

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 June 30, 2009

Universal Biosensors, Inc.

(Exact name of registrant as specified in its charter)

Delaware

98-0424072

(State or other jurisdiction of
incorporation or organization)

(I.R.S. Employer Identification Number)

Universal Biosensors, Inc.
1 Corporate Avenue,
Rowville, 3178, Victoria
Australia

Not Applicable

(Address of principal executive offices)

(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 the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☐

Smaller reporting company ☒

(Do not check if a 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: 156,976,936 shares of Common Stock, U.S.\$0.0001 par value, outstanding as of August 7, 2009.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Universal Biosensors, Inc.:

We have reviewed the accompanying condensed consolidated balance sheet of Universal Biosensors, Inc and its subsidiary as of June 30, 2009, and the related condensed consolidated statements of operations for each of the three month and six month periods ended June 30, 2009 and June 30, 2008, the condensed consolidated statement of changes in stockholders' equity and comprehensive income for the six month period ended June 30, 2008 and the condensed consolidated statement of cash flows for the six month period ended June 30, 2009 and June 30, 2008. These interim financial statements are the responsibility of the Company's management.

We conducted our review in accordance with the standards of the Public Company Accounting Oversight Board (United States). A review of interim financial information consists principally of applying analytical procedures and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with the standards of the Public Company Accounting Oversight Board (United States), the objective of which is the expression of an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

Based on our review, we are not aware of any material modifications that should be made to the accompanying condensed consolidated interim financial information for it to be in conformity with accounting principles generally accepted in the United States of America.

We previously audited in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet as of 31 December 2008, and the related consolidated statements of operations and of cash flows for the year then ended (not presented herein), and in our report dated 30 March 2009 we expressed an unqualified opinion on those consolidated financial statements. In our opinion, the information set forth in the accompanying condensed consolidated balance sheet as of 30 June 2009, is fairly stated in all material respects in relation to the consolidated balance sheet from which it has been derived.


PricewaterhouseCoopers
7 August, 2009

UNIVERSAL BIOSENSORS, INC.

(A Development Stage Enterprise)

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PART I

Item 1 Financial Statements

UNIVERSAL BIOSENSORS, INC. (A Development Stage Enterprise) CONSOLIDATED CONDENSED BALANCE SHEETS (Unaudited)		
	June 30, 2009	December 31, 2008
	A\$	A\$
ASSETS		
Current assets:		
Cash and cash equivalents	22,284,881	28,334,864
Accrued income	118,305	118,305
Accounts receivables	3,459	31,657
Prepayments	2,910,572	3,730,246
Other current assets	500,855	535,000
Total current assets	25,818,072	32,750,072
Property, plant and equipment	26,553,746	23,522,706
Less accumulated depreciation	(5,173,249)	(3,767,457)
Property, plant and equipment — net	21,380,497	19,755,249
Total assets	47,198,569	52,505,321
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	504,753	630,977
Accrued expenses	813,451	838,697
Financial instruments	63,396	—
Borrowings	119,918	—
Deferred income	1,230,707	—
Employee entitlements provision	495,300	435,387
Total current liabilities	3,227,525	1,905,061
Non-current liabilities:		
Asset retirement obligations	1,770,841	1,699,133
Employee entitlements provision	222,402	197,897
Deferred income	77,088	—
Total non-current liabilities	2,070,331	1,897,030
Total liabilities	5,297,856	3,802,091
Stockholders' equity:		
Preferred stock, \$0.01 par value. Authorized 1,000,000 shares; issued and outstanding nil in 2009 (2008: nil)		
Common stock, \$0.0001 par value. Authorized 300,000,000 shares; issued and outstanding 156,976,936 shares in 2009 (2008: 156,976,936)	15,698	15,698
Additional paid-in capital	73,595,973	73,338,995
Accumulated deficit	(24,353,151)	(12,357,265)
Current year loss	(6,996,099)	(11,995,886)
Accumulated other comprehensive income	(361,708)	(298,312)
Total stockholders' equity	41,900,713	48,703,230
Total liabilities and stockholders' equity	47,198,569	52,505,321

See notes to consolidated condensed financial statements which are an integral part of these statements

UNIVERSAL BIOSENSORS, INC.

(A Development Stage Enterprise)

CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS

(Unaudited)

	Period from Inception (September 14, 2001) to June 30, 2009	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2009	2008	2009	2008
	A\$	A\$	A\$	A\$	A\$
Revenue					
Revenue from products	\$ —	\$ —	\$ —	\$ —	\$ —
Revenue from services	4,901,808	312,590	1,240,801	1,780,054	1,240,801
Total revenue from ordinary activities	4,901,808	312,590	1,240,801	1,780,054	1,240,801
Costs of revenues					
Cost of goods sold	—	—	—	—	—
Cost of services	3,183,874	47,285	1,240,801	62,120	1,240,801
Total costs of revenues	3,183,874	47,285	1,240,801	62,120	1,240,801
Gross profit	1,717,934	265,305	—	1,717,934	—
Operating expenses					
Research and development (1 and 2)	36,253,859	4,104,205	2,065,317	7,337,840	4,005,946
General and administrative (3)	16,948,642	1,395,286	1,432,689	2,585,878	2,821,702
Total operating expenses	53,202,501	5,499,491	3,498,006	9,923,718	6,827,648
Research and development income	13,816,131	349,848	274,213	738,167	553,511
Loss from operations	(37,668,436)	(4,884,338)	(3,223,793)	(7,467,617)	(6,274,137)
Other income/(expense)					
Interest income	5,059,291	193,184	702,517	460,258	1,476,474
Interest expense	(16,716)	(3,614)	(9,489)	(7,227)	(9,489)
Fee income	1,131,222	—	—	—	1,131,222
Other	163,183	52,265	(67,433)	18,487	(83,661)
Total other income/(expense)	6,336,980	241,835	625,595	471,518	2,514,546
Net loss before tax	(31,331,456)	(4,642,503)	(2,598,198)	(6,996,099)	(3,759,591)
Income tax benefit/(expense)	(17,794)	—	(2,848)	—	206
Net loss	<u>\$ (31,349,250)</u>	<u>\$ (4,642,503)</u>	<u>\$ (2,601,046)</u>	<u>\$ (6,996,099)</u>	<u>\$ (3,759,385)</u>
Basic and diluted net loss per share	\$ (0.41)	\$ (0.03)	\$ (0.02)	\$ (0.04)	\$ (0.02)
Average weighted number of shares outstanding during the period	76,022,193	156,976,936	156,969,888	156,976,936	156,964,319

Notes:

1. Net of research grant income in these amounts	2,366,063	—	59,862	—	300,613
2. Includes non-cash compensation expense (research and development)	1,325,773	81,024	253,212	177,021	331,056
3. Includes non-cash compensation expense (general and administrative)	931,095	35,506	55,910	79,957	151,674

See notes to consolidated condensed financial statements which are an integral part of these statements

UNIVERSAL BIOSENSORS, INC.
(A Development Stage Enterprise)
CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

	Period from Inception (September 14, 2001) to June 30, 2009	Six Months Ended June 30,	
		2009	2008
	A\$	A\$	A\$
Cash flows from operating activities:			
Net loss	(31,349,250)	(6,996,099)	(3,759,383)
Adjustments to reconcile net loss to net cash used in operating activities:			
Net exchange difference	1,102,572	—	—
Depreciation and impairment of plant & equipment	5,696,111	1,414,828	889,150
Share based payments expense	2,256,868	256,978	482,730
Loss on fixed assets disposal	206,506	55,821	—
Change in assets and liabilities:			
Inventory	—	—	(216,091)
Accounts receivables	(910,787)	28,198	(1,206,710)
Prepaid expenses and other current assets	(3,899)	(195,627)	16,608
Accrued income	(108,855)	—	(152,123)
Income tax payable	—	—	(18,000)
Deferred revenue	1,307,795	1,307,795	—
Employee entitlements	717,702	84,418	220,563
Accounts payable and accrued expenses	1,313,171	(179,361)	(87,384)
Net cash used in operating activities	(19,772,066)	(4,223,049)	(3,830,640)
Cash flows from investing activities:			
Proceeds/(purchases) from sale of investment securities	—	—	3,123,501
Instalment payments to acquire plant and equipment	(5,146,240)	(1,530,005)	(2,663,339)
Purchases of property, plant and equipment	(21,160,745)	(416,847)	(2,961,114)
Net cash used in investing activities	(26,306,985)	(1,946,852)	(2,500,952)
Cash flows from financing activities:			
Gross proceeds from share issue	73,517,472	—	—
Transaction costs on share issue	(4,099,870)	—	(16,659)
Proceeds from borrowings	479,673	479,673	—
Repayment of borrowings	(359,755)	(359,755)	—
Proceeds from stock options exercised	184,045	—	5,047
Net cash provided by/(used in) financing activities	69,721,565	119,918	(11,612)
Net increase/(decrease) in cash and cash equivalents	23,642,514	(6,049,983)	(6,343,204)
Cash and cash equivalent at beginning of period	—	28,334,864	41,958,285
Effect of exchange rate fluctuations on the balances of cash held in foreign currencies	(1,357,633)	—	—
Cash and cash equivalents at end of period	22,284,881	22,284,881	35,615,081

See notes to consolidated condensed financial statements which are an integral part of these statements

UNIVERSAL BIOSENSORS, INC.

(A Development Stage Enterprise)

CONSOLIDATED CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS’
EQUITY AND COMPREHENSIVE INCOME

(Unaudited)

	Preference Shares		Ordinary shares		Additional Paid-in Capital	Accumulated Deficit	Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
		A\$		A\$	A\$	A\$	A\$	A\$
Balance at September 14, 2001 (1)								
Changes during the period from September 14, 2001 through December 31, 2007								
Preference and ordinary shares issued for cash	40,386,962	16,701,436	116,071,631	11,607	54,474,378	—	—	71,187,421
Conversion of preference shares to ordinary shares	(40,386,962)	(16,701,436)	40,386,962	4,039	16,697,397	—	—	—
Exercise of stock options issued to employees	—	—	500,219	50	178,948	—	—	178,998
Stock option expense	—	—	—	—	1,038,782	—	—	1,038,782
Comprehensive Income								
Foreign currency translation reserve	—	—	—	—	—	—	(298,312)	(298,312)
Net loss for the period	—	—	—	—	—	(12,357,265)	—	(12,357,265)
Total comprehensive income								(12,655,577)
Balances at December 31, 2007	—	—	156,958,812	15,696	72,389,505	(12,357,265)	(298,312)	59,749,624
Transaction costs on shares issued in 2007	—	—	—	—	(16,663)	—	—	(16,663)
Exercise of stock options issued to employees	—	—	18,124	2	5,045	—	—	5,047
Stock option expense	—	—	—	—	482,730	—	—	482,730
Comprehensive Income								
Loss on derivatives and hedges	—	—	—	—	—	—	(21,316)	(21,316)
Net loss for the period	—	—	—	—	—	(3,759,385)	—	(3,759,385)
Total comprehensive income								(3,780,701)
Balances at June 30, 2008	—	—	156,976,936	15,698	72,860,617	(16,116,650)	(319,628)	56,440,037
Balances at December 31, 2008	—	—	156,976,936	15,698	73,338,995	(24,353,151)	(298,312)	48,703,230
Changes during the six month period ended June 30, 2009								
Comprehensive Income								
Loss on derivatives and hedges	—	—	—	—	—	—	(63,396)	(63,396)
Net loss for the period	—	—	—	—	—	(6,996,099)	—	(6,996,099)
Total comprehensive income								(7,059,495)
Stock option expense	—	—	—	—	256,978	—	—	256,978
Balances at June 30, 2009	—	—	156,976,936	15,698	73,595,973	(31,349,250)	(361,708)	41,900,713

(1) Incorporation date

UNIVERSAL BIOSENSORS, INC.
(A Development Stage Enterprise)

NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

(Unaudited)

Basis of Presentation and Summary of Significant Accounting Policies

Organization of the Company

Universal Biosensors, Inc. (the “Company”) was incorporated on September 14, 2001 in the United States, and its wholly owned subsidiary and operating vehicle, Universal Biosensors Pty Ltd, was incorporated in Australia on September 21, 2001. Collectively, the Company and its wholly owned subsidiary Universal Biosensors Pty Ltd are referred to as “Universal Biosensors” or the “Group”. The Company’s shares of common stock in the form of CHESS Depositary Interests (“CDIs”) were quoted on the Australian Securities Exchange (“ASX”) on December 13, 2006 following the initial public offering in Australia of the Company’s shares of common stock. Our securities are not currently traded on any other public market.

The Company is a specialist medical diagnostics company focused on the development, manufacture and commercialization of a range of in vitro diagnostic tests for point-of-care use. In vitro diagnostic testing involves the testing of a body fluid or tissue sample outside the body. The Company’s diagnostic tests comprise a novel disposable test strip and a reusable meter and are small, portable and easy-to-use.

Universal Biosensors has rights to an extensive patent portfolio comprising certain patent applications owned by our wholly owned Australian subsidiary, Universal Biosensors Pty Ltd, and a large number of patents and patent applications licensed to us by LifeScan, Inc. (“LifeScan”), an affiliate of Johnson & Johnson Corporation.

The Group has a range of point-of-care blood tests in development including an immunoassay point-of-care test to measure the amount of C-reactive protein in the blood which may be used to assist in the diagnosis and management of inflammatory conditions and a prothrombin time test which may be used for monitoring the therapeutic range of the anticoagulant, warfarin. The Group has developed a working prototype of the immunoassay C-reactive protein test and the prothrombin time test. The Group has also started work on a point-of-care dry immunoassay to measure the amount of D-dimer in the blood. D-dimer is a well established marker currently being used as point-of-care 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). Universal Biosensors also intends to develop additional immunoassay based point-of-care test devices by taking selected disease biomarkers currently measured in the central laboratory environment and creating tests using those biomarkers for the point-of-care setting using its novel platform of electrochemical cell technologies. Universal Biosensors proposes to focus on the development of products, which do not rely on the discovery of new medicines, treatments or biomarkers, but instead proposes to focus on areas where existing therapies or practice can be enhanced significantly by simple and accurate diagnostic tools incorporating well-known biomarkers.

On October 29, 2007 Universal Biosensors entered into a master services and supply agreement which contains the terms pursuant to which Universal Biosensors Pty Ltd would provide certain services in the field of blood glucose monitoring to LifeScan and would act as a non-exclusive manufacturer of an original version of the initial blood glucose test strips we developed for LifeScan (“Master Services and Supply Agreement”). On December 11, 2008, Universal Biosensors entered into an additional services addendum to provide manufacturing process support to assist LifeScan to establish LifeScan’s own manufacturing line for blood glucose test strips at a location of its choosing. On December 11, 2008, the Master Services and Supply Agreement was amended to reflect certain definitional matters. On May 15, 2009, the Master Services and Supply Agreement was amended and restated to incorporate certain amendments made in December 2008 and to update the commercial terms of the agreement to reflect a change from the original version of the initial blood glucose test strip to an enhanced version of the initial blood glucose test strip. The Master Services and Supply Agreement is structured as an umbrella agreement which enables Universal Biosensors and LifeScan to enter into a series of additional arrangements for the supply by Universal Biosensors of additional services and products in the field of blood glucose monitoring.

Additionally, the Group will continue to provide research and development services to LifeScan in the area of diabetes management to extend and develop the glucose sensor technology owned by LifeScan under a development and research agreement (“Development and Research Agreement”).

UNIVERSAL BIOSENSORS, INC.
(A Development Stage Enterprise)

NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

(Unaudited)

All business operations and research and development activities are undertaken in Melbourne, Australia by the Company’s wholly owned subsidiary, Universal Biosensors Pty Ltd, under the Master Services and Supply Agreement and a research and development sub-contract and sub-license agreement between Universal Biosensors Pty Ltd and the Company.

The Group is considered a development stage enterprise, as its planned commercial manufacturing operations have not yet commenced.

Interim Financial Statements

The accompanying unaudited consolidated condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States 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 accounting principles generally accepted in the United States 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 six months ended June 30, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009. For further information, refer to the financial statements and footnotes thereto as of and for the year ended December 31, 2008, included in the Form 10-K of Universal Biosensors, Inc.

The year-end condensed balance sheet data as at December 31, 2008 was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States.

Basis of Presentation

These financial statements are presented in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). All amounts are expressed in Australian dollars (“A\$”) unless otherwise stated.

The Company’s financial statements have been prepared assuming the Company will continue as a going concern. Other than a small profit in the Company’s first year of operations, the Company has sustained operating losses since inception. The Company expects to continue to incur losses as it continues the development of its point-of-care tests and expands the organization and commercial manufacturing capability until the Company is able to generate sufficient revenues under the Master Services and Supply Agreement and/ or from the sale of any of its own products.

Principles of Consolidation

The consolidated financial statements include the financial statements of the Company and its wholly owned subsidiary Universal Biosensors Pty Ltd. All intercompany balances and transactions have been eliminated in 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 inventory and property, plant and equipment, deferred income taxes, asset retirement obligations and obligations related to employee benefits. Actual results could differ from those estimates.

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.

UNIVERSAL BIOSENSORS, INC.

(A Development Stage Enterprise)

NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

(Unaudited)

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 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 are invested with two of Australia’s four largest banks. The Company is exposed to credit risk in the event of default by the banks holding the cash or cash equivalents to the extent of the amount recorded on the balance sheets. The Company has not experienced any losses on its deposits of cash and cash equivalents.

Product candidates developed by the Company may require approvals or clearances from the U.S. Food and Drug Administration or other international regulatory agencies prior to commercialized sales. There can be no assurance that the Company’s product candidates will receive any of the required approvals or clearances. If the Company was denied approval or clearance of such approval was delayed, it may have a material adverse impact on the Company.

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.

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 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. If a hedge of a forecast transaction subsequently results in the recognition of a financial asset or a financial liability, then the associated gains and losses that were recognized directly in equity are reclassified into the income statement in the same period or periods during which the asset acquired or liability assumed affects the income statement.

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 income statement in the same period or periods during which the hedged forecast transaction affects the income statement and on the same line item as that hedged forecast transaction. The ineffective part of any gain or loss is recognized immediately in the income statement.

UNIVERSAL BIOSENSORS, INC.

(A Development Stage Enterprise)

NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

(Unaudited)

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 income statement.

Inventory

Raw materials are stated at the lower of cost and net realizable value. Costs of purchased inventory are determined after deducting rebates and discounts.

Receivables

Receivables are recognized initially at fair value and subsequently measured at amortized cost, less provision for doubtful debts. Receivables are due for settlement no more than 45 days from the receipt of the invoice by the customer.

Collectibility of receivables is reviewed on an ongoing basis. Debts which are known to be uncollectible are written off. A provision for doubtful receivables is established when there is objective evidence that the Group will not be able to collect all amounts due according to the original terms of receivables. The amount of the provision is the difference between the asset’s carrying amount and the present value of estimated future cash flows, discounted at the original effective interest rate. Cash flows relating to short-term receivables are not discounted if the effect of discounting is immaterial. The amount of the provision is recognized in the income statement.

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 minor corrections and normal services and does not include items of capital nature.

	June 30, 2009	December 31, 2008
	A\$	A\$
Plant and equipment	13,214,904	13,003,248
Leasehold improvements	8,188,072	8,123,925
Capital work in process	5,150,770	2,395,533
	26,553,746	23,522,706
Accumulated depreciation	(5,173,249)	(3,767,457)
Property, plant & equipment, net	21,380,497	19,755,249

Capital work in process relates to assets under construction and comprises primarily of specialized manufacturing equipment. Legal right to the assets under construction rests with the Company. The amounts capitalized for capital work in process represents the percentage of expenditure that has been completed, and once the assets are placed into service the Company begins depreciating the respective assets. The accumulated amortization of capitalized leasehold improvements for the fiscal year ended December 31, 2008 and for the six month period ended June 30, 2009 was A\$1,501,516 and A\$2,127,683, respectively.

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The Company receives Victorian government grant monies under a grant agreement to support the establishment of a medical diagnostic manufacturing facility in Victoria through the purchase of plant and equipment. Plant and equipment is presented net of the government grant of A\$280,000 at December 31, 2008 and June 30, 2009, respectively. The grant monies are recognized against the acquisition costs of the related plant and equipment as and when the related assets are purchased. Grant monies received in advance of the relevant expenditure are treated as deferred income and included in “Current Liabilities” on the balance sheet as the Company does not control the monies until the relevant expenditure has been incurred. Grants due to the Company under the grant agreement are recorded as “Currents Assets” on the balance sheet.

Depreciation expense was \$5,696,111 for the period from inception to June 30, 2009 and \$696,958 and \$506,773 for the three months ended June 30, 2009 and 2008, respectively and \$1,414,828 and \$889,150 for the six months ended June 30, 2009 and 2008, respectively.

The movement in accumulated depreciation is agreed to depreciation expense as follows:

	Six months ended June 30, 2009	Year ended December 31, 2008
	A\$	A\$
Movement in accumulated depreciation	1,405,792	2,195,236
Accumulated depreciation of fixed assets disposed	9,036	71,611
Depreciation expense	1,414,828	2,266,847

Research and Development

Research and development expenses consists 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 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.

The Group receives Australian Commonwealth government grant funding under an R&D Start Grant Agreement as compensation for expenses incurred in respect of certain research activities into dry chemistry immunosensors. Such grants reduce the related research and development expenses as and when the relevant research expenses are incurred. Grants received in advance of incurring the relevant expenditure are treated as deferred research grants and included in current liabilities on the balance sheet as the Group has not earned these amounts until the relevant expenditure has been incurred. Grants due to the Group under research agreements are included in current assets as accrued income on the balance sheet.

Research and development expenses for the period from inception to June 30, 2009 and for the three months ended June 30, 2009 and 2008 and for the six months ended June 30, 2009 and 2008 are as follows:

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	Period from inception to June 30, 2009	Three months ended June 30,		Six months ended June 30,	
		2009	2008	2009	2008
	A\$	A\$	A\$	A\$	A\$
Research and development expenses	38,619,922	4,104,205	2,125,179	7,337,840	4,306,559
Research grants received recognized against related research and development expenses	(2,366,063)	—	(59,862)	—	(300,613)
Research and development expenses as reported	36,253,859	4,104,205	2,065,317	7,337,840	4,005,946

Income Taxes

The Company applies Statement of Financial Accounting Standards No. 109 — Accounting for Income Taxes (“SFAS 109”) 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. At present there is a full valuation allowance recognized.

The Company adopted FASB Interpretation FIN No. 48, “Accounting for Uncertainty in Income Taxes” effective January 1, 2007 which has not had a material impact on the Company’s consolidated financial statements.

We are subject to income taxes in the United States and Australia. U.S. federal income tax returns up to the 2007 financial year have been lodged. Internationally, consolidated income tax returns up to the 2008 financial year have been lodged.

Asset Retirement Obligations

Asset retirement obligations (“ARO”) are legal obligations associated with the retirement and removal of long-lived assets. SFAS No. 143 “Accounting for Asset Retirement 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 wherein in accordance with the terms of the lease, the lessee has to restore part of the building upon vacating the premises.

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Our overall ARO changed as follows:

	Six months ended June 30, 2009 A\$	Year ended December 31, 2008 A\$
Opening balance	1,699,133	1,566,892
Accretion expense	71,708	132,241
Ending balance	1,770,841	1,699,133

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 by using available market information and appropriate valuation methodologies.

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. Impairment, if any, is measured as the amount by which the carrying amount of the assets exceeds its fair value. Impairment, if any, is assessed using 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. Cash flows are presented on a gross basis.

Revenue Recognition

Revenue from services

We provide certain services to LifeScan. We perform services for LifeScan based on their requirements. There are different arrangements for each service being provided. Revenue recognition principles are assessed for each new contractual arrangement and the appropriate accounting is determined for each service. Revenues received in advance of performing the services are treated as deferred income and included in liabilities on the balance sheet as the Group has not earned these amounts until the relevant services have been performed. We recognize revenue from these services on the following bases:

- (1) as we perform the services

Under the terms of our arrangement with LifeScan, we provided certain services relating to the development and scale up of the production of our blood glucose sensor strip. Production scale up includes activities such as producing strips and testing strips. Under this arrangement, no margin was earned as the costs of providing the services were equal to the revenue recognized. In accordance with Emerging Issues Task Force (“EITF”) Issue 99-19, revenue has been recognized on a gross basis as the Company has earned revenue from the provision of services. Other factors which management considered, which support the gross basis of revenue recognition are as follows:

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- the Company was responsible for providing the service and was also the primary obligor with respect to purchasing goods and services from third party suppliers which in turn were used to provide services to LifeScan;
- the Company had unmitigated general inventory risk;
- the Company had credit risk; and
- pricing was not fixed but determined by the level of activity.

The transaction with LifeScan satisfies the revenue recognition criteria outlined in Staff Accounting Bulletin (“SAB”) 101/104. The principles of revenue recognition in SAB 104 have all been satisfied; services were performed by us which were supported by purchase orders issued by LifeScan on a regular basis, collection was assured, delivery of the services had occurred and the amount was objectively determined and reflected the cost of the services that were to be provided by us. The costs of the services, consisting of materials, labor hours and factory overheads, were largely dependant on the number of test runs that were required to be carried out by us on a monthly basis. The arrangement consisted of only one deliverable which was the development and scale up of the production activities of our blood glucose sensor strips. The relevant services performed under this arrangement were completed and ceased in September 2008. We recognized revenue from these services as we performed the services. Furthermore, the revenue received was not contingent on performing any other services.

- (2)
- on a proportional performance basis where revenues is related to costs incurred in providing the services required under the contract

The Company has been providing services to LifeScan to enable LifeScan to establish its own manufacturing line for the blood glucose sensor strips. The proportional performance method has been used to recognize revenue. We believe this method is appropriate as the contract amount was determined prior to the commencement of the service, LifeScan receives value as the services are performed and LifeScan need not re-perform the services that it has already received from the Company should the service arrangement be terminated.

Research and development revenue

On April 1, 2002, the Company and LifeScan entered into a License Agreement, pursuant to which LifeScan granted to the Company a worldwide, royalty free, exclusive license, with a limited right to sub-license, to make, have made, use, sell under and exploit in any way a range of key patents, patent applications and know-how owned by LifeScan, relating to electrochemical sensor technologies in all fields in the area of diabetes and blood glucose management generally (“LifeScan Fields”), the rights to which are retained by LifeScan. The exclusive license is subject to LifeScan having retained the right to make, have made, use, and sell under and exploit in any way the key patents, patent applications and know-how owned by LifeScan in all fields including in the fields of the Company’s own point-of-care tests. At the time of the original execution of the Master Services and Supply Agreement in October 2007, the License Agreement was amended to grant the Company a license to certain new patents outside of such field of use.

LifeScan has assumed responsibility for the cost of maintaining the licensed patents and patent applications. In the event that LifeScan elects not to proceed with the prosecution of any patent application, the Company may assume responsibility for those patents. Pursuant to the License Agreement, if the Company receives a lump sum, actual or minimum royalties payment from any sub-licence, 50% of such lump sum or royalties is payable to LifeScan.

Also on April 1, 2002, the Company and LifeScan entered into a Development and Research Agreement pursuant to which the Company agreed to undertake contract research and development for LifeScan in the area of diabetes management to extend and develop the glucose sensor technology owned by LifeScan. The research and development activities are supervised by a steering committee comprised of representatives from both the Company and LifeScan. In consideration of us undertaking the research and development activities, LifeScan makes quarterly payments to the Company. The Development and Research Agreement automatically renews for successive one year periods on the same terms and

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conditions unless either LifeScan or the Company gives written notice of termination not less than nine months prior to the end of the relevant one year period (in which case the agreement terminates at the end of the relevant one year period), or the Development and Research Agreement is otherwise terminated in accordance with its terms. LifeScan owns all intellectual property developed by the Group under the Development and Research Agreement and the Group receives a license to such intellectual property outside of the LifeScan Field.

The Development and Research Agreement provides details of the amount to be charged to LifeScan each year for the provision of research and development services. Revenue is recognized ratably over the period to which it relates and when the amount of the payment can be reliably measured and collectibility is reasonably assured. For fiscal 2009, LifeScan is paying the Company US\$250,000 per quarter under the Development and Research Agreement. For fiscal 2010, the Development and Research Agreement sets out a range of values that the Company or Universal Biosensors Pty Ltd will be paid depending on the level of research and development services required by LifeScan. In subsequent years, the steering committee will recommend the level of funding consistent with LifeScan’s requirements.

The revenue derived from the Development and Research Agreement is recognized over the period in which the agreed upon research services are completed. The Company recognizes revenue for accounting purposes ratably over the annual grant period. Under the Development and Research Agreement, the Company is not matching the revenue to a specific expenditure but to a specified period of research. The annual research and development revenue received from LifeScan is agreed with LifeScan from time to time and is subject to the Company continuing its research and development activities in the blood glucose area, the provision of quarterly reports and other obligations under the Development and Research Agreement. The Company has and continues to satisfy the requirements of the Development and Research Agreement.

The Company considers the income received under the Development and Research Agreement not to be indicative of its core operating activities or revenue producing goals of the Company, and as such account for this income as “other operating income” per SEC Regulation S-X Article 5-03. The Company is of the view that presenting the income from the Development and Research Agreement as top line revenue with estimated costs that do not include all fixed charges on a full “absorption” basis would not provide the reader of the financial statements with a true indication of future operating margins.

Revenue recognized pursuant to the Development and Research Agreement has all been received in the financial years stated. No upfront payments have been received from LifeScan. There are no claw backs or repayment obligations relating to the Development and Research Agreement.

Fee Income

Pursuant to the agreement with LifeScan, consideration of A\$1,131,222 was paid by LifeScan in consideration of the grant of rights by us. The grant of rights to LifeScan included a detailed written description of the Company’s process for the manufacture of the enhanced blood glucose product, including all underlying know-how relevant to the process. Whilst the non-refundable fee was part of an arrangement with multiple deliverables (other deliverables primarily relates to the manufacturing activities), this fee and the deliverable associated with it was considered a separate unit of accounting There are no other activities related to this deliverable and there is objective and reliable evidence of the fair value of the undelivered items. The fair value of the rights as determined by management was based on estimated market value of labour hours consumed in writing up the documents relating to the rights. There are no general rights of return of the delivered items. These rights were internally generated and were carried at zero value within our financial statements. Management had assessed that the fair value of the associated intellectual property deliverable was A\$1,131,222. The rights were transferred and the consideration received in January 2008 at which time the service requirements (granting of the rights) had been fully satisfied.

The grant of these rights is considered to be a discrete earnings event as they are not linked in any way to the other deliverables in the arrangement and there is a risk that the other deliverables may not be achieved. The other deliverables in the arrangement are primarily related to manufacturing and the Company’s ability to manufacture which can only occur once regulatory approval is received to market the product. Regulatory approval to market the product has not yet been received

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and there is a risk that the regulatory approval may not be received. Under the arrangement we have with LifeScan, they have the option of terminating the arrangement, which includes the rights for us to manufacture the product, if regulatory approval is not received. There was no such risk involved in fulfilling our service requirements for the grant of rights as the service requirements were completed and fully satisfied when the consideration was received at which point the rights were transferred to LifeScan. These rights have value to LifeScan as they are able to use this information to build their own manufacturing capability.

The consideration outlined for each of other elements in the LifeScan agreement have been separately and independently determined for each element, based on the fair value price that a third party manufacturer would charge. There is no link to the price paid for the grant of the rights and the revenue for the manufacturing element will only ever been received if regulatory approval is obtained and LifeScan order product from the company. The price outlined for manufacturing is in no way linked to the determination of the fair value of the grant of rights.

Management has concluded that the core operations of the Company in the short term are expected to be the commercial manufacture of approved medical or testing devices and the provision of services such as those specified under the Master Services and Supply Agreement. The Company’s ultimate goal is to utilize the underlying technology and skill base for the development of a marketable product that the Company will be hired to manufacture. The Company considers the income received for the grant of rights is not indicative of its core operating activities or revenue producing goals of the Company, and as such have accounted for this income as “non-operating income” per Statement of Financial Accounting Concepts No. 6, Elements of Financial Statements and SEC Regulation S-X Article 5-03. The Company believes that presenting these as top line revenue would not provide the reader of the financial statements with a true indication of future operating margins.

Interest revenue

Interest revenue is recognized as it accrues, taking into account the effective yield on the financial asset.

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 Universal Biosensors Pty Ltd is Australian Dollars for all years presented.

The consolidated financial statements are presented using a reporting currency of Australian dollars. Effective October 2008, the Company changed its reporting currency from U.S. Dollars (USD) to Australian Dollars (AUD). Prior to October 2008, the Company reported its consolidated balance sheet, statement of operations and stockholder’s equity and cash flows in USD. The related statements and corresponding notes for and prior to September 30, 2008 have been revised to reflect Australian Dollars as the reporting currency for comparison to the financial results for the year ended December 31, 2008. The change in reporting currency is to better reflect the Company’s performance and to improve investor’s ability to compare the Company’s financial results.

The functional currency of the Company for financial years up to December 31, 2005 was determined by management to be US dollars. This was based on the facts that the denomination of a significant proportion of transactions and the major source of finance were in US dollars.

In 2006, the Company expanded significantly its Australian based research activities. All of the Company’s directors became and continue to be resident in Australia. All of the Company’s expenditure on research and development is Australian dollar denominated. It also began planning for and successfully accomplished a capital raising in Australian dollars and listed on the Australian Stock Exchange. The majority of cash and other monetary assets now held by the Company are denominated in Australian dollars.

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Due to these changes in circumstance, management is of the view that the functional currency of the Company changed in 2006 to Australian dollars. This change was effective from December 1, 2006. The difference in the foreign exchange movements recognized in 2006 as a result of the change in functional currency was A\$44,430.

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 Statement of Operations.

The Company has recorded foreign currency transaction gains/(losses) of A\$18,487, (A\$83,662) and A\$164,221 for the six month period ended June 30, 2009 and 2008 and the period from inception to June 30, 2009, respectively.

Group companies

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 Foreign Currency Translation Reserve (“FCTR”).

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.

Patent and License Costs

Legal fees incurred for patent application costs have been charged to expense and reported in research and development expense.

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 product development 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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Leased Assets

All of the Group’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

Prior to January 1, 2006, the Company applied Accounting Principles Board (APB) Opinion No. 25, “Accounting for Stock Issued to Employees” and related interpretations, in accounting for its fixed-plan stock options. For periods prior to January 1, 2006, the Company complied with the disclosure only provisions of FASB Statement No.123, “Accounting for Stock-Based Compensation”, or SFAS 123. No stock-based employee compensation cost was reflected in net income, as all options granted under those plans had an exercise price equal to or greater than the market value of the underlying common stock on the date of grant (or within permitted discounted prices as it pertains to the Employee Option Plan). Results for periods before January 1, 2006 have not been restated to reflect, and do not include the impact of, FASB Statement No. 123(R), “Share Based Payment”, or SFAS 123(R).

As of January 1, 2006, the Company adopted SFAS 123(R), using the modified prospective method, which requires measurement of compensation expense of all stock-based awards at fair value on the date of grant and amortization of the fair value over the vesting period of the award. The Company has elected to use the straight-line method of amortization. Under the modified prospective method, the provisions of SFAS 123(R) apply to all awards granted or modified after the date of adoption. In addition, the unrecognized expense of awards not yet vested at the date of adoption, determined under the original provisions of SFAS No. 123 shall be recognized in net income in the periods after adoption. The fair value of stock options is determined using the Trinomial Lattice model, which is consistent with valuation techniques previously utilized for options in footnote disclosures required under SFAS No. 123, as amended by SFAS No. 148 “Accounting for Stock-Based Compensation Transition and Disclosure”.

Such value is recognized as an expense over the service period, net of estimated forfeitures, using the straight-line method under SFAS 123(R). There were no transitional adjustments on adoption of SFAS 123 (R).

The total share-based compensation expense recorded by the Company for the period from inception to June 30, 2009 and for the three months ended June 30, 2009 and 2008 and for the six months ended June 30, 2009 and 2008 is allocated among the following categories:

	Period from inception to June 30, 2009	Three Months Ended June 30,		Six Months Ended June 30,	
		2009	2008	2009	2008
	\$	\$	\$	\$	\$
Research and development	1,325,773	81,024	253,212	177,021	331,056
General and administrative	931,095	35,506	55,910	79,957	151,674
Total share-based compensation expense	2,256,868	116,530	309,122	256,978	482,730

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The above charges had no impact on the Company’s cash flows.

The assumptions for the option grants computed using a Trinomial Lattice model for options issued during the 2008 financial year and for the six month period ended June 30, 2009 were:

	Grant Date					
	June 2009	June 2009	May 2009	February 2009	August 2008	March 2008
Exercise Price (A\$)	Nil	\$0.94	Nil	\$0.50	\$0.70	\$0.89
Share Price at Grant Date (A\$)	\$0.95	\$0.95	\$1.18	\$0.43	\$0.71	\$0.91
Volatility	80%	80%	81%	77%	71%	76%
Expected Life	10 years	10 years	10 years	10 years	10 years	10 years
Risk Free Interest Rate	5.49%	5.49%	4.87%	4.26%	5.85%	5.87%
Fair Value of Option (A\$)	\$0.95	\$0.62	\$1.04	\$0.28	\$0.45	\$0.59

A summary of activity in the Employee Option Plan for the six month period ended June 30, 2009 is as follows:

	Number of Options Over Shares	Weighted-Average Exercise Price A\$
Outstanding Balance, December 31, 2008	6,373,284	0.66
Lapsed	(65,337)	1.04
Granted	2,279,200	0.70
Outstanding Balance, June 30, 2009	8,587,147	0.66
Exercisable shares as of June 30, 2009	4,820,562	0.56

All our employees are eligible for options under the Employee Option Plan. Broadly speaking, options are issued to staff under two categories — options to new staff and options to existing staff (recurring options). Options to new staff are generally granted within the year they commence employment. Recurring options are issued based on the events that transpired during the year. The number of options to be granted as part of a recurring grant of options is determined in salary bands.

As of June 30, 2009, there was A\$1,866,219 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\$
2009 — remaining periods	828,580
2010	669,416
2011	260,417
2012	68,346
2013	30,263
2014	9,197
	<u>1,866,219</u>

Pension Costs

As required by Australian law, Universal Biosensors Pty Ltd 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. Universal Biosensors Pty Ltd 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.

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Net Loss per Share and Anti-dilutive Securities

Basic and diluted net loss per share is presented in conformity with Statement of Financial Accounting Standards No. 128 — Earnings Per Share (“SFAS 128”). Basic and diluted net loss per share has been computed using the weighted-average number of common shares outstanding during the period. All periods present in these financial statements have been retroactively adjusted to give effect to the stock split in December 2006. 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 Group’s loss making position in this and previous years.

Total Comprehensive Income

The Company follows SFAS No. 130, “Reporting Comprehensive Income (Loss)” (“SFAS 130”). 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.

Recent Accounting Pronouncements

In March 2008, the Financial Accounting Standards Board (“FASB”) issued SFAS No. 161, “Disclosures about Derivative Instruments and Hedging Activities”. The new standard is intended to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity’s financial position, financial performance, and cash flows. The Company adopted SFAS No. 161, “Disclosures about Derivative Instruments and Hedging Activities” effective January 1, 2009 which has not had a material impact on the Company’s consolidated financial statements.

EITF Issue 07-01: “Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property”. This issue addresses the income statement classification of payments made between parties in a collaborative arrangement. The Company adopted EITF 07-01 effective January 1, 2009 which has not had a material impact on the Company’s consolidated financial statements.

Effective July 1, 2009, the FASB issued Statement of Financial Standards (SFAS) No. 168, “The Hierarchy of Generally Accepted Accounting Principles”. SFAS No. 168 reduces the U.S. GAAP hierarchy to two levels, one that is authoritative and one that is not. The adoption of this pronouncement is not expected to have a material effect on the consolidated financial statements.

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:

Johnson & Johnson Development Corporation, a wholly owned subsidiary of Johnson & Johnson, owns approximately 12% of the Company’s shares.

LifeScan, a wholly owned subsidiary of Johnson & Johnson, makes payments to the Company or Universal Biosensors Pty Ltd through the Development and Research Agreement, Master Services and Supply Agreement and issuance of purchase orders to Universal Biosensors Pty Ltd to undertake additional services in the field of blood glucose monitoring.

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The following transactions occurred with LifeScan:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
	A\$	A\$	A\$	A\$
<i>Current Receivables</i>				
Reimbursement of expenses			2,730	432,305
Revenue from services			—	1,236,263
			<u>2,730</u>	<u>1,668,568</u>
<i>Sale of Goods and Services</i>				
Revenue from services	<u>312,590</u>	<u>1,240,801</u>	<u>1,780,054</u>	<u>1,240,801</u>

Other transactions with LifeScan are detailed as follows:

- the Company received research and development revenue of A\$349,848 and A\$274,212 for the three months ended June 30, 2009 and 2008 and A\$738,167 and A\$553,511 for the six month ended June 30, 2009 and 2008, respectively under the Development and Research Agreement with LifeScan;
- Universal Biosensors Pty Ltd received an initial non-refundable fee of A\$1,131,222 in January 2008 in consideration for the grant of certain rights to LifeScan pursuant to the Master Services and Supply Agreement; and
- Universal Biosensors Pty Ltd was reimbursed \$0 and A\$384,900 for the three months ended June 30, 2009 and 2008 and A\$32,353 and A\$692,608 for the six months ended June 30, 2009 and 2008, respectively for certain expenditure incurred on behalf of LifeScan

Borrowings

In March 2009, Universal Biosensors Pty Ltd entered into an arrangement with Pacific Premium Funding Pty Limited to fund the Group’s insurance premium. The total amount financed is A\$479,673 at inception. Interest is charged at a rate of 2% per annum and the short-term borrowing is repayable over an 8-month period. The short-term borrowing is secured by the insurance premium refund.

Subsequent Events

On August 5, 2009, 36,248 employee stock options with an exercise value of US\$0.26 per option were exercised.

There has not arisen in the interval between the end of the second quarter and the date of this report any item, transaction or event of a material and unusual nature likely, in the opinion of the directors of the Company, to affect significantly the operations of the Company, the results of those operations, or the state of affairs of the Company in future financial years.

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.

Overview

Established in 2001, we are a specialist medical diagnostics company focused on the development, manufacture and commercialization of in vitro diagnostic test devices for point-of-care use. In vitro diagnostic testing involves the testing outside of the body of a body fluid (e.g. blood or saliva) or tissue sample (biopsies or swabs). The diagnostic blood test devices we are developing comprise a novel disposable test strip and a reusable meter. The devices are designed to be used near to or at the site of the patient (at the “point-of-care”) to provide accurate and quick results to enable treatment to be immediately reviewed. We have rights to an extensive patent portfolio comprising of certain patent applications owned by our wholly owned Australian subsidiary, Universal Biosensors Pty Ltd, and a large number of patents and patent applications licensed to us by LifeScan, an affiliate of Johnson & Johnson.

We are developing an immunoassay point-of-care test to measure the amount of C-reactive protein in the blood. A C-reactive protein test may be used to assist in the diagnosis and management of inflammatory conditions. We are also developing a prothrombin time test for monitoring the therapeutic range of the anticoagulant, warfarin and have also started work on a second point-of-care dry immunoassay to measure the amount of D-dimer in the blood. D-dimer is a well established marker currently being used as a point-of-care test for the detection and monitoring of several potentially life threatening conditions associated with thrombotic disease, particularly deep venous thrombosis (clots in the leg) and pulmonary embolism (clots in the lung). We also intend to leverage our intellectual property platform to develop additional immunoassay based point-of-care test devices by taking proven disease biomarkers currently used in the central laboratory environment and adapting those diagnostic tests to the point-of-care setting.

All of our operating activities are undertaken through our wholly-owned subsidiary, Universal Biosensors Pty Ltd which is located in Australia. We have funded our operations primarily through the sale of our equity securities, payments from LifeScan in connection with the Development and Research Agreement, an initial payment under the Master Services and Supply Agreement received in January 2008 and revenue from certain services provided to LifeScan and government and state grants.

Master Services and Supply Agreement with LifeScan

On October 29, 2007, we entered into a Master Services and Supply Agreement which contains the terms pursuant to which Universal Biosensors Pty Ltd would provide certain services in the field of blood glucose monitoring to LifeScan and would act as a non-exclusive manufacturer of an original version of the initial blood glucose test strips we developed for LifeScan (“Master Services and Supply Agreement”). On December 11, 2008, we entered into an additional services addendum to provide manufacturing process support to assist LifeScan to establish LifeScan’s own manufacturing line for new blood glucose test strips at a location of its choosing. On December 11, 2008, the Master Services and Supply Agreement was amended to reflect certain definitional matters in the document. On May 15, 2009, the agreement was

UNIVERSAL BIOSENSORS, INC.

amended and restated to incorporate the amendments made in December 2008 and to update the commercial terms of the agreement to reflect a change from the original version of the initial blood glucose test strip to an enhanced version of the initial blood glucose test strip. The enhanced initial blood glucose test strip is based on the same technology as the original product and would be manufactured using the same production processes and manufacturing equipment and infrastructure. The Master Services and Supply Agreement is structured as an umbrella agreement which enables LifeScan and us to enter into a series of additional arrangements for the supply by us of additional services and products in the field of blood glucose monitoring.

Development and Research Agreement with LifeScan

On April 1, 2002, we entered into a Development and Research Agreement with LifeScan pursuant to which we agreed to perform certain research and development activities for LifeScan in the area of diabetes management to extend and develop the glucose sensor technology owned by LifeScan. At the time of execution of the Master Services and Supply Agreement, the Development and Research Agreement was amended to conform the intellectual property provisions in the Development and Research Agreement with those in the Master Services and Supply Agreement such that LifeScan would own all intellectual property developed by us under the Development and Research Agreement and we would receive a license to such intellectual property outside of the LifeScan field of diabetes and blood glucose management generally.

In consideration of undertaking the development and research, LifeScan makes quarterly payments to us. For fiscal 2009, LifeScan is paying the Company US\$250,000 per quarter under the Development and Research Agreement. For fiscal 2010, the Development and Research Agreement sets out a range of values that the Company or Universal Biosensors Pty Ltd will be paid depending on the level of research and development services required by LifeScan. In subsequent years, the steering committee will recommend the level of funding consistent with LifeScan’s requirements. The Development and Research Agreement automatically renews for successive one year periods on the same terms and conditions unless either party has given to the other party prior written notice of termination not less than nine months prior to the end of the relevant one year period, in which case the Development and Research Agreement will terminate at the end of the relevant one year period, or the agreement is otherwise terminated in accordance with its terms.

License Agreement with LifeScan

In 2002, we entered into a License Agreement with LifeScan pursuant to which LifeScan granted to us a worldwide, royalty free, exclusive license to certain electrochemical cell technologies in all fields of use excluding the LifeScan Fields. LifeScan has retained all rights in the LifeScan Field. Under the License Agreement, we have a right to sub-license, make, have made, use, and sell under and exploit in any way a range of key patents, patent applications and know-how owned by LifeScan, relating to electrochemical cell technologies in all fields excluding the LifeScan Fields, the rights to which are retained by LifeScan. We must pay LifeScan 50% of any royalties or payments we receive under any such sublicense. We are also contractually bound to use our best efforts to exploit the licensed intellectual property outside the LifeScan Fields, for example, in our C-reactive protein, prothrombin time tests and D-dimer tests. At the time of execution of the Master Services and Supply Agreement, the License Agreement was amended to: a) clarify the scope of the LifeScan Field in which LifeScan have exclusive rights to the relevant patents; and b) to grant us a license to certain new patents outside of the LifeScan Field.

The License Agreement may be terminated by LifeScan in the event that we fail to exploit the licensed patents and patent applications or if we are liquidated or wound up or commit a persistent and material breach of our obligations under the License Agreement and fail to rectify the breach within 90 days of written notice from LifeScan requiring it to do so. The License Agreement otherwise continues on a perpetual basis until the expiration of the last licensed LifeScan patent or patent application. LifeScan may also convert the license from an exclusive license to a non-exclusive license in certain limited circumstances where we fail to comply with the requirements of the License Agreement.

Results of Operations

Gross Profit on Services Performed

Under the terms of our arrangement with LifeScan, we will assist LifeScan to establish its own manufacturing line for the new blood glucose sensor strips. Under this arrangement, revenue from the services is recognized on a proportional performance method where revenues are related to costs incurred in providing the services required under the contract.

UNIVERSAL BIOSENSORS, INC.

Research and Development Expenses

Our operating expenses to date have substantially been for research and development activities. 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. All research and development costs, including those funded by an Australian research and development grant program, are expensed as incurred. Research and development expenses include:

- consultant and employee related expenses, which include 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
- 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.

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

	Period from inception to June 30, 2009	Three months ended June 30,		Six months ended June 30,	
		2009	2008	2009	2008
	A\$	A\$	A\$	A\$	A\$
Research and development expenses	38,619,922	4,104,205	2,125,179	7,337,840	4,306,559
Research grants received recognized against related research and development expenses	(2,366,063)	—	(59,862)	—	(300,613)
Research and development expenses as reported	36,253,859	4,104,205	2,065,317	7,337,840	4,005,946

These expenses are related to developing our electrochemical cell platform technologies and producing and testing strips. Research and development expenditure attributable to services performed on behalf of LifeScan have been recorded separately under the caption “Cost of services” in the consolidated condensed statements of operations (see section above titled “Gross Profit on Services Performed”). We expect that our expenses will increase significantly during 2009 as we expand our research and development programs and expand our organization and our commercial manufacturing capability and capacity.

We have not reported our internal historical research and development costs or our personnel and personnel-related costs on a project-by-project basis. Our programs share a substantial amount of our common fixed costs such as facilities, depreciation, utilities and maintenance. Accordingly, we do not track our research and development costs by individual research and development program.

In addition, we expect research and development expenditures to grow as we advance our development programs and explore other commercial opportunities our technology platform can be applied to. We cannot predict what it will cost to complete our research and development programs or when or if they will be completed and 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 if appropriate we may enter into collaborative arrangements with third parties for one or more of our programs. In the event that third parties assume responsibility for certain research or development activities, the estimated completion dates of those activities will be under the control of the third party rather than with us. We cannot forecast with any certainty, which programs, if any, will be subject to future collaborative arrangements, in whole, or in part, and how such arrangements would affect our research and development plans or capital requirements.

As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development programs or when and to what extent we will receive cash inflows from the commercialization and

UNIVERSAL BIOSENSORS, INC.

sale of products. Our inability to complete our research and development programs in a timely manner or our failure to enter into collaborative agreements, when appropriate, could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to seek additional, external sources of financing from time to time in order to continue with our strategy. Our inability to raise additional capital on terms reasonably acceptable to us would jeopardize the future success of our business.

General and Administrative Expenses

General and administrative expenses decreased by 3% and 8% during the three and six months ended June 30, 2009 compared to the same period last year. This reduction is attributed to management reducing its expenditures primarily those related to professional/consultancy fees, repairs and travel. General and administrative expenses currently consist principally of salaries and related costs, including stock option expense, for personnel in executive, 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.

We expect that our general and administrative expenses will increase as we expand our legal, accounting, marketing and sales staff, add infrastructure and incur additional costs related to operating as a company whose shares in the form of CDIs are quoted on the ASX and compliance costs associated with being a domestic United States issuer subject to SEC reporting requirements.

Research and Development Income

We receive research and development revenue under the Development and Research Agreement with LifeScan. The Development and Research Agreement provides details of the amount to be charged to LifeScan each year for the research and development services carried out by us. Revenue is recognized when services have been performed, and the amount of the payment can be reliably measured and collectability is reasonably assured. The recognition of revenue is not based on the completion of any milestones, or on a percentage of completion basis. We recognize revenue for accounting purposes ratably over the annual grant period.

The revenue derived from the Development and Research Agreement is recognized over the period in which the agreed upon research services are completed. Under the Development and Research Agreement, we are not matching the revenue to a specific expenditure but to a specified period of research. The annual research and development revenue received from LifeScan is agreed with LifeScan from time to time and is subject to us continuing our research and development activities in the blood glucose area, the provision of quarterly reports and other obligations under the Development and Research Agreement. We have and continue to satisfy the requirements of the Development and Research Agreement.

Research and development income for the period from inception to June 30, 2009 was A\$13,816,131. Research and development income for the three months ended June 30, 2009 and 2008 was A\$349,848, A\$274,213, respectively. Research and development income for the six months ended June 30, 2009 and 2008 was A\$738,167 and A\$553,511, respectively.

Fee Income

The Company received an initial non-refundable fee of A\$1,131,222 in January 2008 in consideration for the grant of certain rights to LifeScan pursuant to the Master Services and Supply Agreement. This revenue is recorded as non-operating income in the consolidated statements of operations.

Interest Income

Interest income decreased by 73% and 69% during the three and six months ended June 30, 2009, compared to the same period last year. The decrease in interest income is attributable to the lower level of funds invested during the year and decreased returns on the funds invested.

UNIVERSAL BIOSENSORS, INC.

Interest Expense

Interest expense of A\$3,614 and A\$7,227 for the three and six months ended June 30, 2009 relates to a 2% interest being charged on a short-term borrowing. Our interest expense for the three and six months ended June 30, 2008 was A\$9,489 for each period.

Liquidity and Capital Resources

Since inception, our operations have mainly been financed through the issuance of equity securities. Additional funding has come through payments received from LifeScan under the Development and Research Agreement, revenue from services, an initial one time payment under the Master Services and Supply Agreement and a one-time payment for manufacturing process support and research grants and interest on investments. Through to June 30, 2009, we had received aggregate net cash proceeds from the following: (a) A\$32,518,792 from the renounceable rights issue; (b) A\$37,082,855 from the issuance of equity securities other than those issued under the renounceable rights offer; (c) A\$13,816,131 from LifeScan under our Development and Research Agreement; (d) A\$6,209,603 from LifeScan as revenue from services performed; (e) A\$2,646,063 as contributions from government and state grants; (f) A\$1,131,222 from LifeScan in consideration of the grant of rights by us and (g) A\$5,059,291 from interest on investments. As of June 30, 2009, we had A\$22,284,881 in cash, cash equivalents and short-term investments. Our cash and investment balances are held in money market accounts and short-term instruments. Cash in excess of immediate requirements is invested in short-term instruments with regard to liquidity and capital preservation.

For the six month period ended June 30, 2009, we used net cash of A\$4,223,049 for operating activities. This consisted of a net loss for the period of A\$6,996,099, which included A\$1,414,828 of non-cash depreciation and amortization and non-cash stock option expense of A\$256,978. Net cash used in investing activities during the six months ended June 30, 2009 was A\$1,946,852, which consisted of the purchase of property, plant and equipment of A\$416,847 and deposit towards manufacturing equipment of A\$1,530,005. Net cash provided by financing activities during the six months ended June 30, 2009 was A\$119,918, which consisted of A\$479,673 in proceeds from borrowings offset by A\$359,755 used in the repayment of borrowings.

As at June 30, 2009, we had cash and cash equivalents of A\$22,284,881 as compared to A\$35,615,081 as of June 30, 2008. The decrease in cash and cash equivalents balance is as a result of our payments for our ongoing operations including our capital expenditure outlay. The decrease has been to some extent offset by receipts from LifeScan.

In October 2007, we entered into a Master Services and Supply Agreement with LifeScan. In February 2009 we received A\$3,087,849 in connection with the provision by us to LifeScan of certain manufacturing support services. The receipt and timing of any further revenue under the Master Services and Supply Agreement is uncertain.

Choice and timing of market entry(ies) for blood glucose products covered by the Master Services and Supply Agreement are at LifeScan’s discretion. If at any time LifeScan indicates that it will not proceed with commercialization of the enhanced initial blood glucose test covered by the Master Services and Supply Agreement, or if the product does not obtain regulatory approval, we will use the installed manufacturing equipment for the immunoassay and prothrombin time tests we are developing, contingent on those tests reaching the point of manufacture. To reach that point, development efforts will need to continue to be successful. If development efforts continue to be successful and we are able to enter into a strategic partnership to support the development and commercialization of the tests, we expect to be in a position to commence formal validation of the C-reactive protein test and the prothrombin time test this financial year and 2010 for D-dimer test, following which, we will seek regulatory clearance for these tests. As appropriate, we will likely seek partners to assist in the development, sales and distribution of these tests. We also intend to develop additional immunoassay based point-of-care test devices by taking selected disease biomarkers currently measured in the central laboratory environment and creating tests using those biomarkers for the point-of-care setting using our novel platform of electrochemical cell technologies.

The total cost of the projects which we are undertaking is subject to a range of factors. As a result, we consider that at this stage of our development we are unable to provide investors with reliable details in relation to the potential cost of our project to us. We believe that with our cash, cash equivalents and the interest we earn on these balances, will allow the Group to perform under the Master Services and Supply Agreement and to progress the Group’s other development programs. In the event we do not receive the milestone payment as described under the Master Services and Supply Agreement, nor are we able to generate revenue from the manufacturing and supply of the blood glucose test, we expect to receive advance payments

UNIVERSAL BIOSENSORS, INC.

under the Development and Research Agreement and therefore we believe that our current cash and cash equivalents will be sufficient to fund our ongoing operations until the end of 2010. Notwithstanding this, by actively managing our cash flows, controlling costs and revising our development plans as necessary we believe we have sufficient cash reserves to continue as a going concern through the next 12 months. In order to achieve our objectives, we may require additional funding and/or to revise our business plans. The amount and timing of these future funding requirements is uncertain. To meet these financing requirements, we may raise funds through public or private equity offerings, debt financings, and through other means, including collaborations and license agreements or other means determined by the directors at that time.

We note our forecasted ability to maintain our financial resources to support our operations for this period is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue one or more of our planned research, development and commercialization activities. Management will determine at that point in time the activities that will be delayed, scaled-back or discontinued.

Operating Capital and Capital Expenditure Requirements

The sale of additional equity securities, if undertaken, may result in dilution to our shareholders. If we raise additional funds in the future through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research, development and commercialization activities, which could materially harm our business.

As a result of the numerous risks and uncertainties associated with our business strategy, we are unable to estimate the exact amounts of our capital and working capital requirements. We estimate our total capital expenditures in 2009 to be in the range of A\$5,000,000 to A\$6,000,000 for the purchase of equipment to support our activities under the Master Services and Supply Agreement, capacity expansion, for ongoing development of our existing products, and for other ongoing research and development activities. We have also funded the majority of the fit out cost of our new facilities at Corporate Avenue from our existing cash. Our future funding requirements will depend on many factors, including, but not limited to:

- expenses we incur in manufacturing, developing, marketing and selling products;
- any need to scale our manufacturing operations to meet demand for blood glucose strips under the Master Services and Supply Agreement, or for our point-of-care tests, including additional costs related to the fit out of our manufacturing facility in Melbourne, Australia and the acquisition of additional manufacturing equipment;
- changes to our operations to enable us to perform services required under the Master Services and Supply Agreement;
- the timing and amount of receipts of revenue from LifeScan under the Master Services and Supply Agreement;
- the success of our research and development efforts, and whether or not additional funds are required to support these;
- the rate of progress and cost of our product development activities;
- the timing and amount of revenue generated by sales of our point-of-care tests;
- costs and timing of regulatory approvals;
- costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish; and
- the acquisition of businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

UNIVERSAL BIOSENSORS, INC.

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 June 30, 2009 are:

Less than 1 year	A\$ 517,366
1 — 3 years	1,088,908
3 — 5 years	1,008,523
More than 5 years	—
Total minimum lease payments	<u>A\$2,614,798</u>

The above relates to our operating lease obligations in relation to the lease of our premises.

Contractual Obligations

Our future contractual obligations primarily for future rental payment obligations on the current office and manufacturing space, including financing costs, at June 30, 2009 were as follows:

	Total	Payments Due By Period			
		Less than 1 year	1–3 years	3–5 years	More than 5 years
Long-Term Debt Obligations	—	—	—	—	—
Asset Retirement Obligations (1)	1,770,841	—	—	—	1,770,841
Operating Lease Obligations (2)	2,614,798	517,366	1,088,908	1,008,523	—
Purchase Obligations	—	—	—	—	—
Other Long-Term Liabilities on Balance Sheet under GAAP (3)	<u>222,402</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>222,402</u>
Total	<u>4,608,041</u>	<u>517,366</u>	<u>1,088,908</u>	<u>1,008,523</u>	<u>1,993,243</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 long service leave owing to the employees

Segments

We operate in one segment. Our principal activities are the research, development, manufacture and commercialization of in vitro diagnostic test devices for point-of-care use. We operate predominantly in one geographical area, Australia.

UNIVERSAL BIOSENSORS, INC.

Item 3 Quantitative and Qualitative Disclosures About Market Risk

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.

The following table sets out the notional amounts and weighted average exchange rates by expected (contractual) maturity dates. These notional amounts generally are used to calculate the contractual payments to be exchanged under the contract.

	2009 (*)	Fair Value
Anticipated Transactions and Related Derivatives		
\$AUD Functional Currency:		
Forward exchange agreements (Sell \$AUD/Buy Euros)		
Contract amount	AUD\$615,803	A\$679,198
Average contractual exchange rate	0.5151	

* Expected maturity or transaction date

Interest Rate Risk

Our exposure to interest income sensitivity, which is affected by changes in the general level of Australian interest rates, particularly because the majority of our investments are in Australian dollars in cash and cash equivalents. 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 and will fall in value in the event market interest rates increase. 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.

UNIVERSAL BIOSENSORS, INC.

Item 4 Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

With the participation of our management, including the Company’s principal executive officer and principal financial officer, our management has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the “Exchange Act”)) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, the Company’s principal executive officer and principal financial officer have concluded that:

- information required to be disclosed by the Company in this Quarterly Report on Form 10-Q and other reports that the Company files or submits under the Exchange Act would be accumulated and communicated to the Company’s management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure;
- information required to be disclosed by the Company in this Quarterly Report on Form 10-Q and other reports that the Company files or submits under the Exchange Act would be recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms; and
- the Company’s disclosure controls and procedures are effective as of the end of the period covered by this Quarterly Report on Form 10-Q to ensure that material information relating to the Company and its consolidated subsidiaries is made known to them, particularly during the period in which the periodic reports of the Company, including this Quarterly Report on Form 10-Q, are being prepared.

Changes in Internal Control Over Financial Reporting.

During the most recent quarter ended June 30, 2009, there has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

UNIVERSAL BIOSENSORS, INC.

PART II

Item 1 Legal Proceedings

N/A

Item 1A Risk Factors

N/A

Item 2 Unregistered Sales of Equity Securities and Use of Proceeds

N/A

Item 3 Defaults Upon Senior Securities

N/A

Item 4 Submission of Matters to a Vote of Security Holders

The annual general meeting of the Company’s stockholders was held on May 14, 2009. At that meeting, three items were submitted to the Company’s stockholders with details as follows:

Item	Proposal	Details of Proposal
1(a).	Re-election of Mr. Andrew Denver as a Class I director of the Company	Proposal to re-elect Mr. Andrew Denver as a Class I director of the Company to serve a three-year term of office expiring on the date of the 2012 annual general meeting of stockholders
1(b).	Re-election of Mr. Andrew Jane as a Class I director of the Company	Proposal to re-elect Mr. Andrew Jane as a Class II director of the Company to serve a three-year term of office expiring on the date of the 2012 annual general meeting of stockholders
2.	Adoption and approval of remuneration report	Proposal that the security holders have the opportunity to vote in respect of the remuneration report of the Company. The vote on the resolution is advisory only and does not bind the board of directors of the Company

For further information regarding the annual general meeting, please see the Company’s definitive proxy statement filed with the Securities and Exchange Commission on May 14, 2009. The stockholders approved the proposals as follows:

Resolution	Votes For	Votes Against	Abstentions
Proposal 1(a) Re-election of Mr. Andrew Denver	72,010,400	Nil	Nil
Proposal 1(b) Re-election of Mr. Andrew Jane	72,010,400	Nil	Nil
Proposal 2 Adoption and approval of remuneration report	71,970,400	63,985	40,000*

* Abstentions with respect to this resolution is counted as votes against the proposal.

Item 5 Other Information

N/A

UNIVERSAL BIOSENSORS, INC.

Item 6 Exhibits

Exhibit No	Description	Location
10.1	Advanced Care Enhanced Product Agreement (which is an addendum to the Amended and Restated Master Services and Supply Agreement filed with this Form 10-Q as Exhibit 10.3) (Portions of this Exhibit have been omitted pursuant to a request for confidential treatment)	Filed herewith
10.2	Amendment to Development and Research Agreement (which amends the Development and Research Agreement filed on April 30, 2007 on Form 10 as Exhibit 10.2 and the Amendment to Development and Research Agreement filed on November 14, 2007 on Form 10-Q as Exhibit 10.3)	Filed herewith
10.3	Amended and Restated Master Services and Supply Agreement (which amends and restates the Master Services and Supply Agreement filed on November 14, 2007 on Form 10-Q as Exhibit 10.1 and the First Amendment to the Master Services and Supply Agreement filed on March 30, 2009 on Form 10-K as Exhibit 10.14) (Portions of this Exhibit have been omitted pursuant to a request for confidential treatment)	Filed herewith
10.4	Manufacturing Initiation Payment Addendum to Master Services and Supply Agreement (which is an addendum to the Amended and Restated Master Services and Supply Agreement filed with this Form 10-Q as Exhibit 10.3) (Portions of this Exhibit have been omitted pursuant to a request for confidential treatment)	Filed herewith
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
32.0	* Section 1350 Certificate	Filed herewith

* This exhibit is furnished rather than filed, and shall not be incorporated by reference into any filing of the registrant in accordance with Item 601 of Registration S-K

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: August 7, 2009

By: /s/ MARK MORRISSON
Mark Morrisson
Chief Executive Officer and Executive Director

Date: August 7, 2009

By: /s/ SALESH BALAK
Salesh Balak
Chief Financial Officer

INDEX TO EXHIBITS
Quarterly Report on Form 10-Q
Dated August 7, 2009

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10.1	Advanced Care Enhanced Product Agreement (which is an addendum to the Amended and Restated Master Services and Supply Agreement filed with this Form 10-Q as Exhibit 10.3) (Portions of this Exhibit have been omitted pursuant to a request for confidential treatment)	Filed herewith
10.2	Amendment to Development and Research Agreement (which amends the Development and Research Agreement filed on April 30, 2007 on Form 10 as Exhibit 10.2 and the Amendment to Development and Research Agreement filed on November 14, 2007 on Form 10-Q as Exhibit 10.3)	Filed herewith
10.3	Amended and Restated Master Services and Supply Agreement (which amends and restates the Master Services and Supply Agreement filed on November 14, 2007 on Form 10-Q as Exhibit 10.1 and the First Amendment to the Master Services and Supply Agreement filed on March 30, 2009 on Form 10-K as Exhibit 10.14) (Portions of this Exhibit have been omitted pursuant to a request for confidential treatment)	Filed herewith
10.4	Manufacturing Initiation Payment Addendum to Master Services and Supply Agreement (which is an addendum to the Amended and Restated Master Services and Supply Agreement filed with this Form 10-Q as Exhibit 10.3) (Portions of this Exhibit have been omitted pursuant to a request for confidential treatment)	Filed herewith
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
32.0	* Section 1350 Certificate	Filed herewith

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Exhibit 10.1

Fourth Services Addendum — Advanced Care
Enhanced Product

Dated with effect from 14 May, 2009

This Services Addendum (**Fourth Services Addendum**) to the Master Services and Supply Agreement dated 29 October 2007 as amended and restated on 14 May 2009 between LifeScan, Inc., Universal Biosensors Pty Ltd and Universal Biosensors, Inc. (**Master Agreement**) is entered into by and between LifeScan, Inc., a Californian corporation of 1000 Gibraltar Drive, Milpitas, CA 95035-6312, USA (**LifeScan**), Universal Biosensors Pty Ltd ACN 098 234 309, a company incorporated in Victoria, Australia of 1 Corporate Avenue, Rowville, Victoria 3178, Australia (**UBS**) and Universal Biosensors, Inc., a Delaware corporation having its registered office at c/o Corporation Service Company 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808 USA (**UBI**).

The parties agree that this Fourth Services Addendum is to be attached to, and form part of the Master Agreement. In relation to the matters addressed in this Fourth Services Addendum, each of LifeScan, UBS and UBI agree to be bound by all of the terms and conditions of the Master Agreement including without limitation Sections 10.3 (Manner of Performing the Services) and 11.4 (Audit Rights) and each party makes the representations and warranties set forth in the Master Agreement expressed to be made by LifeScan, UBS or UBI, as the case may be.

All capitalized terms used in this Fourth Services Addendum and not otherwise defined herein shall have the meaning ascribed to such terms in the Master Agreement (including all Service Addendums and Product Addendums).

Background

LifeScan wishes for UBS to provide Services in connection with the feasibility, development, validation, and launch and post launch support, of a Product intended for the advanced care setting, and meeting the Product Specification to be set forth in functional specification quality management system MER003 (**ACEP Product Specifications**) as such Product Specifications may be modified from time to time in accordance with clause 5.3 of the Master Agreement (**Advanced Care Enhanced Product** or **ACEP**). The parties agree that the ACEP Product Specifications shall conform with the Target ACEP Product Specifications profile set forth in Annexure A hereto (**Annexure A**). The ACEP shall constitute a “Product” for purposes of the Master Agreement.

The Services shall be performed as generally set forth in the attached Scope of Work, and as otherwise agreed by the Joint Steering Committee.

The Services will be undertaken in phases, generally feasibility, development, validation and launch and post launch support, or as may be mutually agreed from time to time.

In consideration of the mutual promises, covenants and agreements below and in the Master Agreement, the parties further agree as follows:

1. Services

As more fully set forth in the attached Scope of Work, UBS will undertake the Services required to assess the feasibility of, develop, validate, and provide launch and post launch support of, the ACEP. Unless agreed otherwise, in seeking to develop the ACEP, it is anticipated that UBS will use the Initial Product as its development base and will ascertain whether the Initial Product (as defined in the Master Agreement) can be modified to meet the ACEP Product Specifications .

At or prior to the conclusion of the feasibility review, the parties will complete a Product Addendum for the ACEP as provided by Clause 5.2 of the Master Agreement. For purposes of clarification, it is anticipated the parties may amend the Services and Scope of Work and any applicable Product Addendums from time to time. Any amendments will be discussed by the Joint Steering Committee and mutually agreed upon by the parties and no such amendment will be effective until it is reduced to writing and signed by an authorized officer of each party. Notwithstanding the prior sentence, if LifeScan determines an amendment of the Services or the Scope of Work or Addendums are required for safety or quality reasons, UBS will use good faith efforts to agree to the amendment. Amendments to the ACEP Product Specifications are to be made in accordance with clause 5.3 of the Master Agreement.

UBS shall provide written reports of its progress in performing the Services as provided by Clause 13.2 of the Master Agreement. The Parties agree that due to the inherently uncertain nature of research and development activities, the actual outcomes and results of the Services cannot be assured.

2. Consideration

UBS will provide the Joint Steering Committee with its proposed pricing for the Services from time to time for approval. The pricing will include any specific capital items needed to perform the Services. Such items may include laboratory equipment or equipment for manufacturing.

The cost of Services undertaken shall not exceed the approved pricing without the prior written approval of the LifeScan representative on the Joint Steering Committee (such approved exception, an **Exception**). UBS will not be required to provide any Services for which the Parties have been unable to agree on pricing with respect to necessary capital equipment and those applicable Services or in circumstances where there has been a change of scope in the Services and an Exception is not approved. Unless provided for in approved pricing, UBS shall not incur any non-cancelable

commitments in excess of US\$50,000 without the approval of the LifeScan representative on the Joint Steering Committee.

Unless otherwise agreed in writing, funding for the Services will be through the payments made by LifeScan pursuant to the Development and Research Agreement between the Parties, dated 1 April 2002, as amended (**Development Agreement**). To the extent that LifeScan makes any such payments under the Development Agreement for the ACEP before Services to be performed hereunder are rendered, such payment will be credited toward future performance of the Services.

Whilesover the funding for the Services related to the ACEP is being provided under the Development Agreement, the performance by UBS under this Fourth Services Addendum, will satisfy any corresponding requirements that UBS has with regard to the ACEP under the Development Agreement. It is the parties intention that LifeScan’s payment obligations with regard to the activities set out in this Fourth Services Addendum shall be no greater than those set forth in the Development Agreement, and that UBS shall not be obligated to undertake any activity related to the ACEP that may be required by the Development Agreement, if it has performed any substantially similar activity pursuant to this Fourth Services Addendum.

Whilesover the funding for the Services is being provided through the amounts to be paid under the Development Agreement, payments will be made by LifeScan in accordance with the terms of the Development Agreement.

3. Term of Fourth Services Addendum

This Fourth Services Addendum shall be taken to commence on the date of this Fourth Services and shall continue until terminated by LifeScan by providing 30 days prior written notice, or upon termination of the Master Agreement in accordance with its terms. Further, the Parties will determine at the completion of each phase (i.e. feasibility, development, validation, launch and post launch support) whether or not to continue to the next phase of activities under this Fourth Services Addendum, provided this Fourth Services Addendum would terminate unless both parties mutually agree to continue with the relevant next stage of Services.

4. Termination

In the event that this Fourth Services Addendum is terminated, LifeScan must pay (i) any fees and charges incurred prior to termination; and (b) any fees and charges for any non cancellable commitments entered into by UBS prior to termination, provided such fees and charges are in accordance with the approved pricing or any Exception.

Executed as an agreement by the duly authorized representative of each Party as of the date first written above.

Executed by LifeScan, Inc.

)

)

Name

Title

Executed by Universal Biosensors Pty Ltd

)

)

Company Secretary/Director

Director

Name of Company Secretary/Director (print)

Name of Director (print)

Executed by Universal Biosensors, Inc.

)

)

Name

Title

Advanced Care Enhanced Product
Scope of Work

Feasibility

1.

Determine and execute a body of work to ascertain what changes are needed to meet the ACEP Product Specification target profile set forth in Annexure A.
2.

Develop a definitive Functional Specification to conform with the Target ACEP Product Specifications profile set forth in Annexure A, in accordance clause 5.3 of the Master Agreement.
3.

Execute a body of work to determine a formulation to incorporate in feasibility lots.
4.

Define and execute a body of work to determine a strip differentiation mechanism.
5.

*[REDACTED]
6.

*[REDACTED]
7.

*[REDACTED]
8.

Commence a first stability study from the first feasibility lots.
9.

Complete and test final algorithm as determined by the Data Management Team.
10.

*[REDACTED]
11.

Lab link changed where necessary and validated.
12.

Host feasibility review toll-gate when 4 week stability data from second feasibility lots is available (assuming stability dating is gating; otherwise as agreed).

Development and Validation

13.

Complete strip Operational Qualification.
14.

Complete strip Performance Qualification.
15.

Complete UBS portion of DVT as mutually agreed by Data Management Team
16.

Complete stability report to agreed real-time time point.
17.

Complete UBS Quality Management Systems requirements, including toll gates.
18.

Complete UBS portion of regulatory submission deliverables.
19.

Complete transfer into production and production readiness tasks.

*

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

Launch and Post Launch

20. Assist in the assessment of data from the field and use the data to decide methods for adapting process and control methodology to improve ACEP performance.
21. Specify and control ACEP component performance and requirements. Manage or assist in the qualification and approval of all changes to suppliers and materials for ACEP.
22. Identify, validate and implement cost reductions and process improvement in manufacturing the ACEP.
23. Assist on a mutually agreed basis so that LFS may obtain supply agreements with suppliers of components comprising the ACEP.
24. Investigate causes of customer complaints with the ACEP referred to UBS by LifeScan.
25. Assist on a mutually agreed basis to implement design changes to the ACEP

Annexure A

Target Advanced Care Enhanced Product (ACEP) Product Specifications Profile

*[REDACTED 6 Pages]

* 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 10.2

Fifth Amendment to the Development and Research Agreement

Amendment Effective Date: May 14, 2009

This fifth amendment (**Amendment**) to the Development and Research Agreement dated 1 April 2002 is by and among LifeScan, Inc., Universal Biosensors Pty Ltd and Universal Biosensors, Inc. as amended by four letter agreements dated March 31, 2004, December 21, 2004, December 7, 2005 and June 1, 2005, respectively (**Development Agreement**).

The parties agree to hereby add UBS as a party to the Development Agreement and the parties to the Development Agreement shall be LifeScan, Inc, a Californian corporation of 1000 Gibraltar Drive, Milpitas, CA 95035-6312, USA (**LifeScan**), Universal Biosensors Pty Ltd ACN 098 234 309, a company incorporated in Victoria, Australia of 1 Corporate Avenue, Rowville, Victoria 3178, Australia (**UBS**) and Universal Biosensors, Inc., a Delaware corporation of having its registered office at c/o Corporation Service Company 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808 USA (**UBI**).

The Parties wish to amend the Development Agreement in the manner set out in this Amendment to clarify certain matters which have arisen since the Development Agreement was signed.

This Amendment is to take effect upon execution by the Parties and is to operate and be interpreted according to the provisions of the Development Agreement.

In consideration of the mutual promises, covenants and agreements set forth in this Amendment and in the Development Agreement, the Parties agree as follows:

Amendments

1. Paragraph 1.8 of the Development Agreement is deleted and replaced with the following:
“1.8 Program” means the annual list of research and development projects created by UNIVERSAL BIOSENSORS for the Steering Committee in accordance with Section 2.1(a).”
2. Paragraph 2.1(a) of the Development Agreement is deleted and replaced with the following:
“(a) Effective immediately and prior to December in each year for the following year during the term of this Agreement, UNIVERSAL BIOSENSORS shall prepare an annual list of research and development projects including work plans and cost estimates for UNIVERSAL BIOSENSORS to work on during the calendar year or

part thereof and submit it to the Steering Committee. The Steering Committee shall review and determine which projects are to be funded during that calendar year. Notwithstanding the definition in Section 1.8 or Exhibit B, the funded projects shall become the Program for such calendar year or part thereof.”

3. The parties agree to delete paragraph 2.2 to the Development Agreement and replace it with the following:
- “(a) Supervision of the Program shall be provided by the Joint Steering Committee as defined in that certain Amended and Restated Master Services and Supply Agreement between the parties dated 29 October 2007 (the “Master Agreement”) and that any references to the Steering Committee in this Development Agreement shall be deemed to refer to the Joint Steering Committee in the Master Agreement.

(b) For clarification the parties agree the establishment, composition and decision making provisions for the Joint Steering Committee in Article 4 of the Master Agreement shall also apply to and govern the Steering Committee in this Development Agreement.”
4. The parties agree to delete paragraph 4.1 to the Development Agreement and replace it with the following:
- “4.1(a) In the period from April 1, 2009 until December 31, 2009, LIFESCAN shall make payments to UNIVERSAL BIOSENSORS in the amount of US\$250,000 (two hundred and fifty thousand US dollars) per calendar quarter with the payment to be made within 30 days of the beginning of each quarter. LIFESCAN agrees it will fund during the calendar year commencing January 1, 2010, an amount that is to be determined in its discretion, and that is between US\$5,000,000 (five million US dollars) and US\$9,000,000 (nine million US dollars) depending on the Program recommended by the Joint Steering Committee. Unless otherwise agreed, payment will be made in equal quarterly tranches within 30 days of the beginning of each quarter. In subsequent years during the term of this Development Agreement, the Steering Committee will recommend the Program and a funding level for each party based on the success of the Initial Product and consistent with LIFESCAN’s strategic and financial interests for such year.

(b) Notwithstanding the foregoing, in the event: (i) the Milestone (defined in the Master Agreement) for the Initial Product has not been achieved before January 1, 2010, then LifeScan shall fund US\$4,000,000 (four million US dollars) to UNIVERSAL BIOSENSORS within 30 days to prepay the Program; and (ii) the Milestone for the Initial Product has not been achieved before April 1, 2010, then LIFESCAN shall fund an additional US\$4,000,000 (four million US dollars) to

- UNIVERSAL BIOSENSORS within 30 days to prepay the Program for 2010. For clarification, UNIVERSAL BIOSENSORS agrees that if LIFESCAN has paid the payments in paragraph (i) and/or (ii) above, they shall be credited toward the funding in paragraph (a) above for development research due to UNIVERSAL BIOSENSORS in 2010.
- (c)

For clarification, UNIVERSAL BIOSENSORS agrees that any amounts paid to it by LIFESCAN in this Section 4.1 shall be dedicated solely to the Program and/or a Product and cannot be used for any other projects of UNIVERSAL BIOSENSORS without the prior written consent of LIFESCAN.
- (d)

At the direction of UNIVERSAL BIOSENSORS, payments under this clause 4.1 may be made to Universal Biosensors Pty Limited, recognizing that the research and development activities under this Agreement will be conducted by Universal Biosensors Pty. Limited. UNIVERSAL BIOSENSORS shall notify LifeScan of the party to which payment shall be made within 15 days of the date any payment is due.”
5.

The parties agree to delete Exhibit B and Exhibit E in their entirety and in each case replace with a notation “[Intentionally left blank].”

The Parties agree that all other provisions in the Development Agreement remain unchanged and effective.

Executed as a deed by the duly authorized representative of each Party as of the date first written above.

Executed by LifeScan, Inc.

)

)

Name:

Title:

Executed by Universal Biosensors Pty Ltd

)

)

Company Secretary/Director

Director

Name of Company Secretary/Director (print)

Name of Director (print)

Executed by Universal Biosensors, Inc.

)

)

Name

Title

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Exhibit 10.3

Execution Copy

Date: 29 October 2007

First Amended: 11 December 2008

Amended and Restated: 14 May 2009

LifeScan, Inc.

Universal Biosensors Pty Ltd

Universal Biosensors, Inc.

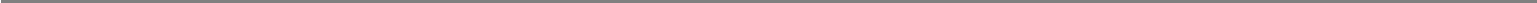
Amended and Restated Master Services and Supply Agreement

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Effective Date of Original Master Agreement: 29 October 2007

Effective Date of First Amendment: 11 December 2008

Effective Date of Amended and Restated Master Agreement: 14 May 2009

Parties

LifeScan, Inc. a California corporation of 1000 Gibraltar Drive, Milpitas, CA 95035-6312, USA (**LifeScan**)

Universal Biosensors Pty Ltd ACN 098 234 309, a company incorporated in Victoria, Australia of 1 Corporate Avenue, Rowville, Victoria 3178, Australia (**UBS**)

Universal Biosensors, Inc., a Delaware corporation of having its registered office at c/o Corporation Service Company 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808, USA (**UBI**)

Background

- A. This Agreement amends and restates that certain Master Service and Supply Agreement, dated 29 October 2007, by and between the Parties. It incorporates any amendments from the First Amendment dated as of 11 December 2008, and any additional amendments included herein as of the Effective Date of this Agreement.
- B. UBS is developing an enhanced version of the Initial Product incorporating a different feature than that used in other versions of the Initial Product. LifeScan has determined that it is advisable to seek regulatory approval to market and commercialize the enhanced version of the Initial Product. In order to facilitate the expeditious completion of development and registration activities required to obtain approval to market the enhanced product, the parties have agreed to certain additional terms set forth in this Amended and Restated Master Services and Supply Agreement.
- C. LifeScan carries on the business of marketing and selling blood glucose monitoring systems for home, clinic and hospital use.
- D. UBS carries on the business of researching, developing, manufacturing and commercialising a range of in vitro diagnostic tests for point of care use.
- E. LifeScan holds certain patents and other intellectual property rights relating to innovative blood glucose testing devices and wishes to distribute strips and meters as part of a new range of its blood glucose monitoring systems.
- F. LifeScan and UBI are parties to a Development Agreement, under which UBS has been developing certain strips, meters and manufacturing methodology for LifeScan.

- G. UBS has developed the capability and established a facility to manufacture and supply such strips to LifeScan.
- H. UBS further has the expertise and information to provide a range of services of interest to LifeScan, including services relating to the development and testing of strips, the development and establishment of manufacturing facilities for strips and the development of variants and future generations of strips and meters.
- I. The parties wish to enter into an agreement in relation to the provision by UBS to LifeScan of Initial Product and Initial Services, and other Product and other Services which LifeScan in the future may require from time to time.
- J. Whereas UBS is entitled to various payment streams under this Agreement which are intended to enable UBS to recover its sunk costs and make a reasonable return.
- K. To facilitate an efficient and effective business and contractual relationship between the parties, they have agreed to establish a Joint Steering Committee.
- L. For these purposes the parties have agreed to enter into this Master Services and Supply Agreement to regulate, on the terms and subject to the conditions set out in this agreement, the relationship between the parties and the provision by UBS of all such products and services to LifeScan.
- M. UBI has agreed to guarantee UBS’ obligations under this Agreement.

In consideration of the mutual promises, covenants and agreements below, the parties agree as follows:

Agreed terms

Part 1: Preliminary Provisions

1 Interpretation

1.1 Definitions

In this Agreement:

Affiliate means any corporation, firm, limited liability company, partnership, or other entity that directly or indirectly controls, or is controlled by, or is under common control with a party to this agreement but only for so long as that control remains, whereafter that entity shall cease to be an Affiliate. For the purpose of this definition, control means ownership, directly or through one or more Affiliates, of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors in the case of a corporation, or fifty percent (50%) or more of the equity interests in the case of any other type of legal entity, or status as a general partner in any partnership, or any other

arrangement whereby a party controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity.

Agreed Standard Cost has the meaning given in **clause 6.2(b)(i)** of this Agreement.

Agreement Intellectual Property Rights has the meaning given in **clause 12(c)** of this Agreement.

Bankruptcy Event means in respect of LifeScan or UBI: (i) it applies for or consents to the appointment of, or the taking of possession by, a receiver, custodian, trustee or liquidator of itself or of all or a substantial part of its property, (ii) it makes a general assignment for the benefit of its creditors, or (iii) it takes any action to take advantage of, or have any action taken against it under, any U.S. law relating to bankruptcy, insolvency or reorganization.

Base Year has the meaning given in **clause 6.2(a)** of this agreement.

Base Year Standard Cost has the meaning given in the Initial Product Addendum.

Business Day means a day which is not a Saturday, Sunday or bank or public holiday in New York City, New York, U.S.A.

Change of Control means (a) the liquidation or dissolution of an entity or the sale or other transfer by an entity (excluding transfers to Affiliates) of all or substantially all of its assets; or (b) the occurrence of a tender offer, stock purchase, other stock acquisition, merger, consolidation, recapitalization, reverse split, sale or transfer of assets or other transaction, as a result of which any person, entity or group (other than an Affiliate of such entity prior to such transaction) (i) becomes the beneficial owner, directly or indirectly, of securities of an entity representing more than 50% of the ordinary shares such entity or representing more than 50% of the combined voting power with respect to the election of directors (or members of any other governing body) of such entity’s then outstanding securities, (ii) obtains the ability to appoint a majority of the Board of Directors (or other governing body) of the entity, or (iii) obtains the ability to direct the operations or management of the entity or any successor to the entity’s business.

Confidential Information means:

- (a) the terms and existence of this Agreement; and
- (b) all confidential and proprietary information in whatever form or manner presented which is disclosed pursuant to this Agreement or any Product Addendum or Services Addendum and which relates to a disclosing party’s business or business plans.

Corporations Act means the *Corporations Act 2001 (Cth)*.

Cost Savings Amount has the meaning given in **clause 6.2(b)(ii)** of this Agreement.

Covered Product means any product covered by at least one valid claim of the LifeScan Relevant Patents; provided, however, that the definition of

Covered Product shall not include any products launched or to be launched based on the platform acquired from Inverness Medical.

Development Agreement means the development and research agreement between UBI and LifeScan, effective as of April 1, 2002, and any and all amendments thereto.

Effective Date means 29 October 2007.

Fee Conversion Reference Date means the end of the Quarter following the receipt by UBS of an aggregate of *[REDACTED] in Quarterly Service Fees.

Financial Year means LifeScan’s fiscal year, as defined in Johnson & Johnson’s internal accounting policies and procedures, which ends on the last Sunday of any given Calendar Year. Appendix F sets forth the applicable Financial Years through 2013.

Force Majeure Event means any cause which is beyond the reasonable control of a party, including fire, explosion, flood, or other acts of God; acts, regulations, or laws of any government; war or civil commotion; strike, lock-out or labour disturbances, failure of public utilities or common carriers.

Government Authority means any relevant federal, state, territory, municipality or other political subdivision, administrative or judicial body, court, ministry, department, commission, authority, instrumentality, tribunal or agency or other governmental, quasi-governmental or regulatory authority or any self-regulatory organisation (including any relevant tax administrator) of any applicable country and includes any person deriving a power directly or indirectly from any other person or body referred to in this definition.

Initial Meter means a blood glucose meter adapted to use the Initial Product and conforming to the specifications set out in the Initial Product Addendum.

Initial Product means a blood testing strip which conforms with the Product Specifications referenced in Schedule 1, as amended in accordance with Section 5.3 of this Agreement.

Initial Product Addendum means the Addendum set out in **Schedule 1**.

Initial Services means the services described in **Schedule 2**.

Initial System means the blood glucose monitoring system consisting of the Initial Meter, Initial Product, control solution, lancets and all other applicable components.

Insolvency Event means in respect of UBS:

- (a) it is (or states that it is) an insolvent under administration or insolvent (each as defined in the Corporations Act);
- (b) it has had a controller (as defined in the Corporations Act) appointed or is in liquidation, in provisional liquidation, under administration or wound up or has had a receiver or a receiver and manager appointed to any part of its property;

* 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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- (c) it is subject to any arrangement, assignment, moratorium or composition, protected from creditors under any statute or dissolved (in each case, other than to carry out a reconstruction or amalgamation while solvent on terms approved by the other parties to this Agreement);
 - (d) an application or order has been made (and in the case of an application, it is not stayed, withdrawn or dismissed within 30 days), resolution passed, proposal put forward, or any other action taken, in each case in connection with that person, which is preparatory to or could result in any of (a), (b) or (c) above;
 - (e) it is taken (under section 459F(1) of the Corporations Act) to have failed to comply with a statutory demand;
 - (f) it is the subject of an event described in section 459C(2)(b) or section 585 of the Corporations Act;
 - (g) it is otherwise unable to pay its debts when they fall due; or
 - (h) something having a substantially similar effect to (a) to (g) happens in connection with UBS under the laws of Australia.

Interim Costing Period means the period beginning upon the commencement of manufacturing following the submission of LifeScan’s first order for commercial launch of the Initial Product until the earlier of (i) the beginning of the first Quarter in which LifeScan places an order in excess of fifty million (50,000,000) Initial Products or (ii) the end of the Quarter during which the third anniversary of the achievement of a Milestone occurs.

Joint Steering Committee has the meaning given in **clause 4.1** of this Agreement.

Joint Steering Committee Member has the meaning given in **clause 4.2** of this Agreement.

Labour and Overhead Costs means actual labour and overhead costs assignable to the manufacturing of Initial Product.

License Agreement means the license agreement between UBS and LifeScan, effective as of 1 April 2002, and any and all amendments thereto.

Licensed Intellectual Property Rights means any and all LifeScan Intellectual Property Rights required by, or reasonably necessary for, UBS to fulfil its obligations under this Agreement.

LifeScan Files and Work Papers has the meaning given in **clause 16.4** of this Agreement.

LifeScan Intellectual Property Rights means any and all intellectual property rights throughout the world, including:

- (a) any patent, copyright, trade secret, know-how, technology, trade mark or domain name (whether registered or unregistered), software, design, circuit layout right, trade, business or company name or other proprietary right or any right to registration of such rights; and

(b) all present and future rights in an invention, discovery, trade secret, know-how, concept, idea, data or formula and rights in information, including any serendipitous discoveries, granted by law or equity from time to time under the law of any jurisdiction which LifeScan owns or is empowered to grant a license prior to or during the Term of this Agreement. LifeScan Intellectual Property Rights shall further include any foreign counterparts thereof, as well as all continuations, continuation-in-part, divisions and renewals thereof, patent applications, all patents which may be granted thereof, and all reissues, re-examinations and extensions.

LifeScan Manufacturing Line Date means the date that LifeScan, a LifeScan Affiliate or a contract manufacturer of LifeScan shall have qualified a manufacturing line that is actually capable of producing the Initial Product in a place other than Rowville, Victoria.

LifeScan Relevant Patents means those patents and patent applications identified on **Schedule 3**, as well as any United States patent application, foreign counterpart, division, continuation, continuation-in-part, reissue, renewal, and re-examination thereof and patents issuing therefrom, patent extensions, certificates of invention and applications for certificates of invention.

Losses means any losses, liabilities, damages, claims, costs, charges and expenses and includes any taxes, duties, levies, legal fees (on a full indemnity basis) and other related expenses.

Lump Sum Service Fee — A has the meaning given in **clause 11.3(a)** of this Agreement.

Lump Sum Services Fee — B has the meaning given in **clause 11.3(c)** of this Agreement.

Material Costs means the cost of material comprising the Initial Product that is consumed during the manufacturing of the Initial Product (e.g. substrates and spacer), excluding the cost of the vials and enzymes.

Maximum Transfer Price means the cost per Initial Product set forth in the Initial Product Addendum.

Milestone means the first grant to LifeScan or its nominated Affiliate of regulatory clearance or approval to market the Initial System.

Milestone Amount has the meaning given in **clause 11.2(a)** of this Agreement.

Policy has the meaning given in **clause 16.2** of this Agreement.

Process has the meaning given in **clause 12** of this Agreement.

Product means a strip which conforms with the relevant Product Specification, and includes the Initial Product and any additional products that the parties agree to include in a Product Addendum.

Product Addendum means a document executed by the parties for Product to be manufactured pursuant to the terms of this Agreement substantially in the form set out in **Appendix A**.

Product Specifications means:

- (a) in the case of the Initial Product, the specifications set out in **Schedule 1** subject to amendment in accordance with Section 5.3 of this Agreement;
- (b) in the case of any other Product, the specifications set out in the relevant Product Addendum to be annexed hereto as the same may be amended in accordance with Section 5.3 of this Agreement.

QSR means the quality system regulations applicable to a Product.

Quality Agreement means the quality agreement attached as **Appendix E** of this Agreement.

Quarter means in respect of any Financial Year, the quarter end designated by a circle on Appendix F for such Financial Year.

Quarterly Service Fee has the meaning given in **clause 11.1(a)(i)** of this Agreement.

Raw Materials means the materials, components and packaging required to manufacture and package the Products in accordance with the Product Specifications.

Restricted Purposes has the meaning given in **clause 14(a)** of this Agreement.

Services means the services described in **Schedule 2** and any other services identified in a Services Addendum.

Services Addendum means a document executed by the parties for services to be provided by UBS to LifeScan pursuant to the terms of this Agreement, substantially in the form set out in **Appendix B**.

Sold means the sale or other transfer of Product by LifeScan or any of its Affiliates to an unaffiliated third party that generates direct sales revenue to LifeScan or any of its Affiliates.

Standards has the meaning given in **clause 16.3** of this Agreement.

Technical Success has the meaning given in **clause 10.4** of this Agreement.

Term has the meaning given in **clause 19.1** of this Agreement.

Territory means the entire world.

UBS Capacity Limitation has the meaning given in **clause 7.1(a)**.

1.2 Construction

Unless expressed to the contrary, in this Agreement:

- (a) words in the singular include the plural and vice versa;
- (b) any gender includes the other genders;

- (c) if a word or phrase is defined its other grammatical forms have corresponding meanings;
- (d) “includes” (and its variants, i.e., “include” and “including”) means includes without limitation;
- (e) no rule of construction will apply to a clause to the disadvantage of a party merely because that party put forward the clause or would otherwise benefit from it; and
- (f) a reference to:
 - (i) a person includes a partnership, joint venture, unincorporated association, corporation and a government or statutory body or authority;
 - (ii) a person includes the person’s legal personal representatives, successors, assigns and persons substituted by novation;
 - (iii) any legislation includes subordinate legislation under it and includes that legislation and subordinate legislation as modified or replaced; and
 - (iv) an obligation includes a warranty or representation and a reference to a failure to comply with an obligation includes a breach of warranty or representation.
- (g) “\$” or “dollar” means the lawful currency of the United States unless otherwise expressly stated.

1.3 Headings

Headings do not affect the interpretation of this Agreement.

2 Action Taken after Effective Date

After the Effective Date but on or before January 15, 2008, and in consideration of the grant of rights in **clause 12**, LifeScan shall take the action prescribed in Appendix I.

3 License

3.1 Grant of License

LifeScan grants to UBS during the Term of this Agreement a worldwide, royalty free, non-exclusive license to use Licensed Intellectual Property Rights for the sole purpose of fulfilling its obligations under this Agreement.

3.2 LifeScan rights

- (a) Nothing in this Agreement shall be construed to restrict the right of LifeScan or LifeScan’s Affiliates to engage in any business activity, investment or other opportunity anywhere in the world. UBS

acknowledges LifeScan shall have sole discretion where and how to market and sell the Products.

- (b) UBS acknowledges and agrees that LifeScan and its Affiliates are, and will continue to be, actively involved in the design, development, acquisition, marketing, manufacturing, promotion and sale of blood glucose monitoring products, including products that directly and indirectly compete with the Products hereunder.

4 Joint Steering Committee

4.1 Establishment

Within 30 Business Days of the Effective Date, a joint committee (**Joint Steering Committee**) shall be established to manage the relationship between the parties and the operation of this Agreement. The Joint Steering Committee shall provide strategic oversight of the performance of the parties’ obligations and the progress of the Products and Services provided under this Agreement. The Joint Steering Committee shall have the power to create and delegate responsibility to various working groups compromised of members from the parties to carry out its obligations under this Agreement.

4.2 Composition

The Joint Steering Committee shall consist of members (**Joint Steering Committee Members**) from each of UBS and LifeScan. The Joint Steering Committee Members shall be comprised of senior management from each party (and the initial Joint Steering Committee members are set out in **Appendix C**). Each party may change their nominated Joint Steering Committee Member by written notice to the other party. Unless otherwise agreed, the Joint Steering Committee will meet at least monthly, until the first regulatory filing for the Initial Product is made. Additionally, the Joint Steering Committee shall convene on a quarterly basis, to review and approve work plans and progress under this Agreement and the Development Agreement. Additionally, the Joint Steering Committee shall be available on a more frequent basis to address key issues that may arise. All meetings of the Joint Steering Committee may be by teleconference, videoconference or any other means of communication agreed to by the parties.

4.3 Decision making

- (a) Each of UBS and LifeScan shall have one vote on the Joint Steering Committee. If more than one representative of a party is present at a meeting, such representatives shall agree upon how that party’s vote shall be cast. If only one representative is present, that party shall be deemed authorized to vote on the matters raised at the meeting. All decisions of the Joint Steering Committee shall be unanimous.
- (b) No decision may be made by the Joint Steering Committee unless a quorum is present, such quorum constituted by at least one member present from each of LifeScan and UBS.

- (c) If the Joint Steering Committee is unable to reach Agreement on any significant matter, then within ten Business Days it shall be referred to the Company Group Chairperson of LifeScan and the Chairperson of UBS and they shall endeavour to resolve such matter in good faith within twenty Business Days of notification by the Joint Steering Committee of the disagreement. If the Chairpersons are unable to reach an agreement on the matter: (i) with respect to any matter involving the quality of the Products, regulatory affairs relating to the Products or any matter that could require expenditures of funds by LifeScan in addition to those already contemplated by this Agreement or the Development Agreement, LifeScan shall have the right to make the decision; and (ii) with respect to all matters not covered by clause (i), the matter shall be resolved pursuant to the provisions of **clause 20** of this Agreement.

Part 2: Products

5 Supply of Products

5.1 Supply of Initial Products

- (a) UBS will supply LifeScan or its designates with Initial Products in accordance with and subject to the terms of this Agreement.
- (b) Except for binding orders placed in accordance with **clause 7**, LifeScan is not obligated to obtain supply of the Initial Products or any other Products exclusively, or at all, from UBS. Further, LifeScan shall have the right to obtain supply of the Initial Products or any other Products solely from its own manufacturing facilities or from any Affiliate or third party supplier at any time.

5.2 Supply of Other Products

- (a) From time to time the parties may agree that UBS will develop and / or manufacture and supply additional Products to LifeScan. For purposes of clarification, the Joint Steering Committee would agree on additional products, cost recovery and success fees based on milestones achieved. In each such event, the parties shall enter into a Product Addendum.
- (b) Each Product Addendum, when executed will be attached to this Agreement and form part of and be subject to the terms of this Agreement.
- (c) During the term of each Product Addendum, UBS will manufacture and supply to LifeScan the Products specified in that Product Addendum in accordance with and subject to the terms of this Agreement.
- (d) In the event of a conflict between the terms of this Agreement and the terms of any Product Addendum, the terms of this Agreement will prevail, except to the extent that the applicable Product Addendum expressly and specifically states an intention to supersede this Agreement on a specific matter.

- (e) If a Product Addendum provides for the amendment of a term of this Agreement, that amendment will be effective only in relation to that Product Addendum and, unless expressly specified to the contrary in the Product Addendum, will not otherwise amend this Agreement or operate in relation to any other Product Addendum or Services Addendum.

5.3 Improvements and Changes to Product Specification.

- (a) From time to time during the term of this Agreement, either party may submit to the other written proposals for the adoption, implementation or development of any change, improvement or modification to the Product (an “Improvement”). In no event shall any such Improvement to the Product (or any change or modification to the Product Specifications) be implemented or made without the prior written agreement of the Parties. If the parties agree on any such Improvement, they shall modify the Product Specifications to reflect the same. For purposes of clarification, UBS agrees that no significant changes or modifications to the method or process of manufacture or production of the Product, the components of the Product or the raw materials shall be made which have the effect of modifying or changing the Product Specifications without the express written consent of LifeScan. In the event of any Improvement, the parties shall mutually determine an appropriate inventory level for the pre-change Product in order to cover on-going requirements during the qualification process.
- (b) Any Improvement made in accordance with this Section 5.3 shall be deemed to amend automatically the definition of Product Specifications to reflect such Improvement.

6 Purchase Price of Initial Products

6.1 Interim Costing Period

During the Interim Costing Period, LifeScan must pay to UBS in respect of each Initial Product supplied by UBS to LifeScan or any of its designates:

- (a) *[REDACTED]; and
- (b) *[REDACTED].

UBS shall use its best efforts to minimize the amount of *[REDACTED] during the Interim Costing Period. In no event shall the aggregate amount due under clause 6.1(a) above for all Initial Products supplied in a given Quarter exceed *[REDACTED]. LifeScan acknowledges and agrees that it has requested UBS to obtain raw materials components known as enzymes and vials at its expense and they shall not be included in the above cap and further provided that UBS is permitted to include the cost of any enzyme and vials consumed in the manufacturing process in any invoice for Initial Product.

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

6.2 Post-Interim Costing Period

- (a) From the period beginning upon the end of the Interim Costing Period through the end of the then current Financial Year (**Base Year**), the standard cost of manufacturing an Initial Product to LifeScan shall be equal to the **Base Year Standard Cost**. For the avoidance of doubt, such Base Year Standard Cost excludes the cost of the enzymes and vials.
- (b) In June of each year, commencing with the Base Year the parties will meet and by July 1st (provided, that if the Base Year commences after June, then the parties shall meet as soon as reasonably possible):
- (i) agree upon the standard cost of Initial Product to apply for the following Financial Year (**Agreed Standard Cost**) taking into account: (A) all relevant costing and manufacturing information, which shall be supplied by UBS along with reasonable supporting data, (B) assuming a volume of Initial Products equal to LifeScan’s forecasted volume for such Financial Year; and (C) excluding the cost of the enzyme and vials; and
 - (ii) compare the Agreed Standard Cost against the Base Year Standard Cost for the purposes of determining whether the Agreed Standard Cost is less than the Base Year Standard Cost, in which case the amount of the relevant difference is the **Cost Savings Amount**.
- (c) Subject to **clauses 6.2(d) and 6.2(e)**, in respect of each Financial Year commencing with the Base Year, LifeScan must pay to UBS in respect of each Initial Product supplied by UBS to LifeScan an amount equal to:
- (i) the standard cost applicable for that year as determined in accordance with **clause 6.2(a)** or **clause 6.2(b)**;
 - (ii) plus an amount equal to *[REDACTED] of the portion of the standard cost of an Initial Product which is not attributable to the cost of Material Costs; and
 - (iii) plus *[REDACTED] of the Cost Savings Amount if applicable.
- LifeScan shall in addition pay to UBS an amount for enzymes and vials in accordance with **clause 6.2(f)**.
- (d) The amount that LifeScan shall be obligated to pay UBS in aggregate for each Initial Product shall in no event exceed the Maximum Transfer Price plus the cost of enzyme and vials, provided, that if in any Quarter following the end of the Interim Costing Period, LifeScan orders less than 50 million Initial Products from UBS, **clause 6.2(c)** will not apply in respect of that Quarter and LifeScan will pay UBS for the relevant Initial Products in accordance with the costing methodology set out in **clause 6.1**.

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

- (e) If there are factors outside the reasonable control of UBS that adversely affect UBS’ ability to provide the Initial Product at a total cost that does not exceed the Maximum Transfer Price plus the cost of the enzyme and vials, the Joint Steering Committee will meet to consider a suspension or ongoing change to the Maximum Transfer Price. If the parties cannot reach Agreement then the provisions of **clause 6.2(d)** will apply and UBS may terminate this Agreement in accordance with **clause 19.7(b)** or such shorter period as may be agreed by the parties.
- (f) LifeScan acknowledges and agrees that it has requested UBS to obtain raw materials components known as enzymes and vials at its expense and that UBS is permitted to include the actual cost paid by UBS of any enzyme and vials consumed in the manufacturing process in any invoice for Initial Product. Such costs shall be excluded from the calculations of the Base Year Standard Cost, the Agreed Standard Cost and the Cost Savings Amount.
- (g) UBS shall invoice LifeScan for all payments due under this **clause 6** with such frequency as is mutually acceptable to the parties. All payments under this **clause 6** shall be payable by LifeScan within 45 days of receipt of an undisputed invoice in immediately available funds. LifeScan shall notify UBS promptly of any portion of an invoice it disputes and, subject to the then current capability of the Accounts Payable system of LifeScan, LifeScan shall pay the undisputed portion of such invoice while the dispute is being resolved.
- (h) In order to support timely invoice processing UBS shall use commercially reasonable efforts to ensure that: (i) the quantity of Products(s) shipped does not exceed the quantity of Products ordered pursuant to the relevant purchase order, (ii) the invoice sent by UBS to LifeScan reflects the correct LifeScan purchase order number to which it relates, (iii) the unit pricing on the invoices matches the unit pricing reflected on the purchase order to which it relates, and (iv) each invoice shall reflect no more than one purchase order number.
- (i) During the term of this Agreement, the parties agree to make all commercially reasonable efforts to achieve cost reductions in cooperation with one another through the continuous improvement of either party’s production, procurement and supply processes in addition to any other general improved efficiencies achieved by such party such as those based on labor efficiencies and volume provided to the extent LifeScan is utilizing the services of a third party vendor or contract manufacturer and is prohibited from sharing those cost reductions with UBS, then it shall not be required to do so. The foregoing notwithstanding, UBS shall in no event modify or substitute any materials, components or processes used in the production, procurement or supply of any Product without the prior written consent of LifeScan, which shall not be unreasonably withheld. No such change shall in any way affect the safety or quality of any Product, and all such changes

shall conform to a QSR compliant change control process mutually agreed to by UBS and LifeScan.

- (j) UBS shall keep complete and accurate records in sufficient detail to evidence its costs and support for its invoices provided to LifeScan (the “**Financial Records**”). For the sole purpose of verifying amounts owed under such invoices, LifeScan (or its designated audit expert) shall have the right no more than one time each calendar year, at its own expense, to review the Financial Records for the preceding Quarters during the Term (other than those already reviewed in a prior audit) at the location(s) where the Financial Records are maintained by UBS upon thirty (30) days notice and during regular business hours. Results of such review shall be made available to UBS. Further, if the review reflects an overpayment to UBS, such overpayment shall be credited against the next payment due UBS. If the overpayment is greater than five percent (5%) of the amount that was otherwise due for a Quarter, UBS shall reimburse LifeScan for the costs of such review. If no further payments are due to UBS (e.g. due to termination of this Agreement), then UBS shall pay to LifeScan the amount of such overpayment within forty-five (45) days of LifeScan’s provision to UBS of the results of LifeScan’s review. If the review reflects an underpayment to UBS, such underpayment shall be remitted by LifeScan to UBS within forty-five (45) days.

7 Orders, Inventory and Delivery

7.1 Forecasts and orders

- (a) On a monthly basis during the Term, LifeScan will provide UBS with a rolling written forecast of LifeScan’s expected requirement for Products during the following 12 months; provided, the first month of such forecast shall be deemed binding on LifeScan and the balance of such written forecast shall be non binding. On a quarterly basis, UBS will provide LifeScan with details of its capacity limitations (the “**UBS Capacity Limitation**”). LifeScan agrees not to order quantities of Product greater than the UBS Capacity Limitation. For clarification purposes only, if there is a reduction in the UBS Capacity Limitation which LifeScan considers arbitrary and capricious, it shall be referred to the Joint Steering Committee for resolution.
- (b) LifeScan is permitted to change the second month of its next forecast by plus or minus 25% and change the third and fourth month of such forecast by plus or minus 50% subject to the UBS Capacity Limitation.
- (c) LifeScan will place any orders for the binding portion of any forecast given in accordance with clause 7.1(a) by written or electronic purchase order (or by such other means agreed to by the parties) to UBS, which will be placed in accordance with the lead-time requirements set out in **clause 7.3**. Subject to clause 7.11, UBS acknowledges that LifeScan is

not obligated to buy any specific amount of Products under this Agreement.

- (d) To the extent of any conflict or inconsistency between this Agreement and any purchase order, purchase order release, confirmation, acceptance or any similar document, the terms of this Agreement will prevail.

7.2 Inventory

- (a) UBS will maintain inventories of Raw Materials sufficient for one month of LifeScan’s forecasted requirements. These quantities may be adjusted as agreed to by the Joint Steering Committee.
- (b) UBS will maintain inventory of the Products on a first-in, first-out basis.

7.3 Lead Time

UBS shall develop a supply chain system (e.g. KanBan levels, efficient processes) in cooperation with LifeScan and LifeScan authorized third parties that will allow, within the UBS Capacity Limitation, for a 30 day lead-time from a binding order until delivery.

7.4 Past Due Orders

UBS shall notify LifeScan immediately in the event that any delivery date with respect to any Products shall not be met. In the event of any such delay in the delivery of Products, UBS shall, at its own expense, use its commercially reasonable efforts to expedite the delivery of any past due order, including but not limited to approving overtime, premiums to component suppliers, the difference between regular freight and premium freight or air freight and any other measures which may be necessary or useful in timely fulfilling LifeScan’s orders for Products hereunder.

7.5 Delivery

- (a) Delivery and shipping terms for the Products will be **FCA (Rowville, Victoria)** (IncoTerms 2000), unless otherwise agreed to by the parties.
- (b) All shipments must be accompanied by a packing slip which describes the articles, states the purchase order number and shows the shipment’s destination. As required, UBS agrees to promptly forward the original bill of lading or other shipping receipt for each shipment in accordance with LifeScan’s instructions.

7.6 Sub-Tier Component Supply Chain

UBS shall be responsible for management of sub-tier suppliers for the Products and the performance of their obligations.

- (a) Additionally, UBS shall provide a supply continuity plan for the Products manufactured by UBS to the Joint Steering Committee at least one hundred and eighty (180) days prior to the commercial launch of the Products or as soon as practicable prior to commercial launch.

- (b) Upon reasonable notice, UBS shall provide LifeScan with access to supplier specifications, documentation, quality process audit records, supplier contracts, scorecards and costing information.
- (c) UBS shall work with the key sub-tier suppliers for the products to put in place written supply agreements. Among other customary terms, UBS shall negotiate to include in such supply agreements:

(i) No volume purchase commitments;

(ii) Provisions to allow assignment of the supply Agreement and all attendant rights to LifeScan or its designee without supplier’s consent;

(iii) Not less than 45 day payment terms; and

(iv) Rights to terminate the contract at UBS’ (or its assignee’s) discretion upon no more than 6 months’ notice.

In the event UBS is unable to obtain the Agreement of a sub-tier supplier to (i)-(iv) above, then it shall notify LifeScan prior to signing the agreement with such supplier in order to permit LifeScan the ability to obtain the agreement of the supplier to such provision.

7.7 Packaging for Shipment

UBS will pack all Products ordered under this Agreement in a manner agreed by LifeScan as being suitable for shipment to the final destination and sufficient to enable the Products to withstand the effects of shipping, including handling during loading and unloading.

7.8 Quarterly Business Reviews

The operations teams of UBS and LifeScan will have Quarterly business reviews to discuss quality performance, delivery performance, cost and other elements as needed.

7.9 Capacity

UBS shall endeavour to provide, qualify, maintain and allocate to LifeScan sufficient capacity on a reasonable work and maintenance schedule to support at least 125% of LifeScan’s forecasted requirements. UBS shall review capacity versus total demand on at least a Quarterly basis and report findings to LifeScan’s management. UBS shall promptly notify LifeScan at any time the forecasted volume during the succeeding twelve (12) month period exceeds 75 percent of the manufacturing capacity.

7.10 Supply Risk

In consultation with LifeScan, UBS shall develop and execute a second sourcing strategy for key raw materials.

7.11 Manufacture of Initial Product in 2010 and 2011

The parties agree that UBS shall have the right and obligation to manufacture and supply *[REDACTED] of LifeScan’s demand for Initial Product in *[REDACTED] subject to and in accordance with the other provisions of this clause 7.

The parties agree that UBS shall have the right and obligation to manufacture and supply *[REDACTED] of LifeScan’s demand for the Initial Product in *[REDACTED] subject to and in accordance with the other provisions of this clause 7, until such time as LifeScan has established manufacturing capacity at its own facilities. After LifeScan has established such capacity, and for the remainder of *[REDACTED], LifeScan shall be obliged to purchase the first *[REDACTED] strips of its demand in each calendar quarter from UBS.

The parties agree that the Joint Steering Committee or their designees will meet in *[REDACTED] to determine what percentage of LifeScan’s demand in *[REDACTED] will be manufactured by UBS, and to meet annually thereafter during the term of this Agreement to determine UBS’s manufacturing volumes for subsequent years.

8 Defective Products

8.1 Disposition of defective Products

LifeScan shall within a reasonable time upon receipt of Product undertake a visual inspection for evidence of any damage to any shipping containers, vials or Product caused during transportation. Without prejudice to any other remedy which LifeScan may have, UBS will replace at its own cost and expense, including reimbursement of freight and disposition costs incurred by LifeScan, the Products that fail to comply with the Products Specifications at the time of delivery FCA Rowville or have any defects that were in existence at the time of delivery FCA Rowville. LifeScan will notify UBS of the existence and nature of any non-compliance or defect within a reasonable time and UBS (or its nominee) will have a reasonable opportunity, not to exceed 10 Business Days from receipt of notification, to inspect such defective Products and provide LifeScan with detailed written instructions to return or dispose of such defective Products. The Joint Steering Committee shall agree on a returned goods authorization process. LifeScan shall have no obligation to pay for any of the Products that are subject to such a claim of non-compliance or defect provided if there is any dispute regarding the claim it shall be handled in accordance with Section 8.2. If UBS fails to so inspect and instructs LifeScan as to the disposition of such defective Products, LifeScan may dispose of such defective Products as it sees fit and UBS shall:

- (a) reimburse LifeScan for all direct, out-of-pocket costs incurred by LifeScan in such disposition; and
- (b) replace such defective Products at its own cost and expense,
- within 45 days of any disposal of Product or resolution of a LifeScan claim.

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

8.2 Independent testing

- (a) If the parties disagree as to the Products’ conformance to the Products Specifications or whether the Products have such a defect, either party may deliver the Products to an independent third-party laboratory, mutually and reasonably acceptable to both parties, for analytical testing to determine whether the Products fail to comply with the Products Specifications at the time of delivery FCA Rowville or have any defects that were in existence at the time of delivery FCA Rowville. The parties agree to accept the results of such independent testing.
- (b) All costs associated with such third-party testing shall be at LifeScan’s expense unless the tested Products are deemed by such third-party to fail to comply with the Products Specifications at the time of delivery FCA Rowville or have any defects that were in existence at the time of delivery FCA Rowville, in which case all such costs, including reimbursement of freight and disposition costs, shall be promptly paid by UBS.
- (c) No inspection or testing of or payment for the Products by LifeScan or any third-party agent of LifeScan shall constitute acceptance by LifeScan thereof, nor shall any such inspection or testing be in lieu or substitution of any obligation of UBS for testing, inspection and quality control as provided in the Products Specifications or under applicable local, state, or federal laws, rules, regulations, standards, codes or statutes.

8.3 Corrective action

- (a) In the event any Governmental Authority having jurisdiction shall request or order, or if LifeScan shall determine that it is required to undertake, any corrective action with respect to any of the Products, including any recall, corrective action or field action, and the cause or basis of such recall or action to the extent it is attributable to:
 - (i) a breach by UBS of any of its warranties, representations, obligations or covenants contained in this Agreement; or
 - (ii) the negligence or wilful misconduct of UBS,then UBS shall be liable, and will reimburse LifeScan for the reasonable costs of such action.
- (b) For the avoidance of doubt, the costs of such recall or action payable by UBS shall only include the reasonable direct costs actually expended by LifeScan in connection with such recall or action of Products manufactured by UBS and shall not include any consequential, punitive, exemplary, or multiplied damages. To the extent more than one party is manufacturing Product and it is difficult to identify the specific Product manufactured by UBS, then UBS shall only be responsible for the proportion of Product it manufactured out of the total amount of Product Sold by LifeScan in the prior Financial Year.

9 Inspection

9.1 Rights of Inspection

LifeScan will have the right (directly or through an agent), upon reasonable notice to UBS and during regular business hours, to inspect and audit the facilities being used by UBS for production and storage of the Products to assure compliance by UBS (and will use reasonable efforts to cause its suppliers) with all applicable rules and regulations and with other provisions of this Agreement.

9.2 Obligations to rectify

UBS will within 30 days remedy or cause the remedy of any deficiencies which may be noted in any such audit of UBS by LifeScan under **clause 9.1** or, if any such deficiencies can not reasonably be remedied within such 30 day period, present to LifeScan a written plan to remedy such deficiencies as soon as possible. The failure by UBS to remedy or cause the remedy of any such deficiencies within such 30 day period or to present such a plan within such 30 day period and then use its best efforts to remedy or cause the remedy of such deficiencies in accordance with such written plan, as the case may be, shall be deemed a material breach of this Agreement.

9.3 Acknowledgment

UBS acknowledges that the provisions of this **clause 9** granting LifeScan certain audit rights shall in no way relieve UBS of any of its obligations under this Agreement, nor shall such provisions require LifeScan to conduct any such audits.

Part 3: Services

10 Provision of Services

10.1 Supply of Initial Services

UBS has been supplying the Initial Services. After the Effective Date, UBS will continue to supply the Initial Services to LifeScan in accordance with **Schedule 2** and in accordance with and subject to the terms of this Agreement.

10.2 Supply of other Services

- (a) From time to time the parties may agree that UBS will provide Services to LifeScan. For purposes of clarification, the Joint Steering Committee would agree on other Services, cost recovery and success fees based on milestones achieved. An example of further Services would be a request from LifeScan to create an additional manufacturing line in a LifeScan Manufacturing facility including payment of the reasonable costs of UBS and a reasonable success fee for qualification of the line. In each such event, the parties shall enter into a Services Addendum.

- (b) During the term of each Services Addendum, UBS will supply the Services specified in the applicable Services Addendum to LifeScan.
- (c) Each Services Addendum, when executed will be attached to this Agreement and form part of and be subject to the terms of this Agreement.
- (d) In the event of a conflict between the terms of this Agreement and the terms of any Services Addendum, the terms of this Agreement will prevail, except to the extent that the applicable Services Addendum expressly and specifically states an intention to supersede this Agreement on a specific matter.
- (e) If a Services Addendum provides for the amendment of a term of this Agreement, that amendment will be effective only in relation to that Services Addendum and, unless expressly specified to the contrary in the Services Addendum, will not otherwise amend this Agreement or operate in relation to any other Services Addendum or Product Addendum.

10.3 Manner of performing the Services

UBS must provide the Services:

- (a) with due care and skill and in a timely manner;
- (b) in a proper and efficient manner using that standard of skill, diligence, and prudence that would reasonably be expected from a prudent and experienced provider of services similar to the Services;
- (c) in compliance with all laws, regulations and standards with which UBS is legally required to comply; and
- (d) in compliance with all policies of LifeScan applicable to its business partners, of which it has been advised ahead of time in this Agreement or the Services Addendum.

10.4 Technical Success

Technical Success shall mean UBS’s completion of those elements of the Design History File and regulatory submission deliverables of UBS, including all LifeScan and UBS design control approvals for the Initial Product. UBS agrees that achieving Technical Success is its highest priority and to allocate resources accordingly. If LifeScan perceives that there is a misallocation of resources, or if issues related to the progress toward achieving Technical Success arise, the issue will be referred to the Joint Steering Committee which will agree within five (5) days to a course of action to remedy the situation as soon as practicable.

11 Fees

11.1 Quarterly Service Fee

- (a) In consideration of the provision by UBS of Initial Services, LifeScan or its designee will pay to UBS:
 - (i) a service fee each Quarter (the “**Quarterly Service Fee**”) calculated in accordance with the remainder of this **clause 11.1**; and
 - (ii) upon achievement of the Milestone described in **clause 11.2**, the Milestone Amount.
- (b) The Quarterly Service Fee will be calculated as follows:
 - (i) *[REDACTED];
 - (ii) *[REDACTED].

For the avoidance of doubt, it is acknowledged the value of the initial service to LifeScan is not easily quantifiable and will fluctuate during the Term and the parties consider it best handled by a Quarterly Services Fee. Therefore, the Quarterly Service Fee will be payable regardless of who manufactures the Covered Products provided any Covered Products that have been provided to third parties as free samples or for testing purposes (including clinical trials) shall not be counted as “Sold” for purposes of calculating the Quarterly Service Fee.

For the further avoidance of doubt, the calculation of the amount of Covered Products Sold shall begin at zero each Financial Year. The Quarterly Service Fee shall apply during the Interim Costing Period.

- (c) Within 30 Business Days, of the end of each Quarter (or such lesser time subject to the then current capabilities of LifeScan), LifeScan will deliver to UBS a written statement setting forth:
 - (i) the number of Covered Products Sold during the previous Quarter; and
 - (ii) the calculation of the Quarterly Service Fee owed in respect of such Quarter.
- (d) Following receipt of the written statement from LifeScan pursuant to **clause 11.1(c)**, UBS will provide to LifeScan an invoice for the Quarterly Service Fee amount reflected on LifeScan’s statement. LifeScan shall pay such invoice within forty-five (45) days of receipt.

11.2 Milestone

- (a) LifeScan shall pay UBS *[REDACTED] within 45 days of achieving the Milestone.
- (b) For clarification, the Milestone Amount shall only be paid once to UBS.

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

- (c) LFS will use commercially reasonable efforts to launch the Initial Product in a first market as soon as practicable after achievement of the Milestone. Such launch shall be made consistent with LifeScan’s rights under Section 3.2(a) of the Agreement. The foregoing notwithstanding, if the Milestone is achieved after *[REDACTED], LifeScan shall not be obligated to launch the Initial Product in any market before *[REDACTED].
- (d) If, despite having achieved the Milestone before *[REDACTED], LifeScan has not launched the Initial System by *[REDACTED], LifeScan shall pay UBS *[REDACTED] by *[REDACTED]. If, despite having achieved the Milestone after *[REDACTED], but before *[REDACTED], LifeScan has not launched the Initial System by *[REDACTED], LifeScan shall pay UBS *[REDACTED] by *[REDACTED]. The parties recognize and agree that it is difficult to calculate with precision UBS’s and UBI’s actual damages arising from LifeScan’s failure to launch the Initial Product within the timeframes set forth above, and thus agree that this amount shall represent LifeScan’s sole payment obligation to UBI and UBS, and UBI and UBS shall not have any claim or remedy, whether based in contract, tort or any other theory, for any claim under the Agreement for failure to launch within the timeframes set forth herein.
- (e) Nothing in this Article 11.2 shall be deemed to amend Article 3.2(a).

11.3 Lump Sum Service Fee

- (a) At any time before the **Fee Conversion Reference Date**, if LifeScan has not Sold Covered Products by *[REDACTED] or ceases selling all Covered Products for eighteen months, LifeScan may, at its option, give notice of conversion of the Quarterly Service Fee to a one time lump sum fee of *[REDACTED] (**Lump Sum Service Fee — A**).
- (b) If such Notice is given pursuant to **clause 11.3(a)**:
 - (i) LifeScan’s obligations to pay Quarterly Service Fees, will permanently cease at the end of the Quarter in which such notice was given; and
 - (ii) the Lump Sum Service Fee — A must be paid by LifeScan within thirty (30) days of the end of the Quarter in which such notice was given.
- (c) At any time after the **Fee Conversion Reference Date**, LifeScan may, at its option, give notice of conversion of the Quarterly Service Fee to UBS. After delivery of the notice of conversion to UBS, LifeScan shall only be required to pay the Quarterly Service Fee for the remainder of the Financial Year in which the notice of conversion was delivered to UBS. Promptly after the end of that Financial Year, LifeScan will calculate and pay within forty-five (45) days a one time lump sum fee (**Lump Sum Service Fee — B**) to be calculated by multiplying the total of the Quarterly

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Service Fee for the relevant Financial Year in which notice of conversion is given by the multiplier for such Financial Year as identified below:

- (i) *[REDACTED];
- (ii) *[REDACTED];
- (iii) *[REDACTED];
- (iv) *[REDACTED];
- (v) *[REDACTED];
- (vi) *[REDACTED]; and
- (vii) *[REDACTED].

11.4 Audit Rights

For the sole purpose of verifying amounts owed under this **clause 11**, UBS (or its designated audit expert) shall have the right no more than one time each Financial Year, at its own expense, to review the Financial Records for the preceding Quarters during the Term (other than those already reviewed in a prior audit) at the location(s) where the Financial Records are maintained by LifeScan upon thirty (30) days notice and during regular business hours. Results of such review shall be made available to LifeScan. Further, if the review reflects an overpayment to UBS, such overpayment shall be deducted from the next payment due to UBS. If the review reflects an underpayment to UBS, such underpayment shall be remitted by LifeScan to UBS within forty-five (45) days. If the underpayment is greater than five percent (5%) of the amount that was otherwise due for a Quarter, LifeScan shall reimburse UBS for the costs of such review. If no further payments are due to UBS (e.g. due to termination of this Agreement), then LifeScan shall pay to UBS the amount of such underpayment within forty-five (45) days of UBS’ provision to LifeScan of the results of UBS’ review.

12 Manufacturing Process Information and Other Intellectual Property

As part of the Services to be provided by UBS to LifeScan, UBS undertakes to comply with the following provisions:

- (a) Upon LifeScan’s request, UBS will provide LifeScan with a detailed written description of UBS’ process for the manufacture of the Products, including all underlying know-how relevant to the process and improvements thereto (collectively the **Process**), in sufficiently clear and detailed terms in a format mutually agreed by the parties so it can be readily followed to make the Products in the manner UBS considers most efficient.
- (b) If UBS alters, modifies or changes the Process, UBS will promptly amend the description to include such alteration, modification or change.

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- (c) In addition to all the rights and licenses granted under the Development Agreement and License Agreement, UBS acknowledges and agrees that all rights to all inventions, improvements, discovery, trade secret, know-how, concept, idea and copyrightable works (including derivatives of UBS’ pre-existing copyrighted works) and the like created by UBS, its Affiliates or their officers, employers, and agents in and to the Process, Products, Initial Meters and improvements thereto (**Agreement Intellectual Property Rights**) will be owned by LifeScan and, if created under this Agreement, will vest in LifeScan immediately upon creation.
- (d) UBS will, and will procure that its Affiliates, officers, employees and agents who have created any Agreement Intellectual Property Rights, execute an assignment in favour of LifeScan and any other documents reasonably requested by LifeScan. LifeScan hereby grants to UBS a non-revocable, worldwide, royalty-free, exclusive license, with the right to sub-license to make, have made, use and sell under and exploit in any way all rights in and to the Agreement Intellectual Property Rights outside LifeScan’s Field (as defined in the License Agreement).
- (e) UBS will allow LifeScan (or its designee) access to UBS’ premises to observe and understand the Process.
- (f) At LifeScan’s request, UBS agrees to assist LifeScan in the implementation of manufacturing capacity at a location of LifeScan’s choosing by entering into a Services Addendum. Assistance may include but not be limited to: procurement and commissioning of manufacturing equipment and processes, training for engineers, operators and other production support personnel and other activities required to produce Product. LifeScan agrees to pay UBS for its reasonable costs (approved in advance by LifeScan) incurred in connection with the implementation of this capacity and may include a success fee payable upon an agreed milestone.

Part 4: Further Provisions

13 Sundry Obligations of UBS

13.1 Records

UBS will keep and maintain proper records of the Products and Services provided to LifeScan. LifeScan may, upon reasonable prior notice, inspect such records at any time.

13.2 Reports

The Joint Steering Committee will agree on any reports and the format they should be in. For example only, such reports may include monthly report setting out details of:

-
- (a) all Products and Services supplied during the preceding month; and

- (b) all Raw Materials, work-in-progress and finished goods held by UBS.

13.3 Equipment

- (a) UBS will provide equipment for the manufacture of strips to go into vials with a minimum capacity of *[REDACTED] (the “**Original Line**”) in Rowville, Victoria.
- (b) The Joint Steering Committee will determine whether additional equipment is required for the Original Line or for additional lines and which party is responsible for paying for such equipment.

13.4 Insurance

UBS must use reasonable commercial efforts to obtain and maintain for the duration of this Agreement the insurances set forth in Appendix G:

14 Restrictions on UBS and UBI activities

- (a) During the Term of this Agreement, neither UBS nor UBI will, directly or indirectly, provide consultancy, advisory or other services to any third party in relation to:
- (i) the measurement of analytes for purposes of diagnosing, managing, monitoring, prognosticating, treating or curing diabetes;
 - (ii) the collection and/or analysis of data for the purpose of diabetes management; or
 - (iii) the delivery of one or more therapeutic agents for the purpose of treating or managing abnormal glucose metabolism, including, without limitation, the delivery of insulin, insulin analogs, Glucagon-like proteins/peptides (**GLPs**), analogs of GLPs or GLP like hormones; or
 - (iv) the measurement of glucose in humans for any purpose, including, without limitation, tight glycemic control, (clauses (i)-(iv) being collectively, **Restricted Purposes**).
- (b) UBS and UBI acknowledge and agree that, other than the licenses expressly granted under this Agreement, the Development Agreement and the License Agreement, neither UBS nor UBI has any rights in any intellectual property owned by LifeScan or its Affiliates, including, without limitation, any intellectual property assigned to LifeScan under this Agreement, the Development Agreement or the License Agreement.

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15 Representations and warranties

15.1 **UBS Warranties**

UBS represents, warrants and covenants to LifeScan that:

- (a) all Products supplied in connection with this Agreement will be:

(i) of merchantable quality;

(ii) fit for the purpose intended by this Agreement;

(iii) free from defects in material and workmanship; and

(iv) manufactured and provided in accordance with the relevant Product Specifications and in compliance with this Agreement;

Notwithstanding the above, UBS shall not be responsible for any breach of these warranties arising as a result of acts or omissions after delivery FCA Rowville.
- (b) it will comply with all applicable present and future laws, statutes, ordinances and regulations and requirements of any applicable Government Authority relating to:

(i) the design, manufacture and supply of the Products provided under this Agreement; and

(ii) the Services provided under this Agreement;
- (c) the provision of the Products and Services to LifeScan by UBS will not involve the misappropriation of confidential information or trade secrets of any third party by UBS or its agents; and
- (d) it and its Affiliates and each of their respective directors, officers, employees, agents and contractors who will provide the Products and or the Services have the requisite skill, knowledge and expertise to provide the Products and the Services in accordance with the provisions of this Agreement.

15.2 **Execution and performance of agreement**

UBS and LifeScan each represents and warrants to the other that:

- (a) it is a corporation or company duly organised, validly existing and registered under the laws of its place of incorporation;
- (b) it has full right, power and authority to enter into and perform its obligations under this Agreement; and
- (c) the performance of its obligations under this Agreement will not result in a violation or breach of, and will not conflict with or constitute a default under any agreement, contract, commitment or obligation to which such party or any of its Affiliates is a party or by which it is bound.

15.3 **EXCLUSION OF OTHER WARRANTIES**

EXCEPT AS SET FORTH ABOVE, THE PARTIES TO THIS AGREEMENT MAKE NO OTHER REPRESENTATIONS AND WARRANTIES, WHETHER

EXPRESSED OR IMPLIED, WRITTEN OR ORAL, STATUTORY OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE IN RESPECT OF THE PRODUCTS OR ANY WARRANTIES ARISING FROM COURSE OF DEALING OR USAGE OF TRADE AND THE PARTIES FURTHER AGREE THAT TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAWS, ANY CONDITIONS OR WARRANTIES IMPOSED BY LEGISLATION OR STATUTE ARE HEREBY EXCLUDED.

16 Compliance

16.1 Compliance with certain laws

In the performance of its obligations under this Agreement, UBS agrees to comply with, and to cause its officers, employees, agents and contractors to comply with, the applicable provisions of all applicable laws, rules and regulations in force from time to time including all such legal requirements:

- (a) prohibiting discrimination against any employee or applicant for employment because of race, colour, religion, sex or national origin;
- (b) prohibiting discrimination against any employee or applicant for employment because of physical or mental handicap;
- (c) establishing fair or minimum standards for workers; and
- (d) the Trade Practices Act (Cth) 1974, the Therapeutic Goods Act (Cth) 1989, the Therapeutic Goods (Charges) Act 1989 and the *Therapeutic Goods Amendment (Medical Devices) Act (Cth)* 2002.

16.2 Compliance with Policy on the Employment of Young Persons

- (a) UBS warrants that it and each of its officers have read and understand the Johnson & Johnson Policy on the Employment of Young Persons attached hereto as Appendix D (**Policy**).
- (b) In the manufacture and supply of all the Products hereunder, UBS will employ young persons only as permitted by the Policy.
- (c) UBS will permit representatives of LifeScan to enter UBS' premises at any reasonable time, and UBS will ensure that representatives of LifeScan will be permitted to enter the premises of any subcontractor involved in the manufacture or supply of any of the Products at any reasonable time, in order to inspect relevant employment, health and safety records and to observe the manufacturing process.
- (d) UBS will maintain the records necessary to demonstrate compliance with the Policy and will provide to LifeScan, upon LifeScan's request, a written certification of such compliance annually during the term of this Agreement.
- (e) If UBS fails to comply with this **clause 16.2**, then it shall be deemed a material breach of this Agreement by UBS.

16.3 Standards for Responsible External Manufacturing

- (a) UBS and its officers have read and understand the Johnson & Johnson Standards for Responsible External Manufacturing (**Standards**) in effect as of the Effective Date and set out in Appendix J.
- (b) LifeScan will have the right to audit UBS to determine compliance with the Standards in accordance with the provisions of **clause 9**.
- (c) UBS will maintain the records necessary to demonstrate compliance with the Standards and shall provide to LifeScan, upon LifeScan’s request, a written certification of such compliance annually during the Term of this Agreement.
- (d) If UBS fails to comply with this **clause 16.3**, then it shall be deemed a material breach of this Agreement by UBS.

16.4 Files and Work papers

- (a) All papers or electronic records, files, documents, work papers and other information in any form, whether marked “confidential” or not, provided by LifeScan, its employees, agents or affiliates pursuant to this Agreement (**LifeScan Files and Work Papers**) will remain the exclusive property of LifeScan.
- (b) UBS and its subcontractors and agents will use LifeScan Files and Work Papers only for purposes of performing UBS’ obligations under this Agreement.
- (c) LifeScan Files and Work Papers must be maintained in a manner that prevents their intentional or accidental disclosure to other clients of UBS.
- (d) LifeScan Files and Work Papers will be kept in UBS’ possession only so long as it serves a necessary business purpose, the Services are ongoing and, in no case, longer than 30 days after the termination of this Agreement, unless otherwise agreed to in writing by an authorised agent of LifeScan.
- (e) Upon 30 days after the termination of this Agreement, all LifeScan Files and Work Papers in the possession, custody or control of UBS, or its subcontractors and agents, will be returned to LifeScan unless directed otherwise by LifeScan. Thereafter, no copies are to be made or retained by UBS.
- (f) UBS must promptly notify LifeScan prior to the production of subpoenaed LifeScan Files and Work Papers.
- (g) Notwithstanding the above requirements, UBS may maintain records to the extent required by applicable statute, regulation or other law and UBS’ counsel may retain one copy of LifeScan Files and Work Papers for its records.

16.5 Compliance with Environment, Safety And Industrial Hygiene

With respect to all environmental, safety and industrial hygiene matters related to UBS’ activities under this Agreement, UBS will:

- (a) inform LifeScan promptly of any significant adverse event (e.g., fires, explosions, accidental discharges);
- (b) inform LifeScan promptly of any allegations or findings of violations of applicable laws or regulations;
- (c) allow LifeScan to inspect UBS’ facilities, such inspections to be at reasonable times and upon reasonable notice; and
- (d) implement promptly any corrective action which may be reasonably requested by LifeScan, including (without limitation) adhering to reasonable and significant elements of the environmental, safety and industrial hygiene program adhered to by LifeScan in its own operations.

17 Quality Agreement

The parties shall enter into the Quality Agreement attached hereto as **Appendix E**.

18 Indemnities

18.1 UBS indemnity

UBS shall indemnify and hold harmless LifeScan, its Affiliates and each of their respective officers, directors, employees and agents from and against any and all Losses that may be sustained, suffered or incurred by such indemnified parties in connection with a third party claim arising from or related to:

- (a) a material breach by UBS or UBI of any warranty, representation, covenant or agreement made by UBS or UBI in this Agreement;
- (b) the failure of any Product supplied by UBS to comply with the relevant Product Specifications;
- (c) the negligence or wilful misconduct of UBS, UBI or their Affiliates pursuant to this Agreement; or
- (d) the: (i) design; (ii) validation; or (iii) manufacture of the Products by UBS, including the presence of any defects or hidden defects in the Products except where UBS was acting at the express written direction of LifeScan;

provided that UBS will not be liable for any Losses to the extent that they arise from (i) the negligence or wilful misconduct of LifeScan or its Affiliates or (ii) any breach by LifeScan of any warranty, representation, covenant or agreement made by LifeScan in this Agreement; and further provided notwithstanding any other provision of this Agreement, the obligation of UBS to indemnify LifeScan under this **clause 18.1** shall terminate immediately upon termination of this Agreement other than with respect to matters where prior to the date of termination the indemnification procedures in **clause 18.3** had already commenced.

18.2 Indemnification by LifeScan

LifeScan shall indemnify and hold harmless UBS and its Affiliates and each of their respective officers, directors, employees and agents from and against any and all Losses that may be sustained, suffered or incurred by such indemnified parties in connection with a third party claim arising from or related to:

- (a) a material breach by LifeScan of any warranty, representation, covenant or agreement made by LifeScan in this Agreement;
- (b) the negligence or wilful misconduct of LifeScan or its Affiliates pursuant to the Agreement;
- (c) the (i) design of any meter (ii) validation of any meter (iii) manufacture of any meter or (iv) sale of any meter, including any defects or hidden defects resulting therefrom; or
- (d) any claims that the Products and/or meter infringes or violates the intellectual property rights of any third party in the Territory;

provided, that LifeScan will not be liable for any Losses to the extent that they arise from (i) the negligence or wilful misconduct of UBS or its Affiliates or (ii) any breach by UBS or UBI of any warranty, representation, covenant or agreement made by UBS or UBI in this agreement.

18.3 Indemnification procedures

Each indemnified party agrees to give the indemnifying party prompt written notice of any matter upon which such indemnified party intends to base a claim for indemnification (an Indemnity Claim) under this **clause 18**. With respect to any Indemnity Claim relating solely to the payment of money damages and which could not result in the indemnified party becoming subject to injunctive or other equitable relief or otherwise adversely affect the business of the indemnified party in any manner, and as to which the indemnifying party shall have acknowledged in writing the obligation to indemnify the indemnified party hereunder, the indemnifying party shall have the right to control the defense of such claim, subject to the indemnified party’s ability to participate in the defense at its own expense with its own counsel or to control the proceedings if the indemnifying party is unable or unwilling to do so. The indemnifying party shall not have the right to settle any claim without the indemnified party’s written consent; provided, that the indemnifying party shall have the right to settle such a claim without consent if (i) the settlement involves only the payment of money damages and does not involve any equitable relief or any conditions that could adversely affect the business of the indemnified party in any manner and (ii) the settlement includes a complete release of the indemnified party from such claim.

18.4 Other Product Liability Claims

In the case of any claim received by UBS from a third party for Losses related to personal injury or damage to property due to the use of any Product that is not subject to an indemnification obligation by UBS under clause 18.1, then UBS shall promptly notify LifeScan. LifeScan shall have the right to control the

defense of such claim and have the right to settle any claim without UBS’ written consent.

18.5 Limitation of Liability

NOTWITHSTANDING ANY OTHER TERM OF THIS AGREEMENT, THE PARTIES AGREE THAT TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, NO PARTY WILL BE LIABLE TO THE OTHER FOR ANY SPECIAL, INDIRECT, PUNITIVE OR CONSEQUENTIAL DAMAGES ARISING IN CONNECTION WITH THIS AGREEMENT OR IN RESPECT OF ANY OF THE APPLICABLE PRODUCTS OR SERVICES.

19 Term and Termination

19.1 Term

This Agreement commences on the Effective Date of signing and continues until terminated in accordance with this clause 19.

19.2 Termination for breach

Either party may terminate this Agreement (without payment of any penalty or fee) with immediate effect by written notice to the other party if the other party is in material breach of a term of this Agreement and the material breach is not remedied within 90 days of written notice requiring it to do so.

19.3 Termination for insolvency and bankruptcy

LifeScan may terminate this Agreement (without payment of any penalty or fee) with immediate effect by written notice to UBS if UBS undergoes an Insolvency Event or UBI undergoes a Bankruptcy Event. UBS may terminate this Agreement (without payment of any penalty or fee) with immediate effect by written notice to LifeScan if LifeScan undergoes a Bankruptcy Event.

19.4 Termination for change of control

LifeScan may terminate this Agreement (without payment of any penalty or fee) upon thirty (30) days prior written notice if UBS or UBI undergoes a Change of Control. Notwithstanding the above, LifeScan shall not have a right to terminate this Agreement in accordance with the preceding sentence if (i) the LifeScan Manufacturing Line Date has occurred and (ii) UBS or UBI, as the case may be, are not being acquired by a third party that makes products that compete with the Initial Product.

19.5 Regulatory termination

LifeScan may terminate this Agreement (without payment of any penalty or fee) on thirty (30) days prior written notice if LifeScan is prohibited from selling all Covered Products by a competent regulatory authority or is otherwise unable to sell Product(s) due to regulatory or legal constraints in the major markets in the Territory.

19.6 Additional LifeScan termination rights

- (a) LifeScan may terminate this Agreement (without payment of any penalty or fee) upon thirty (30) days prior written notice of its reasonable determination that the Initial Product is not an approvable product.
- (b) Prior to making a submission for approval or clearance to market the Initial System in at least one jurisdiction LifeScan may terminate this Agreement (without payment of any penalty or fee except as provided below)
 - (i) if UBS achieves Technical Success before *[REDACTED], and LifeScan has not made a submission for approval or clearance to market the Initial System in at least one jurisdiction before *[REDACTED], in which case LifeScan shall pay UBS *[REDACTED] by *[REDACTED]; or
 - (ii) if UBS achieves Technical Success after *[REDACTED], but before *[REDACTED], and LifeScan has not made a submission for approval or clearance to market the Initial System in at least one jurisdiction before *[REDACTED], then LifeScan shall pay UBS *[REDACTED] by *[REDACTED].

For the avoidance of doubt, if LifeScan terminates this Agreement pursuant to this **clause 19.6(b)**, then only one of the payments described in clauses (i) and (ii) above will be due, and provided further that, if LifeScan terminates this Agreement pursuant to this clause 19.6(b), then UBS shall not be obliged to complete any work being conducted pursuant to the Development Agreement, nor shall it be obliged to refund any monies paid under the terms thereof.

- (c) After launch of the Initial System, but prior to the Fee Conversion Reference Date, LifeScan may terminate this Agreement without cause upon prior written notice after payment of Lump Sum Service Fee – A to UBS in accordance with **clause 11.3(a)**.
- (d) After the Fee Conversion Reference Date, LifeScan may terminate this Agreement without cause upon 12 months prior written notice to UBS and in addition pay the Lump Sum Service Fee — B to UBS in accordance with **clause 11.3(c)**.
- (e) If LifeScan were to terminate this Agreement pursuant to this **clause 19.6** and make the applicable payments (including any required by Appendix H), the parties recognize and agree that would be difficult to calculate with precision UBS’s and UBI’s actual damages, and thus agree that such amount shall represent LifeScan’s sole payment obligation to UBI and UBI shall not have any claim or remedy, whether based in contract, tort or any other theory for failure to make a submission or for termination of the Agreement in accordance with this **clause 19.6**.

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

19.7 Additional UBS termination rights

UBS may terminate this Agreement by providing two years prior written notice to LifeScan (or such other period as may be agreed between the parties) if:

- (a) the Lump Sum Services Fee — A or the Lump Sum Services Fee — B has been paid to UBS in which case LifeScan and UBS will negotiate a new transfer price for the relevant Covered Products provided any failure to reach agreement will be handled in accordance with **clause 20**; or
- (b) the parties fail to reach agreement in relation to any suspension or change to the Maximum Transfer Price as contemplated by **clause 6.2(e)**.

For the avoidance of doubt, UBS agrees that during the pendency of such two-year notice period prior to termination, it shall fully perform its obligations under this Agreement.

19.8 Consequences of termination

- (a) If LifeScan terminates this Agreement under clause 19.6(c) or (d), it will pay the amount specified in Appendix H:
- (b) In the event of termination of this Agreement due to UBS’ breach pursuant to **clause 19.2** UBS acknowledges and agrees LifeScan shall have the option to require UBS to provide all the manufacturing assistance services listed in **clause 12(e)** to enable LifeScan promptly to put in place LifeScan’s own qualified manufacturing line it being understood (i) LifeScan shall at its expense acquire any equipment it requires for such line and (ii) such assistance shall be at the reasonable expense of UBS.
- (c) In the event of termination of this Agreement by LifeScan (other than for UBS’ breach pursuant to **clause 19.2**), LifeScan shall purchase at book value all inventory of Products or components of Products, in each case relating solely to Products that have been ordered by LifeScan and solely to the extent that such inventory is saleable and in compliance with the applicable Product Specifications (**Qualified Inventory**); provided that, LifeScan shall not be obligated to pay for more than a six month supply (determined on the basis of orders submitted by LifeScan in the course of the six months preceding termination) of such inventory and components.
- (d) In the event of termination of this Agreement by LifeScan for UBS’ breach pursuant to **clause 19.2** or termination of this Agreement by UBS, LifeScan shall have the option to purchase at book value all or any portion of the Qualified Inventory.
- (e) Termination of this Agreement for any reason shall not release either party hereto from any liability which at such time has already accrued or which thereafter accrues from a breach or default prior to such expiration or termination, nor affect in any way the survival of any other right, duty or obligation of either party hereto which is expressly stated elsewhere in this Agreement to survive such termination.

- (f) Upon termination of this Agreement, UBS shall transfer to LifeScan in an orderly and prompt fashion all records and data relating to the Products, including the device master record, device history record, design history file and all product inquiry records, and such records and data shall be the property of LifeScan. UBS shall also cooperate with LifeScan to achieve an orderly transition of the manufacturing operations for the Products to LifeScan or its designee.

20 Dispute Resolution

20.1 Mediation

- (a) Any dispute, controversy or claim arising out of or related to this Agreement, or the interpretation, application, breach, termination or validity thereof, including any claim of inducement by fraud or otherwise, shall, before submission to mediation or arbitration, first be submitted for resolution to the Joint Steering Committee in accordance with **clause 4.3(c)**. If the dispute is not resolved in accordance with that clause, it will then be mediated through non-binding mediation in accordance with The CPR Mediation Procedure then in effect of the International Institute for Conflict Prevention and Resolution (CPR) available at www.cpradr.org/m_proced.htm, except where that procedure conflicts with these provisions, in which case these provisions control. The mediation shall be conducted in New York City, Borough of Manhattan and shall be attended by a senior executive with authority to resolve the dispute from each of the parties.
- (b) The mediator shall be neutral, independent, disinterested and shall be selected from a professional mediation firm such as JAMS or CPR.
- (c) The parties shall promptly confer in an effort to select a mediator by agreement. In the absence of such an agreement within 10 days of initiation of the mediation, the mediator shall be selected by CPR as follows: CPR shall provide the parties with a list of at least 15 names from the CPR Panels of Distinguished Neutrals. Each party shall exercise challenges for cause, two peremptory challenges, and rank the remaining candidates within 5 working days of receiving the CPR list. The parties may together interview the three top-ranked candidates for no more than one hour each and, after the interviews, may each exercise one peremptory challenge. The mediator shall be the remaining candidate with the highest aggregate ranking.
- (d) The mediator shall confer with the parties to design procedures to conclude the mediation within no more than 45 days after initiation. Under no circumstances may the commencement of arbitration under **clause 20.2** be delayed more than 45 days by the mediation process specified herein absent contrary agreement of the parties.

- (e) Each party agrees not to use the period or pendency of the mediation to disadvantage the other party procedurally or otherwise. No statements made by either side during the mediation may be used by the other or referred to during any subsequent proceedings.
- (f) Each party has the right to pursue provisional relief from any court, such as attachment, preliminary injunction, replevin, etc., to avoid irreparable harm, maintain the status quo, or preserve the subject matter of the arbitration, even though mediation has not been commenced or completed.

20.2 Arbitration

- (a) Any dispute, claim or controversy not resolved in accordance with **Clause 20.1**, will be submitted for resolution to arbitration pursuant to the rules then pertaining of the International Institute for Conflict Prevention and Resolution for Non-Administered Arbitration (available at <http://www.cpradr.org/arb-intro.asp?M=9.3>), or successor (**CPR**), except where those rules conflict with these provisions, in which case these provisions control. The arbitration will be held in New York City, Borough of Manhattan.
- (b) The panel shall consist of three arbitrators chosen from the CPR Panels of Distinguished Neutrals (or, by agreement, from another provider of arbitrators) each of whom is a lawyer with at least 15 years experience with a law firm or corporate law department of over 25 lawyers or who was a judge of a court of general jurisdiction. In the event the aggregate damages sought by the claimant are stated to be less than \$5 million, and the aggregate damages sought by the counterclaimant are stated to be less than \$5 million, and neither side seeks equitable relief, then a single arbitrator shall be chosen, having the same qualifications and experience specified above. Each arbitrator shall be impartial and independent of the parties and shall abide by the Code of Ethics for Arbitrators in Commercial Disputes (available at <http://www.adr.org/EthicsAndStandards>).
- (c) The parties agree to cooperate (1) to attempt to select the arbitrator(s) by agreement within 45 days of initiation of the arbitration, including jointly interviewing the final candidates, (2) to meet with the arbitrator(s) within 45 days of selection and (3) to agree at that meeting or before upon procedures for discovery and as to the conduct of the hearing which will result in the hearing being concluded within no more than nine (9) months after selection of the arbitrator(s) and in the award being rendered within 60 days of the conclusion of the hearings, or of any post-hearing briefing, which briefing will be completed by both sides within 45 days after the conclusion of the hearings.
- (d) In the event the parties cannot agree upon selection of the arbitrator(s), the CPR will select arbitrator(s) as follows: CPR shall provide the parties with a list of no less than 25 proposed arbitrators (15 if a single arbitrator is to be selected) having the credentials referenced above. Within 25

days of receiving such list, the parties shall rank at least 65% of the proposed arbitrators on the initial CPR list, after exercising cause challenges. The parties may then interview the five candidates (three if a single arbitrator is to be selected) with the highest combined rankings for no more than one hour each and, following the interviews, may exercise one peremptory challenge each. The panel will consist of the remaining three candidates (or one, if one arbitrator is to be selected) with the highest combined rankings. In the event these procedures fail to result in selection of the required number of arbitrators, CPR shall select the appropriate number of arbitrators from among the members of the various CPR Panels of Distinguished Neutrals, allowing each side challenges for cause and three peremptory challenges each.

- (e) In the event the parties cannot agree upon procedures for discovery and conduct of the hearing meeting the schedule set forth in paragraph c above, then the arbitrator(s) shall set dates for the hearing, any post-hearing briefing, and the issuance of the award in accord with the paragraph c schedule. The arbitrator(s) shall provide for discovery according to those time limits, giving recognition to the understanding of the parties that they contemplate reasonable discovery, including document demands and depositions, but that such discovery be limited so that the paragraph c schedule may be met without difficulty. In no event will the arbitrator(s), absent agreement of the parties, allow more than a total of ten days for the hearing or permit either side to obtain more than a total of 40 hours of deposition testimony from all witnesses, including both fact and expert witnesses, or serve more than 20 individual requests for documents, including subparts, or 20 individual requests for admission or interrogatories, including subparts. Multiple hearing days will be scheduled consecutively to the greatest extent possible.
- (f) The arbitrator(s) must render their award by application of the substantive law of the State of New York and are not free to apply “amiable compositeur” or “natural justice and equity.” The arbitrator(s) shall render a written opinion setting forth findings of fact and conclusions of law with the reasons therefor stated. A transcript of the evidence adduced at the hearing shall be made and shall, upon request, be made available to either party. The arbitrator(s) shall have power to exclude evidence on grounds of hearsay, prejudice beyond its probative value, redundancy, or irrelevance and no award shall be overturned by reason of such ruling on evidence. To the extent possible, the arbitration hearings and award will be maintained in confidence.
- (g) In the event the panel’s award exceeds \$5 million in monetary damages or includes or consists of equitable relief, or rejects a claim in excess of that amount or for that relief, then the losing party may obtain review of the arbitrators’ award or decision by a single appellate arbitrator (the **Appeal Arbitrator**) selected from the CPR Panels of Distinguished Neutrals by agreement or, failing agreement within seven working days, pursuant to the selection procedures specified in paragraph d above. If

CPR cannot provide such services, the parties will together select another provider of arbitration services that can. No Appeal Arbitrator shall be selected unless he or she can commit to rendering a decision within forty-five days following oral argument as provided in paragraph h. Any such review must be initiated within thirty (30) days following the rendering of the award referenced in f above.

- (h) The Appeal Arbitrator will make the same review of the arbitration panel’s ruling and its bases that the U.S. Court of Appeals of the Circuit where the arbitration hearings are held would make of findings of fact and conclusions of law rendered by a district court after a bench trial and then modify, vacate or affirm the arbitration panel’s award or decision accordingly, or remand to the panel for further proceedings. The Appeal Arbitrator will consider only the arbitration panel’s findings of fact and conclusions of law, pertinent portions of the hearing transcript and evidentiary record as submitted by the parties, opening and reply briefs of the party pursuing the review, and the answering brief of the opposing party, plus a total of no more than four (4) hours of oral argument evenly divided between the parties. The party seeking review must submit its opening brief and any reply brief within seventy-five (75) and one hundred thirty (130) days, respectively, following the date of the award under review, whereas the opposing party must submit its responsive brief within one hundred ten (110) days of that date. Oral argument shall take place within five (5) months after the date of the award under review, and the Appeal Arbitrator shall render a decision within forty-five (45) days following oral argument. That decision will be final and not subject to further review, except pursuant to the Federal Arbitration Act.
- (i) The parties consent to the jurisdiction of the Federal District Court for the district in which the arbitration is held for the enforcement of these provisions and the entry of judgment on any award rendered hereunder (including after review by the Appeal Arbitrator where such an appeal is pursued). Should such court for any reason lack jurisdiction, any court with jurisdiction shall act in the same fashion.
- (j) Each party has the right before or, if the arbitrator(s) cannot hear the matter within an acceptable period, during the arbitration to seek from the appropriate court provisional remedies such as attachment, preliminary injunction, replevin, etc. to avoid irreparable harm, maintain the status quo, or preserve the subject matter of the arbitration.
- (k) Each party hereto waives its right to trial of any issue by jury.
- (l) Each party hereto waives any claim to punitive, exemplary or multiplied damages from the other.
- (m) Each party hereto waives any claim of consequential damages from the other.
- (n) Each party hereto waives any claim for attorneys’ fees and costs and prejudgment interest from the other.

21 Confidentiality and public announcements

21.1 Non-disclosure

Each party must keep all Confidential Information of the other party confidential in the same manner that it applies to its own confidential information and must not use that Confidential Information except as necessary for the purposes of this Agreement or to exercise rights and obligations under this Agreement, the License Agreement or the Development Agreement. Confidential Information received by a party may also be disclosed or revealed to employees of that party or employees of its Affiliates who are under an obligation to keep confidential proprietary information, or to a party’s contractors, suppliers, consultants, advisors or customers under a similar obligation of confidentiality. Nothing herein is intended to prevent a party using confidential Information for purposes of seeking a patent application, or seeking or maintaining regulatory approvals of a Product or for regulatory compliance.

21.2 Exceptions

Each party’s obligations under **clause 21.1** do not apply to any information which:

- (a) is known to the receiving party prior to being received from the disclosing party, as established by its written records;
- (b) is or, without fault of the receiving party becomes, publicly known;
- (c) is received by either party from a third party without an obligation of confidence and having a right to disclose the same;
- (d) is developed by the receiving party independent of any disclosure of Information hereunder, as established by its written records; or
- (e) is required to comply with a court or administrative subpoena or order, provided the receiving party, where reasonably practicable, gives the other timely notice of the contemplated disclosure and provides the disclosing party the opportunity to intervene to preserve the confidentiality of the Confidential Information.
- (f) is required to be disclosed by law or the listing rules of a recognized stock exchange, provided the party using this exception shall have given, to the extent reasonably possible, not less than two calendar days prior notice to the other party to seek confidential treatment for any required disclosure.

21.3 Public Announcements

The parties hereto covenant and agree that, except as provided for herein below, each will not from and after the date hereof make, issue or release any public announcement, press release, statement or acknowledgment of the existence of, or reveal publicly the terms, conditions and status of, the transactions contemplated herein, without the prior written consent of the other party as to the content and time of release of and the media in which such statement or announcement is to be made; provided, however, that in the case

of announcements, statements, acknowledgments or revelations which either party is required by law or the listing rules of a recognised stock exchange by which it is bound, to make, issue or release, the making, issuing or releasing of any such announcement, statement, acknowledgment or revelation by the party so required to do so by law shall not constitute a breach of this Agreement if such party shall have given, to the extent reasonably possible, not less than two (2) calendar days prior notice to the other party, and shall have attempted, to the extent reasonably possible, to clear such announcement, statement, acknowledgment or revelation with the other party. UBS shall not use the name of LifeScan or the name of any of LifeScan’s Affiliates for advertising or promotional purposes without the prior written consent of LifeScan. In furtherance of the foregoing, UBS shall not originate any publicity or other announcement, written or oral, whether to the public, the press, the trade, LifeScan’s or UBS’ customers or otherwise, relating to this Agreement or the existence of an arrangement between the parties, without the prior written approval of LifeScan. Notwithstanding the above, it is contemplated by the parties that UBS may issue an announcement on or after the Effective Date and a redacted form of the Agreement will be filed by UBI with the United States Securities and Exchange Commission.

22 Notices

22.1 General

A notice, demand, certification, process or other communication relating to this Agreement must be in writing in English and may be given by an agent of the sender.

22.2 How to give a communication

In addition to any other lawful means, a communication may be given by being:

- (a) personally delivered;
- (b) left at the party’s current address for notices;
- (c) sent to the party’s current address for notices by pre-paid international courier, ordinary mail or pre-paid airmail, as applicable; or
- (d) sent by fax to the party’s current fax number for notices.

Notwithstanding the above, any written notice actually received by a party shall be deemed sufficient for purposes of this clause.

22.3 Particulars for delivery of notices

- (a) The particulars for delivery of notices are initially:

LifeScan

Address:

1000 Gibraltar Drive, Milpitas, CA 95035-6312, USA

Fax:

1 408-956-4404

Attention:

Vice President, Office of Program Management

With a copy to:

Address: Johnson & Johnson,
One Johnson & Johnson Plaza, New Brunswick,
NJ 08933, USA

Fax: 1 732-524-2788

Attention: Associate General Counsel, Medical Device & Diagnostics

UBI

Address: 1 Corporate Avenue,
Rowville, Victoria 3178

Fax: 61 3 9213 9099

Attention: Chief Executive Officer

With a copy to:

Address: Venable LLP,
8010 Towers Crescent Drive, Suite 300, Vienna, Virginia 22182, USA

Fax: 1 703-821-8949

Attention: Elizabeth Hughes, Esq.

(b) Each party may change its particulars for delivery of notices by notice to each other party.

UBS

Address: 1 Corporate Avenue,
Rowville, Victoria 3178
Australia

Fax: 61 3 9213 9099

Attention: Chief Executive Officer

With a copy to:

Address: PFM Legal,
Level 12, 117 York Street,
Sydney NSW 2000

Fax: 61 2 9267-8196

Attention: Cameron Billingsley

(c) Each party may change its particulars for delivery of notices by notice to each other party.

22.4 Communications by post or international courier

Subject to **clause 22.6**, a communication is given if posted or couriered:

- (a) within Australia to an Australian address, three Business Days after posting; or
- (b) in any other case using the post, ten Business Days after posting; or.
- (c) three business days after delivery to a recognized international courier.

22.5 Communications by fax

Subject to **clause 22.6**, a communication is given if sent by fax, when the sender’s fax machine produces a report that the fax was sent in full to the addressee. That report is conclusive evidence that the addressee received the fax in full at the time indicated on that report.

22.6 After hours communications

If a communication is given:

- (a) after 5.00 pm in the place of receipt; or
- (b) on a day which is a Saturday, Sunday or bank or public holiday in the place of receipt,

it is taken as having been given at 9.00 am on the next day which is not a Saturday, Sunday or bank or public holiday in that place.

22.7 Process service

Any process or other document relating to litigation, administrative or arbitral proceedings relating to this Agreement may be served by any method contemplated by this **clause 22** or in accordance with any applicable law.

23 Force Majeure

23.1 Force Majeure Event

- (a) If either party is prevented from performing any of its obligations under this Agreement due to a Force Majeure Event, such non-performing party will not be liable for breach of this Agreement with respect to such non-performance to the extent any such non-performance is due to a Force Majeure Event.
- (b) Such non-performance will be excused for three months or as long as such event shall be continuing (whichever occurs sooner), provided that the non-performing party gives immediate written notice to the other party of the Force Majeure Event.
- (c) Such non-performing party must use all reasonable endeavours to remedy the Force Majeure Event and to resume performance of its affected obligations as soon as practicable.

23.2 Failure to supply

- (a) Notwithstanding the provisions of **clause 23.1**, in the event that UBS is unable or unwilling or fails to supply any of the Products in such quantities as LifeScan requests and in compliance with the required delivery periods and subject to the UBS Capacity Limitation (whether due to the occurrence of a Force Majeure Event or otherwise), then:
 - (i) UBS will make available to LifeScan or its designee access to any technical and proprietary materials, information and techniques necessary or helpful for LifeScan to procure required raw materials or produce or arrange an alternative supplier of the Products; and
 - (ii) UBS will provide advice and consultation at its facilities or the facilities of any alternate supplier of the Products.
- (b) Notwithstanding anything to the contrary contained in this Agreement, in the event that LifeScan shall make or have made the Products, pursuant to this **clause 23.2**, LifeScan will be permitted to disclose to any third party any Confidential Information as is reasonably necessary in connection with such activities (subject to such third party agreeing in writing to be bound by the terms of **clause 21**)
- (c) If LifeScan gives an order within the UBS Capacity Limitation and UBS has an inability, unwillingness or failure to supply Product which conforms with the applicable Product Specifications within the relevant delivery periods and this occurs more than three times in any Quarter (unless due to a Force Majeure Event), such inability, unwillingness or failure shall be deemed a material breach of this Agreement.

24 Guarantee

24.1 Guarantee and Indemnity

In consideration of LifeScan entering into this Agreement at the request of UBI (the receipt and good value of which is acknowledged by UBI), UBI irrevocably and unconditionally:

- (a) guarantees to LifeScan the due and punctual observance and performance of all the obligations of UBS under this Agreement (including any warranties, covenants and indemnities given in favour of LifeScan); provided that in the event this guarantee is enforced and UBI is obligated to performance such obligations, then in such event LifeScan hereby grants to UBI all of the same rights granted to UBS under this Agreement solely to enable UBI to perform its obligations in this Agreement;
- (b) without limiting **clause 24.1(a)**, guarantees the due and punctual payment to LifeScan of all money due or which becomes due from UBS under this Agreement or arising out of breach by UBS of the terms, obligations, warranties and conditions contained in or implied in this Agreement; and

- (c) as a separate and independent principal obligation, indemnifies LifeScan against any Losses incurred or suffered by LifeScan which arise from any default by UBS in the performance of any obligations under this Agreement or from any express or implied obligations of UBS in this Agreement being unenforceable.

24.2 Survival

The liability of UBI under **clause 24.1** will not be released or discharged (in whole or in part) by:

- (a) any time, concession, waiver or other indulgence being given by LifeScan to UBS (or any surety) for or in relation to the observance or performance of UBS’ obligations under this Agreement provided UBI shall have the benefit of any time, concession, waiver or other indulgence actually granted by LifeScan to UBS;
- (b) any other security or contractual obligations to secure the performance of UBS’ obligations under this Agreement being or not being taken, held, renewed, varied or enforced by LifeScan or such security being void, defective, informal or unenforceable;
- (c) all or any of UBS’ obligations under this Agreement being discharged otherwise than by their due performance or by this Agreement being terminated by LifeScan by due exercise of its rights under this Agreement;
- (d) an Insolvency Event affecting UBS;
- (e) the sale or other disposal of some or all of the shares in UBS which are owned by UBI; or
- (f) anything done or omitted to be done by LifeScan or by anything else which, but for this **clause 24.2**, might operate to release wholly or partially or discharge or otherwise exonerate UBI from its liability under this guarantee and indemnity.

24.3 Continuing Guarantee

The guarantee and indemnity given under this **clause 24**:

- (a) is a continuing guarantee and indemnity and will remain in force until the whole of the obligations of UBS have been duly performed and satisfied in full;
- (b) is irrevocable; and
- (c) constitutes a separate and independent obligation of UBI.

24.4 Remedy

LifeScan may enforce the guarantee and indemnity given under this **clause 24** without first making any demand or taking any action or proceedings to enforce its rights or remedies against UBS.

24.5 Reinstatement

The obligations of UBI under this **clause 24** will continue to be effective or will be reinstated if, at any time any amount under this Agreement is avoided or any payment must be replaced or restored, either in whole or in part, by UBS for any reason whatsoever and the liability of UBI will extend to any such payment as if that payment had not been made.

24.6 Warranties

UBI represents and warrants that:

- (a) it has full power and authority to enter into this Agreement and has taken all necessary action to authorise the execution, delivery and performance of this Agreement in accordance with its terms;
- (b) this Agreement constitutes a legally valid and binding obligation of UBI enforceable in accordance with its terms; and the execution, delivery and performance of this Agreement by UBI will not violate any provision of:
 - (i) any law or any order or decree of any applicable Government Authority;
 - (ii) the certificate of incorporation or bylaws of UBI; or
 - (iii) any encumbrance or other agreement which is binding on UBI.

25 GST

25.1 Construction

In this **clause 25**:

- (a) words and expressions which are not defined in this Agreement but which have a defined meaning in GST Law have the same meaning as in the GST Law; and
- (b) **GST Law** has the same meaning given to that expression in the A New Tax System (Goods and Services Tax) Act 1999.

25.2 Consideration GST exclusive

Unless otherwise expressly stated, all prices or other sums payable or consideration to be provided under this Agreement are exclusive of GST.

25.3 Payment of GST

If GST is payable by a supplier or by the representative member for a GST group of which the supplier is a member, on any supply made under this Agreement, the recipient will pay to the supplier an additional amount equal to the GST payable on the supply. Notwithstanding the above, Section 38-185 of the GST Law provides a supply of goods exported from Australia within 60 days of invoice or payment is not required to pay GST. The parties will cooperate to export any Products within 60 days of invoice or payment for such Products.

25.4 Timing of GST payment

The recipient will pay the amount referred to in **clause 25.3** in addition to and at the same time that the consideration for the supply is to be provided under this Agreement.

25.5 Tax invoice

The supplier must deliver a tax invoice or an adjustment note to the recipient before the supplier is entitled to payment of an amount under **clause 25.3**. The recipient can withhold payment of the amount until the supplier provides a tax invoice or an adjustment note, as appropriate.

25.6 Adjustment event

If an adjustment event arises in respect of a taxable supply made by a supplier under this Agreement, the amount payable by the recipient under **clause 25.3** will be recalculated to reflect the adjustment event and a payment will be made by the recipient to the supplier or by the supplier to the recipient as the case requires.

25.7 Reimbursements

Where a party is required under this Agreement to pay or reimburse an expense or outgoing of another party, the amount to be paid or reimbursed by the first party will be the sum of:

- (a) the amount of the expense or outgoing less any input tax credits in respect of the expense or outgoing to which the other party, or to which the representative member for a GST group of which the other party is a member, is entitled; and
- (b) if the payment or reimbursement is subject to GST, an amount equal to that GST.

26 General

26.1 Duty

- (a) UBS as between the parties is liable for and must pay all Victorian stamp duty (including any fine or penalty except where it arises from default by the other party) on or relating to the execution of this Agreement, or any document executed under it.
- (b) If a party other than UBS pays any Victorian duty (including any fine or penalty) on or relating to the execution of this Agreement, or any document executed under it, UBS must pay that amount to the paying party on demand.
- (c) It is acknowledged by the parties that none of the payments provided for under this Agreement are intended to be or are in fact in the nature of royalties, but rather are in the nature of payments for products and services.

- (d) LifeScan shall be entitled to deduct or withhold taxes where required by applicable law. UBS shall provide LifeScan as reasonably requested thereafter any tax documentation required to reduce or eliminate such deduction or withholding. LifeScan shall provide UBS with proof of payment of any taxes withheld or deducted pursuant to this clause.

26.2 Legal costs

Except as expressly stated otherwise in this Agreement, each party must pay its own legal and other costs and expenses of negotiating, preparing, executing and performing its obligations under this Agreement.

26.3 Amendment

No modification, change or amendment to this Agreement shall be effective unless in writing signed by each of the parties hereto.

26.4 Waiver and exercise of rights

- (a) A single or partial exercise or waiver by a party of a right relating to this Agreement does not prevent any other exercise of that right or the exercise of any other right.
- (b) A party is not liable for any loss, cost or expense of any other party caused or contributed to by the waiver, exercise, attempted exercise, failure to exercise or delay in the exercise of a right.

26.5 Rights cumulative

Except as expressly stated otherwise in this Agreement, the rights of a party under this Agreement are cumulative and are in addition to any other rights of that party.

26.6 Consents

Except as expressly stated otherwise in this Agreement, a party may conditionally or unconditionally give or withhold any consent to be given under this Agreement and is not obliged to give its reasons for doing so.

26.7 Governing law and jurisdiction

This Agreement is governed by and is to be construed in accordance with the laws applicable in the State of New York, USA, without giving effect to any provisions thereof that would cause the application of the laws of any other jurisdiction.

26.8 Assignment

This Agreement may not be assigned by LifeScan without the prior written consent of UBS, except that LifeScan may with prior written notice to UBS assign all or a portion of its rights and/or obligations hereunder to any of its Affiliates or to a successor, acquirer or licensee to the portion of its business to which this Agreement pertains without consent. UBS acknowledges that LifeScan has entered into this Agreement after consideration of the unique talent, experience and particular attributes of UBS to supply the Products. Therefore, this Agreement and all rights and obligations hereunder are

personal to UBS and may not be assigned by UBS without the express written consent of LifeScan, which consent may be withheld or given in LifeScan’s sole discretion. Any such assignment or any attempted assignment in the absence of the prior written consent of LifeScan, shall be void and without effect at the option of LifeScan. Subject to the foregoing terms of this **clause 26.8**, this Agreement shall bind and inure to the benefit of the parties hereto and their respective permitted successors and assigns.

26.9 Counterparts

This Agreement may consist of a number of counterparts and, if so, the counterparts can be executed separately by each party but taken together shall constitute one document.

26.10 Entire understanding

- (a) This Agreement contains the entire understanding between the parties as to the subject matter of this Agreement.
- (b) All previous negotiations, understandings, representations, warranties, memoranda or commitments concerning the subject matter of this Agreement are merged in and superseded by this Agreement and are of no effect. No party is liable to any other party in respect of those matters.
- (c) No oral explanation or information provided by any party to another:
 - (i) affects the meaning or interpretation of this Agreement; or
 - (ii) constitutes any collateral agreement, warranty or understanding between any of the parties.

26.11 Severability

In the event that any one or more of the provisions (or any part thereof) contained in this Agreement or in any other instrument referred to herein, shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, then to the maximum extent permitted by law, such invalidity, illegality or unenforceability shall not affect any other provision of this Agreement or any other such instrument. Any term or provision of this Agreement which is invalid, illegal or unenforceable in any jurisdiction shall, to the extent the economic benefits conferred by this Agreement to both parties remain substantially unimpaired, not affect the validity, legality or enforceability of any of the terms or provisions of this Agreement in any other jurisdiction.

26.12 Survival

Clauses 9.1, 12, 13.4, 17, 18, 19, 20, 21, 22, 24, 25 and 26 shall survive the termination of this Agreement in accordance with the respective terms thereof. In addition, any other clauses of this Agreement that are expressly stated to survive by their terms shall survive termination of this Agreement.

26.13 Relationship of parties

The relationship of LifeScan and UBS established by this Agreement is that of independent contractors, and nothing contained herein shall be construed to (a) give either party any right or authority to create or assume any obligation of any kind on behalf of the other or (b) constitute the parties as partners, joint venturers, co-owners or otherwise as participants in a joint or common undertaking.

26.14 LifeScan Affiliates

LifeScan, its successors or assigns may delegate to any of its Affiliates the right to exercise any rights or obligations of LifeScan under this Agreement in which case LifeScan shall give prior notice to UBS, it being acknowledged and agreed that LifeScan, its successors or assigns shall be the sole party looked to by UBS for all intents and purposes under this Agreement.

[The remainder of this Page left blank]

Schedule 1 — Initial Product Addendum

This Product Addendum (**Product Addendum**) to the Master Services and Supply Agreement dated [*insert date of Master Agreement*] between LifeScan, Inc., Universal Biosensors Pty Ltd and Universal Biosensors, Inc (**Master Agreement**) is entered into by and between LifeScan, Inc., a Californian corporation of 1000 Gibraltar Drive, Milpitas, CA 95035-6312, USA (**LifeScan**), Universal Biosensors Pty Ltd ACN 098 234 309, a company incorporated in Victoria, Australia of 1 Corporate Avenue, Rowville, Victoria 3178 Australia (**UBS**) and Universal Biosensors, Inc., a Delaware corporation of having its registered office at c/o Corporation Service Company 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808 USA (**UBI**).

The parties agree that this Product Addendum is to be attached to, and form part of the Master Agreement. In relation to the matters addressed in this Product Addendum, each of LifeScan and UBS agrees to be bound by all of the terms and conditions of the Master Agreement and makes the representations and warranties set forth in the Master Agreement expressed to be made by LifeScan or UBS, as the case may be. All capitalised terms used in this Product Addendum and not otherwise defined in this agreement shall have the meaning ascribed to such terms in the Master Agreement.

The parties further agree as follows:

1. Price
- (i) Base Year Standard Cost =*[REDACTED].

(ii) Maximum Transfer Price = *[REDACTED]
2. Specifications below

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

Initial Product Specification GEM 0078 FS as amended from time to time, in accordance with the provisions of clause 5.3 of the Agreement. As of the effective date of the Restated Agreement, the operative version of GEM 0078 is 1.9.

*[REDACTED]

Initial System Specification GEM 0135 as amended from time to time, in accordance with the provisions of clause 5.3 of the Agreement. As of the effective date of the Restated Agreement, the operative version of GEM 0135 is 1.9.

*[REDACTED 5 pages]

* 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.

Executed as an Addendum to the Agreement by the duly authorized representative of each Party as of the date first above written.

Executed by LifeScan, Inc.

)

Name

Title

Executed by Universal Biosensors Pty Ltd

)

Director

Name of Director (print)

Executed by Universal Biosensors, Inc.

)

Name

Title

Schedule 2 — Initial Services Addendum

For the purposes of regulatory approvals, LifeScan will be the legal manufacturer of the Initial System. UBS will facilitate the regulatory approvals of the Initial System by providing the following initial services to LifeScan. In addition, after approval of the Initial System, UBS will provide certain ongoing services in connection with the Initial System as set out below (the initial services and ongoing services for the Initial System shall be defined as the “Initial Services” for purposes of this addendum).

1. Design verification testing of the Initial System in accordance with all regulatory requirements necessary to market the Initial System in the*[REDACTED].
2. Complete a Design History File for the Initial Product in accordance with all regulatory requirements necessary to market the Initial System in*[REDACTED]. LifeScan will review the Design History File to satisfy themselves that it complies with LifeScan internal pre-launch prerequisites.
3. Assist in the preparation and completion of the Initial Meter Design History File in conjunction with Plexus and LifeScan for the benefit of LifeScan. It is anticipated that specific items to be included in the DHF will include Initial Meter Design Input, Design Output (3-D mechanical drawings, Gerber files, firmware, and component specifications), Design Verification on production units (or documented production equivalent), Design Validation on production units (or documented production equivalent), and Design Transfer Summary. Design verification to include documented test methods and sample rationale and Design Transfer Summary to include documented rationale of meter design translated to production specification.
4. Assist in the preparation and completion of the Initial Control Solution Design History File in conjunction with Bionostics and LifeScan for the benefit of LifeScan . It is anticipated that specific items to be included in the DHF will include Design Input, Design Output, Design Verification and Design Validation.
5. Work with LifeScan on a mutually agreed basis to provide documentation to assist LifeScan to prepare and perform clinical trials and regulatory submissions.
6. Work with LifeScan on a mutually agreed basis to provide documentation necessary to assist LifeScan to prepare product labelling for the Initial System.

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

7. Design and manage the procurement of the initial custom-designed process equipment.
8. Work together with LifeScan to assess data from the field and use the data to decide methods for adapting process and control methodology to improve product performance.
9. Manage the specification(s) and all engineering change processes to Initial Product production equipment at UBS’ facility.
10. Specify and control Initial Product component performance and requirements. Manage or assist in the qualification and approval of all changes to suppliers and materials for the Initial Product.
11. Support manufacturing to ensure all work instructions are appropriate.
12. Evaluate the appropriate scope of manufacturing the Initial Product and help manage any change in scope, i.e. outsource or bring in-house certain process steps.
13. Identify, validate and implement cost reductions and process improvement in manufacturing the Initial Product.
14. Work with LFS on a mutually agreed basis so that LFS may enter into supply agreements with suppliers of components comprising the Initial System.
15. Investigate causes of customer complaints with the Initial Product referred to UBS by LifeScan.
16. Work with LFS on a mutually agreed basis to implement design changes to the Initial Meter, Initial Control Solution, Initial System and Initial Product.
17. *[REDACTED]:

a) *[REDACTED]

b) *[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.

Executed as an Addendum to the Agreement by the duly authorized representative of each Party as of the date first above written.

Executed by LifeScan, Inc.

)
)

Name

Title

Executed by Universal Biosensors Pty Ltd

)
)

Company Secretary/Director

Name of Company Secretary/Director (print)

Director

Name of Director (print)

Executed by Universal Biosensors, Inc

)
)

Name

Title

Schedule 3 — LifeScan Relevant Patents

*[REDACTED 6 pages]

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

[E/O]

CRC: 43211

EDGAR 2

BOWW75220 710.03.62.00 0/3



W75220.SUB, DocName: EX-10.3, Doc: 4, Page: 62
Description: Exhibit 10.3

This Amended and Restated Master Services and Supply Agreement is Re-Executed as an agreement by the duly authorized representative of each Party as of the date first above written.

Executed by LifeScan, Inc.

))

Name _____

Title

Executed by Universal Biosensors Pty Ltd

))

Company Secretary/Director

Director

Name of Company Secretary/Director (print)

Name of Director (print)

Executed by Universal Biosensors, Inc

))

Name _____

Title

[Execution page for Amended and Restated Master Services and Supply Agreement]

Appendix A — Form of Product Addendum

Date

This Product Addendum (**Product Addendum**) to the Master Services and Supply Agreement dated [*insert date of Master Agreement*] October 2007 between LifeScan, Inc., Universal Biosensors Pty Ltd and Universal Biosensors, Inc. (**Master Agreement**) is entered into by and between LifeScan, Inc., a Californian corporation of 1000 Gibraltar Drive, Milpitas, CA 95035-6312, USA (**LifeScan**), Universal Biosensors Pty Ltd ACN 098 234 309, a company incorporated in Victoria, Australia of 103 Ricketts Road, Mount Waverley, Victoria 3149, Australia (**UBS**) and Universal Biosensors, Inc., a Delaware corporation of having its registered office at c/o Corporation Service Company 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808 USA (**UBI**).

The parties agree that this Product Addendum is to be attached to, and form part of the Master Agreement. In relation to the matters addressed in this Product Addendum, each of LifeScan, UBS and UBI agree to be bound by all of the terms and conditions of the Master Agreement and makes the representations and warranties set forth in the Master Agreement expressed to be made by LifeScan, UBS or UBI, as the case may be. All capitalised terms used in this Product Addendum and not otherwise defined in this agreement shall have the meaning ascribed to such terms in the Master Agreement.

The parties further agree as follows:

3. [Products]

[*insert Product description*]

4. [Price]

[*insert price and payment terms*]

5. [Specifications]

6. [Minimum Shelf Life]

7. [Product Materials]

8. Term of Product Addendum

1. This Product Addendum shall commence on [*insert date*] and shall continue for a period of [*insert duration*] from such date (**Term**).

Executed by LifeScan, Inc.

)

Name

Title

Executed by Universal Biosensors Pty Ltd

)

)

Company Secretary/Director

Director

Name of Company Secretary/Director (print)

Name of Director (print)

Executed by Universal Biosensors, Inc

)

)

Name

Title

Appendix B — Form of Services Addendum

Date

This Services Addendum (**Services Addendum**) to the Master Services and Supply Agreement dated *[insert date of Master Agreement]* October 2007 between LifeScan, Inc., Universal Biosensors Pty Ltd and Universal Biosensors, Inc. (**Master Agreement**) is entered into by and between LifeScan, Inc, a Californian corporation of 1000 Gibraltar Drive, Milpitas, CA 95035-6312, USA (**LifeScan**) and Universal Biosensors Pty Ltd ACN 098 234 309, a company incorporated in Victoria, Australia of 1 Corporate Avenue, Rowville, Victoria 3178, Australia (**UBS**) and Universal Biosensors, Inc., a Delaware corporation of having its registered office at c/o Corporation Service Company 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808 USA (**UBI**).

The parties agree that this Services Addendum is to be attached to, and form part of the Master Agreement. In relation to the matters addressed in this Services Addendum, each of LifeScan, UBS and UBI agree to be bound by all of the terms and conditions of the Master Agreement and makes the representations and warranties set forth in the Master Agreement expressed to be made by LifeScan, UBS or UBI, as the case may be. All capitalised terms used in this Product Addendum and not otherwise defined in this agreement shall have the meaning ascribed to such terms in the Master Agreement.

The parties further agree as follows:

1. Services

[insert description of Services]

2. Consideration

UBS acknowledges that it will be remunerated for the Services to be provided under this Services Addendum by means of the fees to which it will be entitled pursuant to **clause 11** of the Master Agreement.

3. Term of Services Addendum

This Services Addendum shall commence on *[insert date]* and shall continue for a period of *[insert duration]* from such date (**Term**).

Executed by LifeScan, Inc)

Name

Title

Executed by Universal Biosensors Pty Ltd

)
)

Company Secretary/Director

Director

Name of Company Secretary/Director (print)

Name of Director
(print)

Executed by Universal Biosensors, Inc

)
)

Name

Title

Appendix C — Initial Joint Steering Committee Members

Universal Biosensors Pty Ltd:

*[REDACTED]

LifeScan, Inc.

*[REDACTED]

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

Appendix D — Policy on the Employment of Young Persons

Child Labor Employment Practices: In connection with the performance of its obligations under this Agreement, UBS agrees to comply with the following LifeScan Corporate Policy relating to the Employment of Child Labor:

- (a) No person under the age of 16 shall be employed. No person between the ages of 16 and 18 shall be employed unless such employment is in compliance with the health, safety and morals provisions of the International Labor Organizations Convention 138 Concerning Minimum Age.
- (b) No young person (under age 18) shall be required to work more than 48 regular hours and 12 hours overtime per week nor more than six (6) days per week.
- (c) No young person (under age 18) shall be employed unless such employment is in compliance with all applicable laws and regulations concerning, age, hours, compensation, health and safety.

Appendix E — Quality Agreement

This Quality Agreement is made and entered into as of the effective date of the Master Services and Supply Agreement (“the Agreement”) by and among LifeScan, Inc. (LifeScan), Universal Biosensors Pty Ltd. (UBS) and Universal Biosensors, Inc. The terms of this Quality Agreement are expressly incorporated into, and are a part of, the Agreement.

Below are the primary site locations of LifeScan and UBS:

LifeScan, Inc.	LifeScan 1000 Gibraltar Drive Milpitas, CA 95035 USA
Universal Biosensors Pty Ltd	Universal Biosensors 1 Corporate Ave Rowville, VIC 3178 Australia

WITNESSETH:

WHEREAS, LifeScan desires to engage UBS to manufacture and supply Product and perform Services (as those terms are defined below as well as in the Agreement) on the terms and conditions set forth in the Agreement and as set forth below, and

WHEREAS, UBS desires to manufacture and supply Product and perform Services for LifeScan on the terms and conditions set forth in the Agreement and as set forth below:

NOW, THEREFORE, in consideration of the foregoing premises and of the mutual covenants of the Parties hereinafter set forth, the Parties hereto agree as follows:

1.0 Definitions.

Unless this Quality Agreement shall expressly provide to the contrary, the following terms herein, whether used in the singular or plural, shall have the respective meanings set forth below:

- 1.1. “Applicable Law” means all applicable ordinances, rules, regulations, laws, guidelines, guidance, requirements and court orders of any kind whatsoever of any Authority as amended from time to time.
- 1.2. “Authority” means any government regulatory authority responsible for granting approvals for the performance of Services under this Quality Agreement or for the Manufacturing, use, marketing, sale, pricing and/or other disposition of Product(s).
- 1.3. “Design History File (DHF)” means a compilation of records containing the development history of the Product(s).
- 1.4. “Device History Record (DHR)” means a compilation of records containing the production history of the Product(s).
- 1.5. “Device Master Record (DMR)” means a compilation of records containing the procedures and specifications for the Product(s)
- 1.6. “FDA” means the United States Food and Drug Administration, and any successor agency having substantially the same functions.
- 1.7. “FDCA” means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§321 et seq., as amended from time to time.
- 1.8. “ISO 13485” means the “ISO Quality Management Systems — Medical Devices — System Requirements for Regulatory Purposes” standard.
- 1.9. “Manufacture” and “Manufacturing” means all steps, processes and activities necessary to produce Product(s), including without limitation, the design, manufacturing, processing, quality control testing, release and storage of Product(s) in accordance with the terms and conditions hereof.
- 1.10. “Manufacturing Process” means any and all processes (or any step in any process) used or planned to be used by UBS to Manufacture Product(s).
- 1.11. “Parties” means UBS and LifeScan together, and “Party” means any of them, as the context requires.

- 1.12. “Product(s)” means the products, current and future, described in the Agreement to which this Quality Agreement is attached and into which this Quality Agreement is expressly incorporated by reference.
- 1.13. “Quality Audit” means a systematic independent examination of a manufacturer’s quality system to ensure it complies with applicable law.
- 1.14. “Quality Control Plan” means written descriptions of the systems for controlling the manufacturing of parts and/or manufacturing processes. It provides a written summary description of the system used in minimizing process and finished device variation.
- 1.15. “Quality Management System” means the regulatory requirements for the methods used in, and the facilities and controls used for, the design, manufacture, packing, labeling, storage, installation and servicing of finished devices, as codified in 21C.F.R. Part 820 or embodied in ISO 13485.
- 1.16. “Quality Plan” a written plan demonstrating how the requirements set forth in this agreement will be fulfilled
- 1.17. “Records” means written or electronic accounts, notes, data, record of, and information and results obtained from performance of Services and all work done under this Quality Agreement.
- 1.18. “Services” means the Manufacturing and other services and activities that UBS is engaged to provide to LifeScan under the Agreement.
- 1.19. “Specifications” means the written specifications established for the Manufacture of Product(s) approved by LifeScan, as amended or supplemented from time to time by agreement in writing between the Parties.
- 1.20. “Use As Is (UAI)” is associated with a nonconformance that does not impact form, fit, or function of the product. It implies that the nonconformance will not be remedied for that specific batch.

2.0. **Compliance with Laws Generally.**

- 2.1. Each Party shall comply in all material respects with all applicable statutes, regulations, rules, and ordinances that relate to the performance of such Party’s obligations under the Agreement and this Quality Agreement and, except as provided for herein, shall bear their own cost and expense of complying therewith.
- 2.2. The termination or expiration of this Quality Agreement shall not relieve either Party of its responsibility to comply in all material respects with any statutory or regulatory requirements associated with the Product(s).

3.0. **Compliance with Applicable Quality Management System Requirements.**

- 3.1. Generally. UBS shall develop and manufacture the Product(s) in accordance with the approved specifications set forth in the Agreement and in substantial compliance with relevant Quality Management System requirements including 21 CFR PART 820, ISO 13485 and any other applicable laws appropriate to the geography in which the product will be manufactured, whether or not specifically identified in this Quality Agreement. Where there are other regulatory requirements not specifically required by the Quality Management System requirements, LifeScan will expect compliance. Without limiting the generality of the foregoing:
- 3.1.1. Quality Management System Requirements. Each Party shall establish and maintain a quality system that is appropriate for the activities for which the Party is responsible under this Quality Agreement and that is in substantial compliance with Quality Management System requirements.
- 3.1.2. Quality Plan. UBS shall establish a Quality Plan being a controlled document defining Quality System Requirements set-forth in this agreement and the details of how UBS shall fulfill these requirements. This shall be accomplished in the form of references to the procedures, documents, or other controls in place to ensure the requirements are consistently met. LifeScan shall review this document as a part of their audit and inspection process (refer to section 10.)

- 3.1.3 Quality Control Plan. For the production lines, UBS shall establish quality control plans. These control plans shall be controlled documents located at the manufacturing facility. These plans shall ensure that there is a consistent, validated process used to manufacture the Products. It may contain specific requirements and reference to UBS procedures and methods to ensure these requirements are consistently met. It shall also define how UBS verifies these activities, detects deviations or non-conformances and reacts to those deviations or non-conformances.
- 3.2 Validation

3.2.1 Validation responsibilities, consisting of a Validation Master Plan, Validation protocols and their execution/testing, and completion reports, will be created by UBS and available for review by LifeScan. UBS shall provide copies of validation documents (for example, protocols, completion reports) to LifeScan upon request.

3.2.2 All process validations must be completed prior to the release of the product batches for commercial use. Equipment qualification/validation shall be completed prior to the process validations. Successful process validation batches may be considered as fit for release with LifeScan approval.

3.2.3 Post validation changes such as described in Section 7.0 shall be communicated to LifeScan, prior to their implementation.
- 3.3 Control of Nonconforming Product. UBS shall establish and maintain procedures to control product that does not conform to specified requirements. LifeScan is to be notified promptly in writing of any non-conformances that may potentially affect product safety, efficacy, quality or stability should product have been released from UBS. LifeScan must approve Use As Is (UAI) non-conformances and their associated investigation/justification/impact analysis.
- 3.4. Corrective and Preventive Actions. Both Parties shall establish and maintain procedures for implementing corrective and preventive actions. The Parties shall collaborate to determine the division of responsibility for implementation of quality solutions depending upon the nature of the quality problem and the proposed solution. Where necessary, LifeScan shall cooperate with UBS to determine the root cause of quality problems, identifying corrective actions, and assuring their implementation and effectiveness.

- 3.5 Statistical Techniques. UBS shall, where appropriate, establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of validations, process capability and product testing and other appropriate activities.
- 3.6 Finished Controls.

3.6.1 UBS may be qualified to release product after a certain number of batch records have been reviewed and approved by LifeScan. The number and form of the records to be reviewed prior to UBS being qualified to release product will be defined in the Quality Plan. The Quality Plan will also define the turnaround time that LifeScan shall meet in reviewing and approving/not approving the records.

3.6.2 The test methods deployed in qualifying product shall be validated. Retained samples of the Product(s) will be held by UBS. Expiry dating of Product(s) shall be determined from stability studies undertaken by UBS and agreed upon by LifeScan. UBS shall collect samples from each UBS released lot, which will be sent to LifeScan’s facility in Inverness Scotland for final release testing. These samples will be used for final blood release testing and retained for special event testing at LifeScan’s facility in Inverness Scotland. Each lot will have up to 200 vials collected and packaged per agreed upon method. These samples will be shipped along with the rest of the lot and identified using an agreed upon method. The sample size may be modified per mutual agreement. These samples will be provided at no cost to LifeScan and will be listed as a separate line item on the shipping documents.

3.6.3 UBS and its external contract manufacturers shall maintain manufacturing DHRs of the Product(s) produced under the Agreement. Copies of DHRs are to be available within 3 business days of a routine request by LifeScan and within 24 hours of an urgent request by LifeScan.
- 3.7 Labelling and Packaging. LifeScan shall be responsible for the development of Labelling and Packaging. UBS shall provide the necessary documentation required to support this development.
- 4.0. Complaint Handling and Adverse Event Reporting.

4.1. Each Party shall cooperate fully with the other party in dealing with customer and third-party complaints concerning the Product(s) and shall take such action to promptly resolve such complaints as may be reasonably requested by the other party.

-
- 4.2. UBS shall be responsible for investigating, in a timely manner, returned Product(s), if any, and providing LifeScan with reports detailing the investigation results.

4.3. UBS shall be responsible for allocating the proper resources to investigate post launch design and manufacturing issues that have resulted in interruptions of supply or customer complaints.

4.4. UBS shall be responsible for implementing appropriate effective corrective actions with respect to Product(s) in order to prevent/reduce customer complaints. Records of investigations and corrective actions shall be maintained in connection with related complaints or notable trends.

4.5. LifeScan shall be responsible for complying with all FDA and applicable foreign regulatory requirements pertaining to the reporting of malfunctions, near incidents and adverse events, including the Medical Device Reporting requirements, codified at 21 C.F.R Part 803, MEDDEV and CMDCAS. UBS shall reasonably cooperate with LifeScan to enable LifeScan to fulfill such requirements. Without limiting the generality of the foregoing, LifeScan shall:

4.5.1 Maintain a record of all customer and third-party complaints received by LifeScan relating to the Product(s).

4.5.2 Make determinations as to whether the complaint information about Product(s) is required to be reported to the FDA in a Medical Device Report or to foreign governments in accordance with applicable adverse event, malfunction or near incident reporting requirements.

4.5.3 Make all necessary correspondence with all applicable regulatory authorities with respect to complaints about the Product(s).

4.5.4 Maintain files in accordance with FDA and international adverse event reporting requirements.

4.6. Customer Service Scripts. Both parties shall provide input in order to develop appropriate customer service call scripts specific to the Product(s) in order to comply with reporting requirements.

4.7 LifeScan Complaint Management shall provide summaries of complaint statistics to UBS, and this information will be an input to Management Reviews as outlined in section 11.0.

5.0 Device Removals and Corrections.

- 5.1. Subject to compliance with applicable laws and regulations, either Party who becomes aware of any serious defect, problem or adverse condition in any Product(s) shall notify the other of such defect, problem or adverse condition as soon as is practical and within five (5) business days.
- 5.2. If it is determined that a field removal, correction or other action is appropriate, LifeScan shall initiate such correction or removal and shall track the Product(s) in accordance with applicable laws and regulation.
- 5.3. LifeScan shall make any necessary reports of removals, corrections and other actions to appropriate regulatory authorities. LifeScan and UBS shall maintain records for the activities each performs related to all removals, corrections and other actions conducted for Product(s) as required by law.

6.0. Product Clearances and Approvals.

- 6.1 LifeScan shall obtain and maintain all necessary regulatory approvals and clearances necessary for the manufacturing, marketing, sale and distribution of the Product(s). UBS shall be responsible for providing LifeScan the necessary information required for submission filing. LifeScan shall be responsible for filing and obtaining any required approvals and/or clearances related to Product modifications after initial regulatory approval/clearance.
- 6.2 UBS shall provide the required support activities to LifeScan in support of LifeScan obtaining all necessary regulatory clearances / approvals. This includes but is not limited to registering the UBS facility (ies) with regulatory authorities as required (e.g., US FDA Establishment Registration, Japan Foreign Manufacturer Authorization, etc.).
- 6.3 As part of this approval process, LifeScan shall perform the necessary clinical trails with UBS’s collaboration.
- 6.4 The parties shall determine who will construct and maintain DHFs for the Products and other components of the Initial System. LifeScan shall conduct a compliance audit of UBS constructed DHFs, identify gaps, and have these gaps mitigated prior to approval of product launch. LifeScan shall maintain current copies of all DHFs.

7.0 **Product Modifications.**

- 7.1. Either party may propose a product design or manufacturing modification.
- 7.2. UBS is not permitted to make any modification or manufacturing change that affects the Product(s) without LifeScan’s approval. Examples of such changes but not inclusive are:
 - Changes that may impact regulatory clearances and approvals, such as Intended Use
 - Product performance specifications
 - Design input requirements
 - Critical to Quality (CTQ) Process Parameters
 - Redesign of an existing Quality System

8.0. **Record Production and Retention.**

- 8.1. The Parties shall comply with any regulatory record keeping requirements that apply to the performance of such Party’s obligations under the Quality Agreement.
- 8.2. UBS shall create and maintain DHFs and DHRs that demonstrate that the Product(s) was designed and manufactured in accordance with Quality Management System requirements, the DMR, and meets the design specifications established by LifeScan. These records shall be retained in accordance with LifeScan’s record retention requirements.
- 8.3. Each party will be responsible for creating and maintaining their part of the DMR.
- 8.4. Records and other documents required to be maintained pursuant to this Quality Agreement shall be available at reasonable times for inspection, examination and copying by or on behalf of LifeScan, or for inspection by third parties, including FDA, for so long as any of them are in UBS’s possession.
- 8.5. Records and other documents pursuant to this Quality Agreement shall be maintained at UBS or other location that is reasonably accessible. Such records shall be stored to minimize deterioration and to prevent loss. Upon LifeScan’s request, UBS shall promptly provide LifeScan with copies of these Records and other documents maintained pursuant to this Quality Agreement.

- 8.6 Upon contract termination, UBS is required to continue to provide copies of DHRs within 3 days of a request by LifeScan or transfer ownership of the DHR to LifeScan, including the physical transfer of records to LifeScan.
- 8.7 Upon contract termination, UBS is required to transfer ownership of the product DHFs, including the physical transfer of records to LifeScan.
- 8.8 UBS shall not transfer, deliver or otherwise provide to any third parties original Records or other documents maintained pursuant to this Quality Agreement without prior written consent of LifeScan except as required by Applicable Law. If UBS is required by Applicable Law to provide to third parties copies of such Records or other documents, UBS shall notify LifeScan within five (5) business days of any such request.

9.0 **U.S. FDA Establishment Registration and Listing.**

- 9.1 LifeScan shall be responsible for listing the Product(s) with U.S. FDA in accordance with 21 C.F.R. Section 807.25.
- 9.2 If required by any international regulatory authority to support product Clearances and Approvals:

9.2.1 UBS shall be responsible for compliance with U.S. FDA’s applicable establishment registration requirements set forth in 21 C.F.R. Section 807.25.

9.2.2 UBS shall be responsible for listing the Product(s) with U.S. FDA in accordance with 21 C.F.R. Section 807.25.

10.0. **Regulatory Audits and Inspections.**

- 10.1 UBS shall provide LifeScan reasonable access upon prior notice to inspect, review and audit DHFs, the manufacturing facilities of UBS and its suppliers and contractors where the Product(s) is designed and developed, tested, handled, stored, distributed, and/or manufactured to determine if the Product(s) is tested, handled, stored, distributed and/or manufactured in accordance with Applicable Laws and any Quality Agreement.
- 10.2 UBS shall, within fifteen (15) business days of receipt of the written audit report, remedy any deficiencies which may be noted in any such audit or, if any such deficiencies cannot reasonably be remedied

within such fifteen (15) business day period, present to LifeScan a written plan to remedy such deficiencies as soon as possible.

- 10.3 LifeScan may conduct no more than one routine audits in any one three hundred sixty-five (365) day period. Notwithstanding the immediately preceding sentence, LifeScan shall have the right to conduct a compliance audit (a) in the event that LifeScan reasonably believes that any such inspection or audit is necessary or prudent with respect to ensuring the safety, efficacy and quality of the Product(s), or (b) subsequent to identifying any safety, efficacy and quality deficiency in connection with any audit(s) conducted.
- 10.4 All information of UBS (or its contractor’s) that LifeScan shall gain access to through such an audit shall be governed by the terms of the Agreement.
- 10.5 UBS shall promptly notify LifeScan when an Authority inspection of its facilities (or an inspection by third parties in accordance with FDA regulations or inspection by a Notified Body) pertaining to the Product(s) is expected and/or underway, and shall promptly provide LifeScan with copies of all regulatory correspondence, including without limitation Forms FDA 483 and Warning Letters and any related correspondence with FDA or any other regulatory authority or notified body.

11.0 **Management Quality Review.**

LifeScan and UBS shall conduct routine Quality Reviews. These reviews shall be prearranged and have an agenda to address: CAPAs, reportable incidents, complaints, critical manufacturing data, non-conformance reports, deviations, process trending, relevant changes to Products, Processes, Quality Management System, and/or personnel and facilities or similar topics.

[Remainder of this Page left Blank]

IN WITNESS WHEREOF, the Parties hereto have caused this Quality Agreement to be executed by their duly authorized representatives as of the date first above written.

LIFESCAN, INC.

By: _____
Name: _____
Title: _____

UNIVERSAL BIOSENSORS PTY. LTD.

By: _____
Name: _____
Title: _____

Appendix F — Financial Years

Circled dates indicate the designated end of Quarter.

2007 UNIVERSAL CALENDAR

M T W T F S S								M T W T F S S							
JAN	1	2	3	4	5	6	7	JUL	2	3	4	5	6	7	8
(4 Weeks)	8	9	10	11	12	13	14	(4 Weeks)	9	10	11	12	13	14	15
	15	16	17	18	19	20	21		16	17	18	19	20	21	22
	22	23	24	25	26	27	28		23	24	25	26	27	28	29
FEB	29	30	31					AUG	30	31					
(4 Weeks)				1	2	3	4	(4 Weeks)			1	2	3	4	5
	5	6	7	8	9	10	11		6	7	8	9	10	11	12
	12	13	14	15	16	17	18		13	14	15	16	17	18	19
	19	20	21	22	23	24	25		20	21	22	23	24	25	26
MAR	26	27	28					SEP	27	28	29	30	31		
(5 Weeks)				1	2	3	4	(5 Weeks)						1	2
	5	6	7	8	9	10	11		3	4	5	6	7	8	9
	12	13	14	15	16	17	18		10	11	12	13	14	15	16
	19	20	21	22	23	24	25		17	18	19	20	21	22	23
	26	27	28	29	30	31			24	25	26	27	28	29	30
							1								
APR	2	3	4	5	6	7	8	OCT	1	2	3	4	5	6	7
(4 Weeks)	9	10	11	12	13	14	15	(4 Weeks)	8	9	10	11	12	13	14
	16	17	18	19	20	21	22		15	16	17	18	19	20	21
	23	24	25	26	27	28	29		22	23	24	25	26	27	28

MAY														NOV															
30														29 30 31															
(4 Weeks)														(4 Weeks)															
1 2 3 4 5 6														1 2 3 4															
7 8 9 10 11 12 13														5 6 7 8 9 10 11															
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JUN														DEC															
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25 26 27 28 29 30														24 25 26 27 28 29 30															
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2008 UNIVERSAL CALENDAR

M T W T F S S														M T W T F S S															
31														30															
JAN														JUL															
(4 Weeks)														(4 Weeks)															
1 2 3 4 5 6														1 2 3 4 5 6															
7 8 9 10 11 12 13														7 8 9 10 11 12 13															
14 15 16 17 18 19 20														14 15 16 17 18 19 20															
21 22 23 24 25 26 27														21 22 23 24 25 26 27															
FEB														AUG															
28 29 30 31														28 29 30 31															
(4 Weeks)														(4 Weeks)															
1 2 3														1 2 3															
4 5 6 7 8 9 10														4 5 6 7 8 9 10															
11 12 13 14 15 16 17														11 12 13 14 15 16 17															

	18	19	20	21	22	23	24		18	19	20	21	22	23	24
MAR	25	26	27	28	29			SEP	25	26	27	28	29	30	31
(5 Weeks)						1	2	(5 Weeks)							
	3	4	5	6	7	8	9		1	2	3	4	5	6	7
	10	11	12	13	14	15	16		8	9	10	11	12	13	14
	17	18	19	20	21	22	23		15	16	17	18	19	20	21
	24	25	26	27	28	29	30		22	23	24	25	26	27	28
APR	31							OCT	29	30					
(4 Weeks)		1	2	3	4	5	6	(4 Weeks)			1	2	3	4	5
		7	8	9	10	11	12		6	7	8	9	10	11	12
		14	15	16	17	18	19		13	14	15	16	17	18	19
		21	22	23	24	25	26		20	21	22	23	24	25	26
MAY	28	29	30					NOV	27	28	29	30	31		
(4 Weeks)				1	2	3	4	(4 Weeks)					1	2	
	5	6	7	8	9	10	11		3	4	5	6	7	8	9
	12	13	14	15	16	17	18		10	11	12	13	14	15	16
	19	20	21	22	23	24	25		17	18	19	20	21	22	23
JUN	26	27	28	29	30	31		DEC	24	25	26	27	28	29	30
(5 Weeks)						1		(5 Weeks)							
	2	3	4	5	6	7	8		1	2	3	4	5	6	7
	9	10	11	12	13	14	15		8	9	10	11	12	13	14
	16	17	18	19	20	21	22		15	16	17	18	19	20	21
	23	24	25	26	27	28	29		22	23	24	25	26	27	28

2009 UNIVERSAL CALENDAR

M T W T F S S								M T W T F S S								
29 30 31								29 30								
JAN	1 2 3 4							JUL	1 2 3 4 5							
(4 Weeks)	5 6 7 8 9 10 11	(4 Weeks)							6 7 8 9 10 11 12							
	12 13 14 15 16 17 18								13 14 15 16 17 18 19							
	19 20 21 22 23 24 25								20 21 22 23 24 25 26							
FEB	26 27 28 29 30 31							AUG	27 28 29 30 31							
(4 Weeks)	1							(4 Weeks)	1 2							
	2 3 4 5 6 7 8								3 4 5 6 7 8 9							
	9 10 11 12 13 14 15								10 11 12 13 14 15 16							
	16 17 18 19 20 21 22								17 18 19 20 21 22 23							
MAR	23 24 25 26 27 28							SEP	24 25 26 27 28 29 30							
(5 Weeks)	1							(5 Weeks)	31							
	2 3 4 5 6 7 8								1 2 3 4 5 6							
	9 10 11 12 13 14 15								7 8 9 10 11 12 13							
	16 17 18 19 20 21 22								14 15 16 17 18 19 20							
	23 24 25 26 27 28 (29)								21 22 23 24 25 26 (27)							
30 31								28 29 30								
APR	1 2 3 4 5							OCT	1 2 3 4							
(4 Weeks)	6 7 8 9 10 11 12	(4 Weeks)							5 6 7 8 9 10 11							
	13 14 15 16 17 18 19								12 13 14 15 16 17 18							
	20 21 22 23 24 25 26								19 20 21 22 23 24 25							

MAR (5 Weeks) 12345678910111213141516171819202122232425262728293031 1234	SEP (5 Weeks) 3031123456789101112131415161718192021222324252627282930 123
APR (4 Weeks) 56789101112131415161718192021222324252627282930 12	OCT (4 Weeks) 45678910111213141516171819202122232425262728293031
MAY (4 Weeks) 3456789101112131415161718192021222324252627282930	NOV (4 Weeks) 12345678910111213141516171819202122232425262728
JUN (5 Weeks) 31123456789101112131415161718192021222324252627282930 1234	DEC (5 Weeks) 293012345678910111213141516171819202122232425262728293031 12

2011 UNIVERSAL CALENDAR

M T W T F S S								M T W T F S S							
JAN (4 Weeks)	3	4	5	6	7	8	9	JUL (4 Weeks)	4	5	6	7	8	9	10
	10	11	12	13	14	15	16		11	12	13	14	15	16	17
	17	18	19	20	21	22	23		18	19	20	21	22	23	24
	24	25	26	27	28	29	30		25	26	27	28	29	30	31
FEB (4 Weeks)	31							AUG (4 Weeks)	1	2	3	4	5	6	7
		1	2	3	4	5	6		8	9	10	11	12	13	14
	7	8	9	10	11	12	13		15	16	17	18	19	20	21
	14	15	16	17	18	19	20		22	23	24	25	26	27	28
	21	22	23	24	25	26	27								
MAR (5 Weeks)	28							SEP (5 Weeks)	29	30	31				
		1	2	3	4	5	6					1	2	3	4
	7	8	9	10	11	12	13		5	6	7	8	9	10	11
	14	15	16	17	18	19	20		12	13	14	15	16	17	18
	21	22	23	24	25	26	27		19	20	21	22	23	24	25
	28	29	30	31					26	27	28	29	30		
					1	2	3						1	2	
APR (4 Weeks)	4	5	6	7	8	9	10	OCT (4 Weeks)	3	4	5	6	7	8	9
	11	12	13	14	15	16	17		10	11	12	13	14	15	16
	18	19	20	21	22	23	24		17	18	19	20	21	22	23
	25	26	27	28	29	30			24	25	26	27	28	29	30
							1								

MAY	2	3	4	5	6	7	8	NOV	31						
(4 Weeks)	9	10	11	12	13	14	15	(4 Weeks)	1	2	3	4	5	6	
	16	17	18	19	20	21	22		7	8	9	10	11	12	13
	23	24	25	26	27	28	29		14	15	16	17	18	19	20
									21	22	23	24	25	26	27

JUN	30	31						DEC	28	29	30				
(5 Weeks)			1	2	3	4	5	(5 Weeks)			1	2	3	4	
	6	7	8	9	10	11	12		5	6	7	8	9	10	11
	13	14	15	16	17	18	19		12	13	14	15	16	17	18
	20	21	22	23	24	25	26		19	20	21	22	23	24	25
	27	28	29	30					26	27	28	29	30	31	
						1	2	3							1

2012 UNIVERSAL CALENDAR

	M	T	W	T	F	S	S		M	T	W	T	F	S	S		
		2	3	4	5	6	7	8									
JAN		9	10	11	12	13	14	15	JUL		9	10	11	12	13	14	15
(4 Weeks)		16	17	18	19	20	21	22	(4 Weeks)		16	17	18	19	20	21	22
		23	24	25	26	27	28	29			23	24	25	26	27	28	29
								</									

MAR272829 (5 Weeks) 1234 567891011 12131415161718 19202122232425 262728293031 1	SEP2728293031 (5 Weeks) 12 3456789 10111213141516 17181920212223 24252627282930
APR (4 Weeks) 2345678 9101112131415 16171819202122 23242526272829	OCT (4 Weeks) 1234567 891011121314 15161718192021 22232425262728
MAY30 (4 Weeks) 123456 78910111213 14151617181920 21222324252627	NOV293031 (4 Weeks) 1234 567891011 12131415161718 19202122232425
JUN28293031 (5 Weeks) 123 45678910 11121314151617 18192021222324 252627282930 1	DEC2627282930 (5 Weeks) 12 3456789 10111213141516 17181920212223 24252627282930

2013 UNIVERSAL CALENDAR

M T W T F S S							M T W T F S S						
31							1 2 3 4 5 6 7						
JAN		1	2	3	4	5 6	JUL	8	9	10	11	12	13 14
(4 Weeks)	7	8	9	10	11	12 13	(4 Weeks)	15	16	17	18	19	20 21
	14	15	16	17	18	19 20		22	23	24	25	26	27 28
	21	22	23	24	25	26 27							
FEB							AUG						
	28	29	30	31				29	30	31			
(4 Weeks)					1	2 3	(4 Weeks)			1	2	3 4	
	4	5	6	7	8	9 10		5	6	7	8	9	10 11
	11	12	13	14	15	16 17		12	13	14	15	16	17 18
	18	19	20	21	22	23 24		19	20	21	22	23	24 25
MAR							SEP						
	25	26	27	28				26	27	28	29	30	31
(5 Weeks)					1	2 3	(5 Weeks)						1
	4	5	6	7	8	9 10		2	3	4	5	6	7 8
	11	12	13	14	15	16 17		9	10	11	12	13	14 15
	18	19	20	21	22	23 24		16	17	18	19	20	21 22
	25	26	27	28	29	30 (31)		23	24	25	26	27	28 (29)
APR							OCT						
	1	2	3	4	5	6 7		30					
	8	9	10	11	12	13 14			1	2	3	4	5 6
(4 Weeks)	15	16	17	18	19	20 21	(4 Weeks)	7	8	9	10	11	12 13
	22	23	24	25	26	27 28		14	15	16	17	18	19 20
								21	22	23	24	25	26 27

[E/O]

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MAY	29	30									NOV	28	29	30	31						
(4 Weeks)			1	2	3	4	5				(4 Weeks)					1	2	3			
	6	7	8	9	10	11	12					4	5	6	7	8	9	10			
	13	14	15	16	17	18	19					11	12	13	14	15	16	17			
	20	21	22	23	24	25	26					18	19	20	21	22	23	24			
JUN	27	28	29	30	31						DEC	25	26	27	28	29	30				
(5 Weeks)						1	2				(5 Weeks)								1		
	3	4	5	6	7	8	9					2	3	4	5	6	7	8			
	10	11	12	13	14	15	16					9	10	11	12	13	14	15			
	17	18	19	20	21	22	23					16	17	18	19	20	21	22			
	24	25	26	27	28	29	30					23	24	25	26	27	28	29			

Appendix G – UBS’ Insurance Requirements

1.0 Insurance Requirements

UBS shall use reasonable commercial efforts to procure and maintain, at all times, and at its own expense, during the Term the types of insurance(s) specified below. For product liability/completed operations, insurance and product recall insurance, coverage (or appropriate run off insurance) will remain in effect for at least two (2) years after termination of the Agreement.

A. Public Liability

Public Liability Occurrence Coverage Form with limits of not less than *[REDACTED] each occurrence and *[REDACTED] annual aggregate. Such insurance shall include worldwide coverage including coverage for USA and Canada jurisdiction claims and occurrences. UBS’ policy shall specifically include LifeScan, its subsidiaries, and its directors, officers and employees, as Additional Insureds. UBS’ policy shall also specifically waive any rights of subrogation against LifeScan, its subsidiaries, and its directors, officers and employees. UBS shall supply LifeScan with the above proof of insurance and forms as required upon the signing of this Agreement, but LifeScan’s failure to demand such proof or forms shall not waive LifeScan’s rights to such coverage as specified herein.

B. Workers’ Compensation

Workers’ Compensation Form in accordance with local regulations.

C. All Risk Property Insurance/Industrial Special Risk Insurance

All Risk Property Insurance/ Industrial Special Risk Insurance in an amount not less than the full replacement cost of UBS’ property.

D. Product Liability Insurance

Product Liability/Completed Operations Insurance on an occurrence form basis with limits of not less than *[REDACTED] each occurrence and *[REDACTED] annual aggregate. Such insurance shall include worldwide coverage including coverage for USA and Canada jurisdiction claims and occurrences. UBS’ policy shall specifically include LifeScan, its subsidiaries, and its directors,

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

officers and employees, as Additional Insureds. Such Additional Insured coverage is only to the extent of the distribution or sale of Products manufactured by UBS or its agents. UBS’ policy shall also specifically waive any rights of subrogation against LifeScan, its subsidiaries, and its directors, officers and employees. UBS shall supply LifeScan with the above proof of insurance and forms as required upon the signing of this Agreement, but LifeScan’s failure to demand such proof or forms shall not waive LifeScan’s rights to such coverage as specified herein.

E. Product Recall Insurance

Product Recall Insurance an occurrence form basis with limits of not less than *[REDACTED] each occurrence and * [REDACTED] annual aggregate. Such insurance shall include worldwide coverage including coverage for USA and Canada jurisdiction claims and occurrences. UBS’ policy shall also specifically waive any rights of subrogation against LifeScan, its subsidiaries, and its directors, officers and employees. UBS shall supply LifeScan with the above proof of insurance and forms as required upon the signing of this Agreement, but LifeScan’s failure to demand such proof or forms shall not waive LifeScan’s rights to such coverage as specified herein.

2.0. Miscellaneous

A. Authorization to do Business; Rating Requirement

All insurance companies must be authorized to do business in the States where business is being transacted covering all operations under this Agreement. All insurance companies must be rated A or better with a financial rating of VII or better in the most recent *A. M. Best’s Rating Guide*.

B. Prior Notice of Cancellation or Nonrenewal

All insurance policies shall provide for thirty days (30) days’ prior written notice to LifeScan of cancellation or nonrenewal.

C. Certificates

Certificates of insurance for all required coverage shall be provided to LifeScan prior to commencement of any work on the project. Copies of the required endorsements to the policies shall also be provided to LifeScan at that time or when appropriate. Failure by LifeScan to request such copies or documents shall not waive LifeScan’s rights to coverage under this agreement.

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

Appendix H – Termination Matters

*[REDACTED]

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

Appendix I – Action Taken after Effective Date

LifeScan shall pay US\$1,000,000 to UBS in accordance with **clause 2** of the Agreement.

Appendix J – Standards for Responsible

External Manufacturing

Guiding Principles

The Johnson & Johnson Family of Companies (J&J) holds itself to high standards of ethical behavior, product quality and social responsibility. These standards reflect our internal values and the expectations of external stakeholders, such as customers, regulators, investors and the public. Furthermore, we find business relationships are more productive and effective when they are built on trust, mutual respect and common values. As such, J&J seeks relationships with external manufacturers of finished goods and active pharmaceutical ingredients (herein referred to as external manufacturing partners) who share a common commitment to:

- 1) Comply with applicable legal requirements,
- 2) Behave ethically and with integrity,
- 3) Integrate quality into business processes,
- 4) Treat people with dignity and respect,
- 5) Promote the safety, health and well-being of employees,
- 6) Operate in an environmentally responsible manner and,
- 7) Implement management systems to ensure ongoing performance and continual improvement.

We believe when these seven guiding principles are followed, business and communities realize economic, social and environmental benefits. We developed the standards set out below to assist us with selecting partners who operate in a manner consistent with these guiding principles and to assist our external manufacturing partners with understanding our expectations. We developed these standards mindful of the different legal and cultural environments in which our external manufacturing partners operate and internationally recognized expectations for business ethics, product quality, labor and employment, health and safety and the environment. J&J assesses conformance to these standards and, when necessary, works with its external manufacturing partners to identify agreed upon actions and schedules in order to achieve improvement. J&J considers progress in meeting these standards and ongoing performance in its sourcing decisions.

Standards

- 1.) *Legal Compliance*

J&J’s external manufacturing partners are expected to operate in compliance with all applicable legal requirements related to business conduct, product quality, labor and employment practices, health and safety and environmental protection. They are expected to obtain all applicable permits and to operate in accordance with permit limitations and requirements at all times.

2.) *Ethics & Business Conduct*

J&J’s external manufacturing partners are expected to behave ethically and with integrity in all business transactions. As such, they shall:

- Uphold standards for fair business practices including accurate and truthful advertising, fair competition, and antitrust.
- Prohibit the exchange of privileges, waiver of penalties or fines, or special benefits through payment of bribes, illegal political contributions, or other illicit payments or methods.
- Safeguard against improper use and disclosure of confidential or sensitive information including intellectual property, pricing, employee and patient information.
- Maintain an environment of transparency, collaboration and innovation.
- Treat any animals used in its activities in an ethical and humane manner and follow the principles of replacement, refinement, and reduction of laboratory research animal testing.

3.) *Product Quality*

J&J’s external manufacturing partners are expected to meet agreed upon quality requirements in order to provide goods and services that consistently meet required specifications and customers’ needs, perform as intended and are safe for their intended use. These requirements shall be defined in a Quality Agreement and product specifications agreed to by J&J and its external manufacturing partner.

4.) *Labor & Employment*

J&J’s external manufacturing partners are expected to treat people with dignity and respect. As such, they shall:

- Not use forced, bonded, indentured or involuntary prison labor.
- Not discriminate against or harass an individual on the basis of race, color, religion, gender, pregnancy, HIV status, sexual orientation, national origin, age, disability, veteran’s status, marital status, or political affiliation.

- Not treat or threaten to treat an individual harshly or inhumanely. Harsh or inhumane treatment includes sexual harassment or abuse, corporal punishment, coercion or verbal abuse.
- Avoid unsafe working conditions by providing sufficient rest periods during the workday and honor agreed upon days off from work and maximum working hours.
- Pay wages for all hours worked and clearly communicate the wages that employees are to be paid to them in advance of commencing work. Communicate to all employees if overtime is required and the wages to be paid for such overtime.
- Comply with J&J’s Employment of Young Persons Policy and not employ anyone under the age of 16 and not employ anyone under the age of 18 to perform hazardous work.
- Respect workers’ rights to make informed decisions free of coercion, threat of reprisal or unlawful interference regarding their desire to join or not join organizations.
- Respect worker’s rights to bargain collectively without unlawful interference.

5.) *Employee Health & Safety*

J&J’s external manufacturing partners are expected to maintain the workplace and any living quarters used to house employees in a clean, orderly and safe manner. As such they shall:

- Implement programs to prevent employee exposures to workplace hazards including chemical, biological, and physical hazards.
- Implement programs to manage processes safely and prevent catastrophic events.
- Identify potential emergency situations, implement preventative measures and be prepared to execute emergency response procedures.

6.) *Environmental Protection*

J&J’s external manufacturing partners are expected to operate in an environmentally responsible manner. As such, they shall:

- Work to reduce the environmental impacts of their operations including natural resource consumption, materials sourcing, waste generation, wastewater discharges and air emissions.
- Prevent accidental releases of hazardous materials into the environment and adverse environmental impacts on the local community.
- Implement programs to ensure products do not contain restricted or banned materials.

7.) Management Systems

J&J’s external manufacturing partners are expected to manage their activities systematically in order to meet the standards set forth in this document and to improve their operations continually. As such, they shall:

- Demonstrate top management commitment through policies, objectives, and formal processes for management review.
- Implement processes to control documents and records.
- Provide resources, including competent personnel and appropriate infrastructure, to ensure conformance to these standards.
- Implement processes to control the production of J&J products, manage change effectively and ensure customer requirements are satisfied.
- Implement processes to manage nonconformity and emergency situations related to products, processes and these standards, including the reporting of such events to applicable regulatory authorities and J&J as appropriate.
- Identify and implement improvement actions, including effective complaint investigation, internal audit and corrective action processes.

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Exhibit 10.4

Manufacturing Initiation Payment Addendum to Master Services and Supply Agreement

This Addendum dated 14 May 2009 is entered into by and between LifeScan, Inc., a Californian corporation of 1000 Gibraltar Drive, Milpitas, CA 95035-6312, USA (**LifeScan**), Universal Biosensors Pty Ltd ACN 098 234 309, a company incorporated in Victoria, Australia of 1 Corporate Avenue, Rowville, Victoria 3178, Australia (**UBS**) and Universal Biosensors, Inc., a Delaware corporation of having its registered office at c/o Corporation Service Company 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808 USA (**UBI**).

The parties agree that this Addendum is to be attached to, and form part of the Master Services and Supply Agreement between LifeScan, UBS and UBI dated 29 October 2007 (the **Master Agreement**). In relation to the matters addressed in this Addendum, each of LifeScan, UBS and UBI agree to be bound by all of the terms and conditions of the Master Agreement, and each party makes the representations and warranties set forth in the Master Agreement expressed to be made by LifeScan, UBS or UBI, as the case may be.

All capitalized terms used in this Addendum and not otherwise defined herein shall have the meaning ascribed to such terms in the Master Agreement (including all Service Addendums and Product Addendums).

LifeScan and UBS agree that during calendar year 2010, LifeScan will pay UBS *[REDACTED].

LifeScan and UBS agree that during calendar year 2011, *[REDACTED].

The amounts actually paid by LifeScan pursuant to the previous two paragraphs are referred to as the “Manufacturing Initiation Payment”.

*[REDACTED].

Executed as an agreement by the duly authorized representative of each Party as of the date first written above.

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

Executed by LifeScan, Inc.

)

)

Name: Dean Dalson

Executed by Universal Biosensors
Pty Ltd

)

)

Title: Vice President

Company Secretary/Director

Director

Name of Company Secretary/Director
(print)

Name of Director (print)

Executed by Universal Biosensors,
Inc.

)

)

Name

Title

[Execution Page for the Manufacturing Initiation Payment Addendum]

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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, Mark Morrisson, Chief Executive Officer and Executive Director of Universal Biosensors, Inc. (“registrant”), 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: August 7, 2009

/s/ Mark Morrisson
Mark Morrisson
Chief Executive Officer and Executive Director
Universal Biosensors, Inc.

<DOCUMENT>

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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, Saleshe Balak, Chief Financial Officer of Universal Biosensors, Inc. (“registrant”), certify that:

- I have reviewed this report on Form 10-Q of Universal Biosensors, Inc.;
- 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;
- 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;
- 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:
 - 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;
 - 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;
 - 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
 - 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
- 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):
 - 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
 - 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: August 7, 2009

/s/ Saleshe Balak
Saleshe Balak
Chief Financial Officer
Universal Biosensors, Inc.

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Exhibit 32.0

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 report of Universal Biosensors, Inc. (the “Company”) on Form 10-Q for the quarterly period ended June 30, 2009, 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 7th day of August 2009.

/s/ Mark Morrisson

Mark Morrisson

Chief Executive Officer and Executive Director

/s/ Salesh Balak

Salesh Balak

Chief 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.