supplied

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- Complaint handling
- Corrective and preventive action management and status
- Obsolescence management
- Changes in materials and processes (made and in progress)
- In-field issues

Annually, at the business reviews UBI will present to Siemens any process improvement activity undertaken during such year. Siemens will present to UBI marketing achievements, plans and support metrics.

**4.8 Packing.** UBI shall pack Product using appropriate protective materials and methods intended to maintain their integrity in transit and protect Product from damage when subjected to ISTA standard tests for air, road and sea freight, consistent with SOPs, and suitably label and package Product for export from Australia, in each case, such that no further packaging actions need be taken before such shipment is transported to the exit port and exported from Australia. The parties shall mutually agree on the packing format to be used (*e.g.*, pallets, boxes), taking into consideration, among other things, the quantity of Product being shipped, provided that if the parties agree that Product will be packed on pallets, UBI and Siemens shall determine the correct size pallets for such purpose. UBI shall strive to use minimal packing materials to the extent reasonably possible and shall use commercially reasonable efforts to minimize any negative environmental impact of packing materials. Each shipment of Product delivered to Siemens in accordance with Section 4.9 shall be accompanied by a delivery docket in UBI's customary form setting forth the total number of cartons in such shipment. Each shipper box of cartons shall be clearly labeled to identify which box of the total number of boxes in the shipment it is, and the number of cartons in each shipper box shall be written on the shipper label. Any loss or damage to a shipment of Product that is solely due to non-compliance with the packing requirements set forth in the first sentence hereof will be borne by UBI.

**4.9 Shipment and Delivery.** Shipment of Product hereunder shall be made FCA (INCOTERMS 2010) UBI's facility in Rowville, Victoria, Australia, in accordance with the quantities and Delivery Dates specified in Siemens' Purchase Orders. Specifically, UBI's obligation is to deliver each shipment of Product (together with the corresponding delivery docket) to Siemens' designated carrier at UBI's facility in Rowville, Victoria, Australia, and Siemens shall be responsible for making all arrangements necessary to take Product from UBI's facility to Siemens' desired destination and shall bear all costs and risks thereof. Prior to the initial shipment of Product hereunder, UBI shall have provided Siemens with reasonable details of the appropriate shipping and storage conditions for Product (*e.g.*, regular shipping temperature and the regular storage temperature for each Product, data showing the influence of elevated or decreased temperatures for a certain period of time) in order to allow Siemens to select the appropriate means of transport and storage location.

**4.10 Certificate of Analysis.** In accordance with the QAA, UBI will provide with each shipment of Product a certificate of analysis, signed by a responsible person duly authorized to certify the quality of such Product, stating the results of UBI's release specification testing of such Product.



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**4.11 Siemens Purchasing Rights.** It is understood and agreed that Purchase Orders for Product under this Supply Agreement may be submitted directly to UBI by Siemens and its Affiliates, or by other contract manufacturers authorized by Siemens in writing to UBI, and the provisions contained herein shall be equally applicable to said purchases, provided that Siemens shall be fully responsible for the compliance of each such Affiliate or other contract manufacturer with the terms and conditions of this Supply Agreement, including, without limitation, the obligation to make payment for Product supplied hereunder.

**4.12 Payment.** UBI will submit invoices via Siemens' online invoicing tool (<http://www.iolportal.com/siemens>). UBI may submit each invoice upon Delivery of Product covered by such invoice. Siemens shall pay each UBI invoice net \*[REDACTED] from receipt of such invoice. The provisions of Section 7.8 of the Collaboration Agreement are hereby incorporated by reference in this Supply Agreement; *provided, however*, that, for purposes of this Supply Agreement, all references to "this Agreement" in such Section shall be deemed to refer to this Supply Agreement (and not to the Collaboration Agreement).

#### **4.13 Technical Support.**

(a) UBI shall provide reasonable technical Product support and training for Siemens technical support, as contemplated by the Collaboration Agreement, and as further detailed in **Exhibit D**. \*[REDACTED]

(b) The parties acknowledge and agree that Siemens shall be solely responsible for interacting with customers. Siemens shall provide prompt and proficient first, second and third level support (as described below and in **Exhibit D** attached hereto) for Product and shall handle all customer complaints and inquiries in a professional and workmanlike manner at the cost of Siemens. In order for Siemens to effectively provide support to its customers, UBI will provide Siemens with monthly updates to stability and quality control data and/or any other data that may impact Product performance or customer satisfaction, to be mutually discussed monthly and agreed upon between the parties, according to the process set forth in **Exhibit D**. For purposes of this Section 4.13, **"first level support"** shall consist of first line phone support and standard troubleshooting techniques by Siemens; **"second level support"** shall consist of an elevated level of support over and above first level support and shall include both internal team assignment and on-site troubleshooting by Siemens; and **"third level support"** shall consist of an elevated level of support beyond second level support and shall include Siemens assigning the matter to one of its regional subject matter experts regarding the problem at issue and onsite trouble-shooting by Siemens.

(c) In the event Siemens experts cannot resolve a service matter and escalation beyond third level support is required, UBI shall advise and consult with Siemens regarding such matter (**"fourth level support"**) and shall respond to any such escalated service call from Siemens within \*[REDACTED] of receiving notice of the matter in accordance with **Exhibit D** in the case of Priority 1 and Priority 2, and within \*[REDACTED] of receiving notice of the matter in accordance with **Exhibit D** in the case of Priority 3. Fourth level support may include root cause investigation, experimentation, analysis, and confirmatory testing to be

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done in coordination with Siemens and in accordance with UBI's Quality Management System. Siemens shall escalate all events deemed as potential Medical Device Reportables ("pMDRs") to the appropriate regulatory affairs personnel of UBI. Siemens shall be responsible for filing all Medical Device Reportables ("MDRs") with the appropriate regulatory agencies and will inform UBI of such filings. If an escalated matter is not responded to timely or is not closed out in accordance with **Exhibit D** by UBI, then upon written request of Siemens the parties shall meet within \*[REDACTED] of said request or as otherwise mutually agreed to by the parties to review the issue and create a plan to bring it to resolution. The parties shall also review and improve the escalation procedure to ensure that escalated matters are responded to and closed timely.

#### 4.14 Recalls and Field Corrective Actions.

(a) For purposes of this Section 4.14, the terms "recall" and "field corrective action" shall have the respective meanings set forth in Siemens Procedure GP-003 Version 9.0 effective March 9, 2012 ("GP-003"). In the event that any Product non-conformity or governmental authority may require a recall of Product (a "Recall"), Siemens shall apply GP-003 to determine whether such Recall is appropriate. Siemens shall be solely responsible for the conduct of Recalls and field corrective actions, including all filings, submissions and communications with regulatory agencies and for all customer communications on the matter. Each party shall be solely responsible for any internal costs (*e.g.*, staff time and travel costs) incurred by such party in connection with any Recall. The parties' respective responsibilities with respect to external expenses (*i.e.*, expenses paid to Third Parties, refunds for recalled Product, replacement Product, and shipping costs for replacement Product) incurred by them in connection with any Recall shall be as set forth below:

(i) \*[REDACTED]

(ii) \*[REDACTED]

(iii) \*[REDACTED]

For the avoidance of doubt, the parties' respective rights and obligations with respect to failure of Product to conform to the Product Warranty are separate and distinct from the parties' respective rights and obligations under this Section 4.14(a).

(b) In the event of a Recall, Siemens shall be permitted to inspect, audit and otherwise have access to UBI's facility records, and personnel in accordance with Article 10 of this Supply Agreement, except that Siemens may perform such an inspection/audit on one week's prior notice.

#### 5. PRODUCT WARRANTY; ACCEPTANCE AND REJECTION; CLAIMS.

**5.1 Product Warranty.** UBI warrants to Siemens that: (a) each lot of Product delivered to Siemens hereunder will, at the time of Delivery, have the manufacturing date specified on UBI's delivery docket for such Product; and (b) each lot of Product delivered to

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Siemens hereunder (1) will, at the time of Delivery and during the Warranty Period (defined below), conform to the applicable Specifications in effect at the time of Delivery (including the minimum shelf-life requirements included in such Specifications) and be free from defects in material and workmanship, and (2) will have been manufactured in compliance with UBI's obligations under the QAA in effect at the time of Delivery (collectively, the **"Product Warranty"**). The Product Warranty for a Product shall begin on Delivery and expire on the applicable expiration date for such Product (the **"Warranty Period"**); *provided, however*, that the Product Warranty with respect to a Product delivered to Siemens hereunder shall be void (and the Warranty Period shall terminate) if: **\*[REDACTED]**.

**5.2 Acceptance; Rejection.** No later than the first day of the month preceding the Initial Shipment Month, the parties shall establish notification procedures for Product rejections and claims for breach of the Product Warranty. Such notification procedures (rather than the provisions of Section 15.5 hereof) shall apply to all notices and communications required or permitted under this Section 5.2 or under Section 5.3 or Section 5.5, and the terms "notice" and "notify" (and similar terms) as used in this Section 5.2 or in Section 5.3 or Section 5.5 shall be deemed to refer to notification in accordance with such notification procedures. Siemens is entitled to reject any shipment of Product that fails to conform to the Product Warranty at the time of Delivery, provided that Siemens has first taken reasonable steps to confirm that the failure to conform to the Product Warranty did not result from Siemens or the carrier's failure to handle or transport Product in accordance with Section 4.9 and the Specifications and has provided UBI with written certification that Siemens has taken such steps. In order to reject a shipment of Product (or any portion thereof), Siemens must give written notice to UBI of Siemens's rejection of such Product within **\*[REDACTED]** after Delivery, which notice shall specify Siemens's reason(s) for rejection. If no such notice of rejection is received within **\*[REDACTED]** after Delivery, Siemens shall be deemed to have accepted such shipment. (For the avoidance of doubt, notwithstanding Siemens' acceptance or deemed acceptance of any shipment of Product, Siemens shall have the rights and remedies set forth in Section 5.3 with respect to claims for breach of the Product Warranty.) Within **\*[REDACTED]** of receiving any notice of rejection from Siemens, UBI will respond stating whether (a) it accepts the rejection or (b) it disputes the rejection, in which case the parties will refer such dispute to a mutually acceptable independent third party laboratory. Such independent laboratory shall analyze the applicable Product and shall determine whether such Product conformed or did not conform to the Product Warranty. The parties agree that such laboratory's determination shall be final and binding upon the parties. The party against whom the independent laboratory rules shall bear the costs of analysis by such independent laboratory, and if such laboratory determines that Siemens' rejection of Product was incorrect, Siemens will pay for both the initially rejected and replacement Product. Product rejected by Siemens will be returned to UBI at UBI's request and expense. Within **\*[REDACTED]** of receipt of any notice of rejection, UBI shall supply replacement Product at no additional cost.

**5.3 Warranty Claims.** If, during the Warranty Period for a Product delivered hereunder, Siemens discovers that such Product fails to conform to the Product Warranty, then, provided Siemens notifies UBI of such non-conformity as promptly as practicable but in any event within **\*[REDACTED]** of Siemens' discovery of such non-conformity, and in any event

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prior to \*[REDACTED], UBI shall promptly, at Siemens' sole option, either replace such Product with conforming Product within \*[REDACTED] thereafter, or issue Siemens a credit in the amount of the purchase price paid by Siemens for such defective Product; *provided, however*, that in the case of any claim made pursuant to this Section 5.3 after expiration or termination of this Supply Agreement, UBI shall refund to Siemens the purchase price paid by Siemens for such defective Product. Siemens' notice to UBI shall include a detailed description of the basis for Siemens' warranty claim. At UBI's request and expense, Siemens shall return the defective Product (or such quantity thereof as Siemens has in its possession or control) to UBI. If UBI in good faith disputes the basis for Siemens' warranty claim, the parties will refer such dispute to a mutually acceptable independent third party laboratory for resolution, and the costs of such laboratory's analysis shall be borne by the non-prevailing party, in each case, as described in Section 5.2, *mutatis mutandis*. Except as expressly set forth in Sections 4.13 and 4.14 and Article 12 of this Supply Agreement and Article 17 of the Collaboration Agreement, this Section 5.3 and Section 5.2 above collectively set forth Siemens' exclusive remedy, and UBI's sole liability, for delivery of any lot of Product (or portion thereof) that fails to conform to the Product Warranty; *provided, however*, that the foregoing shall not be construed to limit Siemens' rights or UBI's obligations hereunder with respect to Failures to Supply or Persistent Supply Failure (*e.g.*, under Section 3.15, 3.21 or 8.3(c)).

**5.4 Product Inspection.** Siemens, at its option and upon reasonable prior notice to UBI, shall have the right to inspect any and all Product at UBI's facility to ensure conformity to the Product Warranty. Such inspections may be made no more frequently than once every six months, or in the event of a Recall.

**5.5 HHS Warranty.** Siemens warrants to UBI that all HHS-Supplied Material delivered to UBI hereunder will, at the time of delivery to UBI, conform to the mutually-agreed specifications for such HHS-Supplied Material in effect at the time of such delivery, including the minimum shelf-life requirements included in such specifications (collectively, the "**HHS Warranty**").

## 6. FORCE MAJEURE.

Neither party shall be liable for any failure to perform, or delay in performing, hereunder by reason of any event beyond such party's reasonable control, including, without limitation, acts of God, acts of a public enemy, war, civil unrest, acts of terrorism, acts of the governments of any state or political subdivision or any department or regulatory agency thereof or entity created thereby, quotas, embargoes, acts of any person engaged in subversive activity or sabotage, fires, floods, earthquakes, other natural forces, explosions, accidents or other catastrophes, epidemics, quarantine restrictions, strikes or other labor stoppages, slowdowns or disputes, lack or failure of transportation facilities, or lack or failure of supply of raw materials, or any other event similar to those enumerated above ("**Force Majeure**"), provided, that (i) the affected party shall keep the other party fully informed as to any events likely to result in failure to perform hereunder, and (ii) the affected party shall use all commercially reasonable efforts to overcome such Force Majeure.

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**7. END-OF-LIFE OR DISCONTINUATION OF MANUFACTURE; NOTIFICATIONS.**

**7.1 Intent to Discontinue Manufacture.** UBI agrees to supply all Products subject to the terms and conditions of this Supply Agreement throughout the Term. In the event that UBI intends to discontinue manufacture of all Products, UBI shall provide Siemens with as much notice as reasonably practicable under the circumstances, but no less than \*[REDACTED] notice, and the parties shall develop a plan to transfer the Manufacturing Know-How and responsibility to Siemens for all Products in accordance with the second paragraph of Section 3.21, *mutatis mutandis*; provided, however, that, in such case, \*[REDACTED]. In such event, Siemens shall have the right to use the Manufacturing Know-How solely for the purpose of exercising the licenses granted to Siemens pursuant to Section 8.1.1(c) of the Collaboration Agreement as applicable to the Products only for so long as such licenses remain in effect, subject to the terms and conditions of the Collaboration Agreement, including, without limitation, the obligation to pay Per-Strip Fees and bonus payments to UBI in accordance with Sections 7.2 and 7.3, respectively, of the Collaboration Agreement.

**7.2 End-of-Life Mitigation Process and Strategy.** UBI shall at all times maintain and keep Siemens advised of its end of life mitigation process and strategy for CRMs. If UBI is notified by suppliers and distributors of the end of availability of a given CRM due to obsolescence or manufacturing changes, UBI will notify Siemens promptly in writing with attached documentation from the supplier or distributor supporting the notification. UBI will use commercially reasonable efforts to work with suppliers and distributors of CRMs to give no less than \*[REDACTED] advance written notice of end-of-life decisions to Siemens, and to \*[REDACTED].

**7.3** \*[REDACTED]

**7.4** \*[REDACTED]

**8. TERM AND TERMINATION.**

**8.1 Term.** This Supply Agreement shall be effective from the Effective Date and shall extend for a term of 10 years from the Effective Date (“**Initial Term**”). Upon 24 months’ written notice before the end of the Initial Term, Siemens may extend the Initial Term by five (5) years (“**Extended Term**”). For purposes of this Supply Agreement, “**Term**” shall mean the Initial Term and, if any, the Extended Term, together with any extension made pursuant to Section 8.2.

**8.2 Additional Extension.** If, during the last three (3) years of the Initial Term or Extended Term, UBI delivers notice to Siemens pursuant to Section 7.3 or Section 7.4 of this Supply Agreement, Siemens may extend the Initial Term or Extended Term, as applicable, to end not sooner than three (3) years from the date that Siemens was so notified, provided that in no event may Siemens extend the Term pursuant to this Section 8.2 beyond the 18<sup>th</sup> anniversary of the Effective Date.

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**8.3 Termination.**

**(a) At Will.** Either party may terminate this Supply Agreement prior to expiration of the Initial Term or Extended Term with 42 months' prior written notice to the other party. In the event of termination of this Supply Agreement by UBI pursuant to this Section 8.3(a):

**(i)** the parties shall develop a plan to transfer the Manufacturing Know-How and responsibility to Siemens in accordance with the second paragraph of Section 3.21, *mutatis mutandis*; *provided, however*, that, in such case, \*[REDACTED]; and

**(ii)** Siemens shall have the right to use the Manufacturing Know-How solely for the purpose of exercising the licenses granted to Siemens pursuant to Section 8.1.1(c) of the Collaboration Agreement as applicable to Products only, for so long as such licenses remain in effect, subject to the terms and conditions of the Collaboration Agreement, including, without limitation, the obligation to pay Per-Strip Fees and bonus payments to UBI in accordance with Sections 7.2 and 7.3, respectively, of the Collaboration Agreement.

**(b) For Material Breach.** Either party may terminate this Supply Agreement prior to expiration of the Initial Term or Extended Term upon written notice to the other party if the other party is in material breach of this Supply Agreement and has not cured such breach within 120 days (or 60 days with respect to any payment breach) after notice from the terminating party specifying the nature of such breach and requiring remedy of the same. Any such termination shall become effective at the end of such 120-day (or 60-day with respect to any payment breach) period, unless the breaching party has cured such breach prior to the end of such period. Any right to terminate under this Section 8.3(b) shall be stayed and the cure period tolled in the event that, during any cure period, the party alleged to have been in material breach shall have initiated dispute resolution in accordance with Article 14 with respect to the alleged breach, which stay and tolling shall continue until such dispute has been resolved in accordance with Article 14. In the event of termination of this Supply Agreement by Siemens pursuant to this Section 8.3(b), Siemens shall be permitted to use UBI's Manufacturing Know-How to manufacture, or to enable an Affiliate or Third Party to manufacture, Products solely for the purpose of exercising the licenses granted to Siemens pursuant to Section 8.1.1(c) of the Collaboration Agreement as applicable to Products only, subject to the terms and conditions of the Collaboration Agreement, including, without limitation, the obligation to pay Per-Strip Fees and bonus payments to UBI in accordance with Sections 7.2 and 7.3, respectively, of the Collaboration Agreement and subject to the jurisdiction limitations of Section 8.3(c)(ii) below. Unless otherwise agreed by the parties in writing, \*[REDACTED].

**(c) For Persistent Supply Failure.** In the event of Persistent Supply Failure:

**(i)** Siemens may, at its discretion, either terminate this Supply Agreement or work with UBI to resolve the cause(s) of the Persistent Supply Failure, until such time as it is cured to Siemens' satisfaction or Siemens determines that cure is not reasonably feasible.

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(ii) whether or not Siemens terminates this Supply Agreement, Siemens shall be permitted to use UBI's Manufacturing Know-How to manufacture, or to enable an Affiliate or Third Party to manufacture, Product solely for the purpose of exercising the licenses granted to Siemens pursuant to Section 8.1.1(c) of the Collaboration Agreement as applicable to Products only, subject to the terms and conditions of the Collaboration Agreement, including, without limitation, the obligation to pay Per-Strip Fees and bonus payments to UBI in accordance with Sections 7.2 and 7.3, respectively, of the Collaboration Agreement; *provided, however*, that, unless otherwise agreed by the parties in writing, \*[REDACTED]:

(1) \*[REDACTED];

(2) \*[REDACTED]; or

(3) \*[REDACTED];

(iii) \*[REDACTED]; and

(iv) \*[REDACTED].

**8.4 Effect of Expiration or Termination.** Neither expiration nor termination of this Supply Agreement shall relieve either party of any obligation or liability accruing prior to such expiration or termination, nor shall expiration or any termination of this Supply Agreement preclude either party from pursuing all rights and remedies it may have under this Supply Agreement, at law or in equity, with respect to breach of this Supply Agreement. Sections 2.3, 3.5, 3.10, 3.22 (second paragraph only), 4.4, 4.12, 4.14, 8.4, 15.1, 15.2, 15.3, 15.4, 15.5, 15.6, 15.8, 15.9, 15.10, 15.11 and 15.13 and Articles 1, 9, 10 (second and third paragraphs only), 12, 13 and 14 of this Supply Agreement shall survive any expiration or termination of this Supply Agreement.

In addition:

(a) Sections 5.1, 5.2 and 5.3 shall survive expiration or termination of this Supply Agreement solely with respect to Product delivered pursuant to Purchase Orders issued and accepted during the Term;

(b) any right to use Manufacturing Know-How granted pursuant to Section 3.6(b), Section 3.6(c), Section 3.21 or Section 7.1 prior to expiration or termination shall survive expiration or termination of this Supply Agreement in accordance with its terms, except in the case of termination of this Supply Agreement by UBI pursuant to Section 8.3(b), in which event any right to use Manufacturing Know-How granted pursuant to Section 3.6(b), Section 3.6(c), Section 3.21 or Section 7.1 prior to expiration or termination shall terminate and be of no further force or effect. If any right to use Manufacturing Know-How granted pursuant to Section 3.6(b), Section 3.6(c), Section 3.21 or Section 7.1 prior to expiration or termination survives expiration or termination of this Supply Agreement in accordance with the preceding sentence, then the last sentence of Section 3.13 shall also survive such expiration or termination in accordance with its terms; and

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(c) any right to use Manufacturing Know-How granted pursuant to Section 8.3(a), Section 8.3(b) or Section 8.3(c) shall survive expiration or termination of this Supply Agreement in accordance with its terms.

#### 9. CONFIDENTIALITY.

The parties acknowledge and agree that any information and data, including, but not limited to, any kind of business, commercial or technical information and data disclosed by one party to the other party in connection with this Supply Agreement, irrespective of the medium in which such information or data is embedded, which is, when disclosed in tangible form, marked "Confidential" by the disclosing party or which is, when disclosed orally or visually, identified as such prior to disclosure and summarized in writing by the disclosing party and said summary is given to the receiving party within 30 days after such disclosure marked "Confidential," shall constitute "Confidential Information" of the disclosing party for purposes of the Collaboration Agreement, including, without limitation, Article 10 thereof, except that \*[REDACTED]. The provisions of Sections 10.1 to 10.4 of the Collaboration Agreement are hereby incorporated by reference in this Supply Agreement and shall apply in analogy to Confidential Information disclosed under this Supply Agreement, except that \*[REDACTED].

#### 10. RIGHT OF INSPECTION; REGULATORY AUDITS.

Siemens or, at Siemens' option, a Third Party engaged by Siemens operating under a confidentiality agreement acceptable to UBI, shall have the right, upon at least \*[REDACTED] prior notice and during normal business hours, to visit UBI's facilities to conduct evaluations and review the performance of UBI's manufacturing operations relating to Product to assess UBI's compliance with this Supply Agreement and the QAA; *provided, however*, that the applicable notice period in the event of an inspection deemed reasonably necessary for cause, such cause including but not limited to a Recall, Persistent Supply Failure, or breach of Product Warranty, shall be two weeks. Such right may be exercised no more than once per year, unless circumstances arise that reasonably require additional inspection and/or audit, such as a Recall, Persistent Supply Failure, or breach of Product Warranty. Siemens shall also have the right, at reasonable intervals and upon reasonable prior written notice to UBI, to meet with UBI personnel and review development, production, process, and quality records relevant to the subject matter in this Supply Agreement subject to the confidentiality provisions of this Supply Agreement. In addition, in the event of a Major Change pursuant to Section 3.7, Siemens may, at its sole discretion and expense, conduct an additional audit of UBI's processes and/or facilities upon reasonable advance notice and during normal business hours.

UBI will permit governmental and/or regulatory body audits with \*[REDACTED] prior notice. UBI shall comply with all governmental, administrative and other approvals, registrations, licenses, permits and other authorizations applicable to the manufacture of Product, and Siemens shall comply with all governmental, administrative and other approvals, registrations, licenses, permits and other authorizations applicable to the marketing of Product.

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UBI will provide Siemens with copies of any FDA Form 483 notices of adverse findings, regulatory letters or similar communications it receives from any Regulatory Authority setting forth adverse findings or non-compliance with applicable laws, regulations or standards relating to the Products supplied by UBI within 10 days of UBI's receipt of such communication, provided that UBI may redact from such copies proprietary information of UBI or any Third Party that does not relate to Products.

#### 11. INSURANCE.

UBI will, at its own expense, maintain during the Term a commercial general liability insurance policy with minimum coverage of \$\*[REDACTED] per occurrence and \$\*[REDACTED] aggregate. UBI shall obtain and maintain workers' compensation insurance as required under applicable law. UBI shall provide Siemens, upon request, with a certificate of insurance evidencing such coverage.

#### 12. INDEMNIFICATION.

The provisions of Article 17 of the Collaboration Agreement are hereby incorporated by reference in this Supply Agreement; *provided, however*, that, for purposes of this Supply Agreement, all references to "this Agreement" in Sections 17.1 and 17.2 of the Collaboration Agreement shall be deemed to refer to this Supply Agreement (and not to the Collaboration Agreement). For purposes of clarification, each party shall be entitled to indemnification for an aggregate of 100% of its actual indemnifiable Losses under this Supply Agreement and the Collaboration Agreement together (*i.e.*, neither party shall be entitled to any double recovery by virtue of a particular item of Losses being indemnifiable under both this Supply Agreement and the Collaboration Agreement).

#### 13. DISCLAIMER; LIMITATION OF LIABILITY.

EXCEPT AS EXPRESSLY SET FORTH IN THIS SUPPLY AGREEMENT OR IN THE COLLABORATION AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

EXCEPT FOR LIABILITY FOR BREACH OF ARTICLE 9, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY, IN CONNECTION WITH THIS SUPPLY AGREEMENT; *provided, however*, that this Article 13 shall not be construed to limit either party's indemnification obligations under Article 12. In addition, and notwithstanding any other provision of this Supply Agreement to the contrary, \*[REDACTED].

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**14. DISPUTE RESOLUTION.**

The parties agree that any dispute arising under or relating to the parties' rights and obligations under this Supply Agreement shall be resolved in accordance with Article 14 of the Collaboration Agreement, and the provisions of Article 14 and Annex 14.1 of the Collaboration Agreement are hereby incorporated by reference in this Supply Agreement.

**15. GENERAL PROVISIONS.**

**15.1 Complete Agreement.** This Supply Agreement, including the Exhibits attached hereto and made a part of this Supply Agreement, together with the Collaboration Agreement (as modified and supplemented by this Supply Agreement), the letter agreement referred to in the Collaboration Agreement, and the HHS Letter, is the entire agreement of the parties relating to the manufacture and supply of Product, and the terms and conditions of this Supply Agreement supersede and replace any previous discussions, negotiations, terms and conditions, written or oral, between UBI and Siemens relating to the manufacture and supply of Product, excluding the Collaboration Agreement and the HHS Letter, which shall remain in full force and effect in accordance with their respective terms. In the event of any conflict between the provisions of this Supply Agreement and any Exhibit hereto, the provisions of this Supply Agreement shall control.

**15.2 Governing Law.** The construction, validity and performance of this Supply Agreement shall be governed by the laws of the State of New York, USA, without regard to conflicts of laws principles. The application of the United Nations Convention for the International Sale of Goods is hereby excluded.

**15.3 Assignment.** Except as expressly provided hereunder, neither this Supply Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either party without the prior written consent of the other party (which consent shall not be unreasonably withheld); *provided, however*, that either party may transfer its rights and obligations under the Supply Agreement, without the other party's consent, (a) in connection with the transfer or sale to a Third Party of all or substantially all of the business of such party to which the Agreement relates, whether by merger, sale of stock, sale of assets or otherwise, or (b) to any Affiliate of such party, provided that the assigning party shall remain liable and responsible to the non-assigning party hereto for the performance and observance of all such duties and obligations by such Affiliate; and, in each case, the assigning party shall provide prompt notice to the other party of any such assignment. The rights and obligations of the parties under this Supply Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the parties, and the name of a party appearing herein shall be deemed to include the name of such party's successors and permitted assigns to the extent necessary to carry out the intent of this Section 15.3. Any assignment not in accordance with this Supply Agreement shall be void.

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.





**15.4 Severability.** The provisions of this Supply Agreement are severable and in the event that one or more of such provisions shall be held to be illegal, invalid or unenforceable, the remaining provisions shall remain in full force and effect so long as the absence of the severed provision does not frustrate the purpose of this Supply Agreement.

**15.5 Notices.** Other than Purchase Orders issued and invoices submitted under this Supply Agreement and notices submitted pursuant to Article 5 of this Supply Agreement, any legal notice required or permitted to be given under this Supply Agreement must be in writing and delivered either in person, by any method of mail (postage prepaid) requiring return receipt, by overnight courier, or facsimile confirmed thereafter by any of the foregoing, to the party to be notified at its address(es) given below, or at any address such party has previously designated by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (a) the date of actual receipt; (b) if mailed, five days after the date of postmark; or (c) if delivered by express courier, the next business day the courier regularly makes deliveries in the country of the recipient. For the avoidance of doubt, notice may not be given by electronic communication.

In the case of notices to Siemens:

Siemens Healthcare Diagnostics Inc.  
511 Benedict Avenue  
Tarrytown, New York 10591-5007  
For the attention of: Law and Patents  
Fax: +1 914 524 3594

with a copy to:

Siemens Healthcare Diagnostics Inc.  
2 Edgewater Drive  
Norwood, MA 02062  
For the attention of: Purchasing Manager  
Fax: +1 781-269-3115

In the case of notices to UBI:

Universal Biosensors Pty. Ltd.  
1 Corporate Avenue  
Rowville, Victoria 3178  
Australia  
Attention: Chief Executive Officer  
Fax: +61 3 9213 9099

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



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with a copy to:

Cooley LLP  
4401 Eastgate Mall  
San Diego, CA 92121  
USA  
Attention: Jane K. Adams  
Fax: +1 (858) 550-6420

**15.6 Other Agreements.** Expiration or termination of this Supply Agreement shall not affect or diminish in any way either party's rights, duties or obligations under any other agreements between the parties, including, without limitation, the Collaboration Agreement.

**15.7 Representations.** Each party represents and warrants to the other that: (a) it is duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation or formation; (b) it has full corporate or other power and authority to enter into this Supply Agreement, and is duly authorized to execute and deliver this Supply Agreement and to perform its obligations hereunder; and (c) this Supply Agreement is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

**15.8 Waiver.** The failure or delay by a party in enforcing any provision of, or exercising any right or remedy under, this Supply Agreement shall not constitute a waiver of that provision, right or remedy, in whole or in part, in that instance or in any other instance. Any waiver by a party of a particular provision, right or remedy shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such party.

**15.9 No Agency.** Siemens and UBI are independent contractors and neither is the agent or representative of the other. The relationship between Siemens and UBI based on this Supply Agreement shall remain that of independent contractor and nothing herein shall create or imply any relationship or agreement of joint venture, partnership, franchise, or hire. NEITHER PARTY HAS AUTHORITY TO ASSUME OR CREATE ANY OBLIGATIONS ON THE OTHER'S BEHALF, EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCT OR OTHERWISE. Without limiting the generality of the foregoing, neither party shall make any representation, guarantee or warranty on the other party's behalf. Neither party shall use the other party's company name, trademarks, trade names, logos, artwork designs or abbreviations thereof in any way.

**15.10 Publication.** Except as permitted by Article 9 hereof, neither party shall disclose the terms of this Supply Agreement to any Third Party, or the nature or existence of the relationship of the parties in connection with this Supply Agreement, without first obtaining the written consent of the other party.



**15.11 Interpretation.** The headings of clauses contained in this Supply Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Supply Agreement, or have any effect on its interpretation or construction. All references in this Supply Agreement to the singular shall include the plural where applicable. Unless otherwise specified, references in this Supply Agreement to any Article shall include all Sections, subsections and paragraphs in such Article, references to any Section shall include all subsections and paragraphs in such Section, and references in this Supply Agreement to any subsection shall include all paragraphs in such subsection. Ambiguities and uncertainties in this Supply Agreement, if any, shall not be interpreted against either party, irrespective of which party may be deemed to have caused the ambiguity or uncertainty to exist. This Supply Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the parties regarding this Supply Agreement shall be in the English language.

**15.12 Counterparts.** This Supply Agreement may be executed in counterparts, including by transmission of facsimile or PDF copies of signature pages to the parties, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument.

**15.13 Amendment.** This Supply Agreement may only be amended, modified or supplemented in a writing expressly stated for such purpose and signed by duly authorized representatives of the parties.

**15.14 Exhibits.** The Exhibits attached to and made part of this Supply Agreement are as follows:

EXHIBIT A \*[REDACTED]

EXHIBIT B Price Tiers

EXHIBIT C Quality Assurance Agreement (QAA)

EXHIBIT D Service and Support Escalation Levels Defined

EXHIBIT E Siemens Declarable Substances

EXHIBIT F Listed Companies

EXHIBIT G Calibration

EXHIBIT H Code of Conduct and Corporate Responsibility

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



IN WITNESS WHEREOF, the parties have caused their respective duly authorized representatives to sign this Supply Agreement in any number of counterparts, effective as of the Effective Date.

**SIEMENS HEALTHCARE DIAGNOSTICS INC.**

\_\_\_\_\_  
/s/ A. M. COOMEY  
Signature

\_\_\_\_\_  
A. M. Coomey  
Printed

\_\_\_\_\_  
Siemens H Dx COO  
Title

\_\_\_\_\_  
9/17/2012  
Date

\_\_\_\_\_  
/s/ WOLFGANG WRUMNIG  
Signature

\_\_\_\_\_  
Wolfgang Wrumnig  
Printed

\_\_\_\_\_  
CFO  
Title

\_\_\_\_\_  
9/18/2012  
Date

\_\_\_\_\_  
/s/ DAVID STEIN  
Signature

\_\_\_\_\_  
David Stein  
Printed

\_\_\_\_\_  
CEO POC  
Title

\_\_\_\_\_  
9/19/12  
Date

**UNIVERSAL BIOSENSORS PTY LTD.**

\_\_\_\_\_  
/s/ PAUL WRIGHT  
Signature

\_\_\_\_\_  
Paul Wright  
Printed

\_\_\_\_\_  
CEO  
Title

\_\_\_\_\_  
20 September 2012  
Date



EXHIBIT A

\*[REDACTED]

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



EXHIBIT B

Price Tiers

Price Tiers:

\*[REDACTED]

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



EXHIBIT C

SIEMENS HEALTHCARE DIAGNOSTICS QUALITY ASSURANCE AGREEMENT

See attached.



SIEMENS HEALTHCARE DIAGNOSTICS



SIEMENS HEALTHCARE DIAGNOSTICS QUALITY ASSURANCE AGREEMENT

\*[REDACTED]

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.





\*[REDACTED]

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



SIEMENS HEALTHCARE DIAGNOSTICS



\*[REDACTED]

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



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SIEMENS HEALTHCARE DIAGNOSTICS

SIEMENS

## SIGNATURE PAGE

Upon signing this Quality Assurance Agreement, both parties have reviewed and agreed upon the above stated Terms as final, the signing of this document constitutes a binding contract. It is further expected that the Supplier's quality system has been established to ensure that all Siemens requirements are understood and are being met.

Siemens Healthcare Diagnostics

Supply Chain Management

By: \_\_\_\_\_  
 Name: \_\_\_\_\_  
 Title: \_\_\_\_\_  
 Date: \_\_\_\_\_

Universal Biosensors Pty Ltd.

Operations Management

(Top most level of authority for the site)

By: /s/ PAUL WRIGHT  
 Name: Paul Wright  
 Title: CEO  
 Date: 20 September 2012

Siemens Healthcare Diagnostics

RA/QS Management

By: \_\_\_\_\_  
 Name: \_\_\_\_\_  
 Title: \_\_\_\_\_  
 Date: \_\_\_\_\_

Universal Biosensors Pty Ltd.

RA/QA Management

(Highest ranking Quality position for the site)

By: /s/ ADRIAN OATES  
 Name: Adrian Oates  
 Title: VP Quality & Reg. Affairs  
 Date: 20 September 2012



EXHIBIT D

Service and Support Escalation Levels Defined

\*[REDACTED]

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



Exhibit E

SIE

MENS DECLARABLE SUBSTANCES

\*[REDACTED]

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



EXHIBIT F

Listed Companies

\*[REDACTED]

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



EXHIBIT G

Summary of Proposed Calibration Value Assignment Process  
and Traceability to WHO

\*[REDACTED]

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



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## EXHIBIT H



## Code of Conduct for Siemens Suppliers

## Siemens Corporate Responsibility

A fundamental and central part of Siemens' strategy is safeguarding the future success of Siemens and its business partners. Through a focus on Corporate Responsibility, Siemens is committing to address economic, social, ethical and environmental issues in its policies and practices. In furtherance of the foregoing: (A) SUPPLIER shall comply with the principles and requirements of the "Code of Conduct for Siemens' Suppliers" attached, (here in after the "Code of Conduct"). (B) SUPPLIER will provide Siemens within reasonable time after such request with a written self assessment as reasonably required by Siemens. (C) SUPPLIER agrees that Siemens or a third party appointed by Siemens may on reasonable notice carry out inspections (audits) on SUPPLIER's premises to verify their compliance with the Code of Conduct. (D) SUPPLIER confirms that they will use commercially reasonable efforts to forward the contents of the Code of Conduct to their suppliers and to convince them to meet the principles and requirements of this Code of Conduct.

## Commercial Supply Chain

Siemens supports internationally recognized initiatives to secure the commercial supply chain (e.g., C-TPAT, WCO SAFE Framework of Standards) so as to assure freight and or merchandise is not compromised contrary to law. Therefore, SUPPLIER must implement reasonable security control standards to ensure integrity and correctness of merchandise and accompanying commercial documentation relative to the Siemens transaction. SUPPLIER must reasonably address the following disciplines when delivering merchandise to the Buyer.

**Procedural Security:** Procedures should be in place to protect against un-manifested materials being introduced into the supply chain.

**Physical & Access Security:** SUPPLIER's facilities should be safeguarded to resist unlawful entry and protect against outside intrusion. Adequate measures should be considered for positively identifying employees, visitors, and vendors and to prevent unauthorized access to information technology systems.

**Education and Training Awareness:** A security awareness program should be provided to employees covering cargo integrity, determining and addressing unauthorized access and communication protocols for notifying policing agencies when suspected or known illegal activities are present.

**Conveyance Security:** SUPPLIER should implement reasonable steps to protect against the introduction of unauthorized personnel and materials in conveyance (e.g., containers, trucks, drums, etc.) destined to Siemens.

If as a result of facilitating a shipment to Siemens, SUPPLIER suspects a supply chain security breach or concern after the dispatch from its facility, SUPPLIER is obligated to notify Siemens immediately.

## Code of Conduct for Siemens Healthcare Diagnostics Suppliers

This Code of Conduct defines the basic requirements placed on Siemens' suppliers of goods and services concerning their responsibilities towards their stakeholders and the environment. Siemens reserves the right to reasonably change the requirements of this Code of Conduct due to changes of the Siemens Compliance Program. In such event Siemens expects the Vendor to accept those reasonable changes.

The Vendor declares herewith:

Legal compliance:

- to comply with the laws of the applicable legal system(s).

Prohibition of corruption and bribery:

- to tolerate no form of and not to engage in any form of corruption or bribery, including any payment or other form of benefit conferred on any government official for the purpose of influencing decision making in violation of law.

Respect for the basic human rights of employees:

- to promote equal opportunities for and treatment of its employees irrespective of skin color, race, nationality, social background, disabilities, sexual orientation, political or religious conviction, sex or age;
- to respect the personal dignity, privacy and rights of each individual;





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- to refuse to employ or make anyone work against his will;
- to refuse to tolerate any unacceptable treatment of employees, such as mental cruelty, sexual harassment or discrimination;
- to prohibit behavior including gestures, language and physical contact, that is sexual, coercive, threatening, abusive or exploitative;
- to provide fair remuneration and to guarantee the applicable national statutory minimum wage;
- to comply with the maximum number of working hours laid down in the applicable laws;
- to recognize, as far as legally possible, the right of free association of employees and to neither favor nor discriminate against members of employee organizations or trade unions.

Prohibition of child labor:

- to employ no workers under the age of 15 or, in those countries subject to the developing country exception of the ILO Convention 138, to employ no workers under the age of 14.

Health and Safety of employees:

- to take responsibility for the health and safety of its employees;
- to control hazards and take the best reasonably possible precautionary measures against accidents and occupational diseases;
- to provide training and ensure that employees are educated in health and safety issues; to set up or-use an occupational health & safety management system according to OHSAS 18001 or equivalent.

Environmental protection:

- to act in accordance with the applicable statutory and international standards regarding environmental protection;
- to minimize environmental pollution and make continuous improvements in environmental protection;
- to set up or-use an environmental management system according to ISO 14001 or equivalent.

Supply Chain:

- to use best efforts to promote among its suppliers compliance with this Code of Conduct;
- to comply with the principles of non discrimination with regard to supplier selection and treatment



### Exhibit 10.3

20 September 2012

Siemens Healthcare Diagnostics Inc.  
511 Benedict Avenue  
Tarrytown, NY 10591  
USA

#### Re: Supplemental Agreement – Reader Product Support Obligations and Responsibilities

Ladies and Gentlemen:

We refer to the Collaboration Agreement between Universal Biosensors Pty Ltd. (“**UBI**”) and Siemens Healthcare Diagnostics Inc. (“**Siemens**”) dated September 9, 2011 (the “**Collaboration Agreement**”). Capitalized terms used but not otherwise defined herein shall have the meanings provided in the Collaboration Agreement; *provided, however*, that the terms “Product” and “PT/INR Product” shall have the meanings provided in the Supply Agreement.

By way of background:

- The Collaboration Agreement does not address the parties’ post-development and post-launch support obligations with respect to Reader Products, and the Supply Agreement currently under negotiation between the parties for the supply of strip Products would not be an appropriate document in which to address such obligations because it does not address Reader Products.
- \*[REDACTED]
- After completion of the Development Work for the Reader Products, Siemens will be free to arrange for manufacture of the Reader Products by a Third Party of Siemens’ choosing (the “**Manufacturer**”) and to make modifications to the designs of the Reader Products and to modify and create derivative works of the UBI Collaboration Software incorporated in Reader Products.
- Although UBI is willing to provide “fourth level support” (defined below) for Reader Products, UBI may not be able to provide such support with respect to Siemens-modified wireless technology and Reader Products, including, without limitation, Reader Products incorporating Siemens’ modifications or derivative works of UBI Collaboration Software.

In consideration of the foregoing premises and the mutual covenants contained in this letter agreement (the “**Supplemental Agreement**”), UBI and Siemens, intending to be legally bound, hereby agree as follows:

**1. Critical Care Reader Amended Requirements.** As reimbursement to UBI for additional development work for the Critical Care Reader including creation of a base unit (being developed under the UBI Project referred to by the parties as “**Rubix**”) as set forth in Annex I and certain form factor changes to the Rubix base unit as set forth in Annex II, Siemens shall pay to UBI a total of US\$\* [REDACTED], which shall be payable in three installments on the schedule set forth below:

(a) US\$700,000 shall be paid by October 30, 2012;

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



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(b) US\$\*[REDACTED] shall be paid no later than\*[REDACTED]; and

(c) US\$\*[REDACTED] shall be paid no later than \*[REDACTED].

For the avoidance of doubt, the amounts payable pursuant to this paragraph 1 are in addition to the amounts payable by Siemens to UBI under the Collaboration Agreement with respect to Reader Product Development Work. All additional development work shall be conducted in accordance with and shall be subject to the terms of the Collaboration Agreement and shall be considered Development Work thereunder. For the avoidance of doubt, references to Reader Product shall now be understood to also include the base unit.

It is understood by the parties that the Requirements, Development Plan, and the additional development work of Annexes I and II hereunder are only high level descriptions and continue to require design choices and additional detail to determine how the high level requirement or specification will be met in practice. All such design choices and detail that are consistent with the high level descriptions are covered under the payments of the Collaboration Agreement or this Supplemental Agreement and Siemens shall not be responsible for any further development cost with respect to design choices and detail consistent with such high level descriptions. To the extent Siemens requests a change of the high level descriptions, \*[REDACTED].

## 2. Reader Product Support.

(a) **Technical Support and Training.** UBI shall provide reasonable technical Reader Product support and training for Siemens technical support, as contemplated by the Collaboration Agreement, and as further detailed in **Annex III**; *provided, however*, that:

(i) Siemens shall be solely responsible for providing technical support and training for Siemens technical support with respect to any change to \*[REDACTED] not made by UBI or its subcontractors incorporated in any Reader Product; and

(ii) Siemens acknowledges that any modification not made by UBI or its subcontractors to the design of a Reader Product following completion of UBI's Development Work on that Reader Product ("**Design Modification**") or modification to or derivative work of UBI Collaboration Software not made by UBI or its subcontractors following completion of UBI's Development Work ("**Software Modification**") may limit or prevent UBI from providing effective technical support and training for Siemens technical support, and Siemens therefore agrees that after reasonable efforts by UBI to provide support and training the inability of UBI to provide such support and training for Reader Products with Design Modifications and/or Software Modifications shall not be deemed a breach by UBI of the Collaboration Agreement or this Supplemental Agreement.

Subject to the foregoing limitations, \*[REDACTED].

(b) **Siemens Customer Support.** The parties acknowledge and agree that Siemens shall be solely responsible for interacting with customers. Siemens shall provide prompt and

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



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proficient first, second and third level support (as described below and in **Annex III** attached hereto) for Reader Products and shall handle all customer complaints and inquiries in a professional and workmanlike manner at the cost of Siemens. For purposes of this paragraph 2(b), “**first level support**” shall consist of first line phone support and standard troubleshooting techniques by Siemens; “**second level support**” shall consist of an elevated level of support over and above first level support and shall include both internal team assignment and on-site troubleshooting by Siemens; and “**third level support**” shall consist of an elevated level of support beyond second level support and shall include Siemens assigning the matter to one of its regional subject matter experts and/or the Manufacturer regarding the problem at issue and onsite trouble-shooting by Siemens.

(c) **UBI Customer Support.** In the event neither Siemens experts nor the Manufacturer can resolve a Reader Product service matter and escalation beyond third level support is required, UBI shall advise and consult with Siemens regarding such matter (“**fourth level support**”) and shall investigate and respond to any such escalated service call from Siemens in accordance with **Annex III**; *provided, however, that:*

(i) UBI shall apply reasonable efforts but will not be obligated to resolve fourth level support issues with respect to \*[REDACTED];

(ii) Siemens acknowledges that a Design Modification or Software Modification to a Reader Product may limit or prevent UBI from providing effective fourth level support for such Reader Product, and Siemens therefore agrees that the inability of UBI to provide effective fourth level support for Reader Products with Design Modifications and/or Software Modifications shall not be deemed a breach by UBI of the Collaboration Agreement or this Supplemental Agreement; and

(iii) because UBI will not be the manufacturer or supplier of Reader Products or components thereof, there will exist fourth level support activities for which the Manufacturer, and not UBI, will be responsible for resolving; however, UBI agrees to cooperate and provide reasonable assistance, support, and advice in working with Siemens and the Manufacturer to investigate and resolve any escalated matter even if the ultimate responsibility lies with the Manufacturer.

Fourth level support by UBI may include root cause investigation and testing, but Siemens shall be responsible for conducting any appropriate confirmatory testing in accordance with Siemens’ Quality Management System. Siemens shall escalate all events deemed as potential Medical Device Reportables (“*pMDRs*”) to the appropriate regulatory affairs personnel of Siemens. Siemens shall be responsible for filing all Medical Device Reportables (“*MDRs*”) with the appropriate regulatory agencies and will inform UBI of such filings. Subject to clauses (i), (ii) and (iii) of this paragraph 2(c), if an escalated matter is not responded to timely or is not closed out in accordance with **Annex III** by UBI, then upon written request of Siemens the parties shall meet within \* [REDACTED] of said request or as otherwise mutually agreed to by the parties to review the issue and create a plan to bring it to resolution. The parties shall also review and improve the escalation procedure to ensure that properly escalated matters are responded to and closed timely.

(d) \*[REDACTED]

(e) \*[REDACTED]

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



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(i) \*[REDACTED]; or

(ii) \*[REDACTED]

\*[REDACTED]

(f) **UBI Design Change Support.** From and after initiation of the Siemens Commercialization Phase for each Reader Product, upon Siemens' request and as specified by Siemens, UBI agrees to make, test and release changes to the Reader Product design or UBI Collaboration Software and to provide reasonable assistance to Siemens with Design Modifications and/or Software Modifications, in each case, \*[REDACTED].

Notwithstanding any provision of the Collaboration Agreement to the contrary, this paragraph 2 of this Supplemental Agreement \*[REDACTED].

**3. Reader Product Recall.** In the event that any Reader Product non-conformity or governmental authority requires, or Siemens or any of its Affiliates or licensees voluntarily conducts, any Reader Product recall, destruction, withholding from the market, or field corrective action (in each case, a "*Recall*"), Siemens shall be solely responsible for conducting such Recall, for making all filings, submissions and communications with regulatory agencies in connection with such Recall, and for all customer communications regarding such Recall, all at Siemens' sole cost and expense.

**4. Miscellaneous.** This Supplemental Agreement, including Annexes I, II and III hereto, together with the Collaboration Agreement (as supplemented and amended by this Supplemental Agreement), is both a final expression of the parties' agreement with respect to Reader Products and a complete and exclusive statement with respect to all terms relating to Reader Products. In the event of any conflict between the provisions of this Supplemental Agreement and Annexes I, II and III hereto, the provisions of this Supplemental Agreement shall control. This Supplemental Agreement may only be amended, modified or supplemented in a writing expressly stated for such purpose and signed by the parties to this Supplemental Agreement. This Supplemental Agreement may be assigned by a party only in conjunction with a permitted assignment by such party of the Collaboration Agreement. This Supplemental Agreement may be executed in counterparts, including by transmission of facsimile or PDF copies of signature pages to the parties or their representative legal counsel, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument.

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If the foregoing is acceptable to you, please sign this Supplemental Agreement in the space provided below and return it to me.

Sincerely,

**UNIVERSAL BIOSENSORS PTY LTD.**

/s/ PAUL WRIGHT

Paul Wright  
Chief Executive Officer

*Agreed to and accepted as of the Effective Date:*

**SIEMENS HEALTHCARE DIAGNOSTICS INC.**

By: /s/ DAVID STEIN 9/19/12  
Name: David Stein  
Title: CEO POC

By: /s/ WOLFGANG WRUMNIG 9/18/12  
Name: Wolfgang Wrumnig  
Title: CFO



Annex I

Rubix Base Unit Description

\*[REDACTED]

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



\*[REDACTED]

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.





\*[REDACTED]

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



\*[REDACTED]

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



Annex II

Rubix Form Factor Changes

\*[REDACTED]

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



Annex III

Service and Support Escalation Levels Defined

\*[REDACTED]

\* Confidential portion has been omitted and has been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.



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Exhibit 31.1**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Paul Wright, certify that:

1. I have reviewed this report on Form 10-Q of Universal Biosensors, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 29, 2012

/s/

Paul Wright  
Principal Executive Officer  
Universal Biosensors, Inc.



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Exhibit 31.2**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Satesh Balak, certify that:

1. I have reviewed this report on Form 10-Q of Universal Biosensors, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 29, 2012

/s/

Satesh Balak

Principal Financial Officer

Universal Biosensors, Inc.



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Exhibit 32**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 \***

In connection with the quarterly report of Universal Biosensors, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company does hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of such officer's knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company. The undersigned have executed this Certificate as of the 29<sup>th</sup> day of October, 2012.

/s/

Paul Wright

Principal Executive Officer

/s/

Salesh Balak

Principal Financial Officer

\* This certification is being furnished as required by Rule 13a-14(b) under the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code, and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section. This certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent such certification is explicitly incorporated by reference in such filing.