



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

**FORM 10-Q**

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

For the quarterly period ended September 30, 2019

Commission File Number: 000-52607

**Universal Biosensors, Inc.**

(Exact name of registrant as specified in its charter)

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

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

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

**Not Applicable**  
(Zip Code)

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

**Securities registered pursuant to Section 12(b) of the Act:**

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
<b>Common Stock</b>	<b>UBIAX</b>	<b>The Australian Securities Exchange</b>

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 every Interactive Data File required to be submitted 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 such files). Yes  No

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

- |                         |                                     |                           |                                     |
|-------------------------|-------------------------------------|---------------------------|-------------------------------------|
| Large Accelerated Filer | <input type="checkbox"/>            | Accelerated Filer         | <input type="checkbox"/>            |
| Non-Accelerated Filer   | <input type="checkbox"/>            | Smaller reporting company | <input checked="" type="checkbox"/> |
| Emerging growth company | <input checked="" type="checkbox"/> |                           |                                     |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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: 177,546,854 shares of Common Stock, U.S.\$0.0001 par value, outstanding as of November 4, 2019.



## UNIVERSAL BIOSENSORS, INC.

## TABLE OF CONTENTS

	Page
<b>PART I FINANCIAL INFORMATION</b>	
Item 1 <a href="#"><u>Financial Statements</u></a>	
1) <a href="#"><u>Consolidated condensed balance sheets at September 30, 2019 and December 31, 2018 (unaudited)</u></a>	1
2) <a href="#"><u>Consolidated condensed statements of comprehensive income/(loss) for the three and nine months ended September 30, 2019 and 2018 (unaudited)</u></a>	2
3) <a href="#"><u>Consolidated condensed statements of changes in stockholder’s equity and comprehensive income/(loss) for the period ended September 30, 2019 and 2018 (unaudited)</u></a>	3
4) <a href="#"><u>Consolidated condensed statements of cash flows for the nine months ended September 30, 2019 and 2018 (unaudited)</u></a>	4
5) <a href="#"><u>Notes to consolidated condensed financial statements (unaudited)</u></a>	5
Item 2 <a href="#"><u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u></a>	24
Item 3 <a href="#"><u>Quantitative and Qualitative Disclosures About Market Risk</u></a>	36
Item 4 <a href="#"><u>Controls and Procedures</u></a>	37
<b>PART II OTHER INFORMATION</b>	
Item 1 <a href="#"><u>Legal Proceedings</u></a>	38
Item 1A <a href="#"><u>Risk Factors</u></a>	38
Item 2 <a href="#"><u>Unregistered Sales of Equity Securities and Use of Proceeds</u></a>	38
Item 3 <a href="#"><u>Defaults Upon Senior Securities</u></a>	38
Item 4 <a href="#"><u>Mine Safety Disclosures</u></a>	38
Item 5 <a href="#"><u>Other Information</u></a>	38
Item 6 <a href="#"><u>Exhibits</u></a>	38
Exhibit 10.23	
Exhibit 31.1	
Exhibit 31.2	
Exhibit 32	
Exhibit 101	
<a href="#"><u>SIGNATURES</u></a>	39

Unless otherwise noted, references on this Form 10-Q to “Universal Biosensors”, the “Company,” “Group,” “we,” “our” or “us” means Universal Biosensors, Inc. (“UBI”) a Delaware corporation and, when applicable, its wholly owned Australian operating subsidiary, Universal Biosensors Pty Ltd (“UBS”) and UBS’ wholly owned Canadian operating subsidiary, Hemostasis Reference Laboratory Inc. (“HRL”). Unless otherwise noted, all references in this Form 10-Q to “\$”, “A\$” or “dollars” and dollar amounts are references to Australian dollars. References to “US\$” are references to United States dollars. References to “CAD\$” are references to Canadian dollars.



**Universal Biosensors, Inc.**

**Item 1 Financial Statements**

**Consolidated Condensed Balance Sheets (Unaudited)**

	September 30, 2019	December 31, 2018
	AS	AS
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	34,485,732	11,797,789
Inventories, net	1,257,720	744,466
Accounts receivable	964,963	50,209,561
Prepayments	343,135	158,492
Restricted cash	16,790	15,589
Other current assets	2,218,020	1,105,291
<b>Total current assets</b>	<b>39,286,360</b>	<b>64,031,188</b>
Non-current assets:		
Property, plant and equipment	28,955,024	29,101,932
Less accumulated depreciation	(24,077,301)	(23,475,544)
Property, plant and equipment - net	4,877,723	5,626,388
Intangible assets	16,371,996	0
Less amortization of intangible assets	(32,896)	0
Property, plant and equipment - net	16,339,100	0
Restricted cash	320,000	320,000
<b>Total non-current assets</b>	<b>21,536,823</b>	<b>5,946,388</b>
<b>Total assets</b>	<b>60,823,183</b>	<b>69,977,576</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	302,664	695,405
Income taxes payable	0	4,352,564
Accrued expenses	1,515,857	1,696,644
Contingent consideration	2,222,551	0
Other liabilities	3,035,416	2,902,525
Deferred revenue	0	2,356,583
Employee entitlements liabilities	833,221	1,196,899
<b>Total current liabilities</b>	<b>7,909,709</b>	<b>13,200,620</b>
Non-current liabilities:		
Asset retirement obligations	2,600,000	2,600,000
Employee entitlements liabilities	28,597	39,468
Deferred income tax liability	4,358,338	0
Deferred revenue	0	3,463,737
<b>Total non-current liabilities</b>	<b>6,986,935</b>	<b>6,103,205</b>
<b>Total liabilities</b>	<b>14,896,644</b>	<b>19,303,825</b>
Commitments and contingencies	0	0
Stockholders' equity:		
Preferred stock, US\$0.01 par value. Authorized 1,000,000 shares; issued and outstanding nil at September 30, 2019 (nil at December 31, 2018)		
Common stock, US\$0.0001 par value. Authorized 300,000,000 shares; issued and outstanding 177,546,854 shares at September 30, 2019 (177,243,520 at December 31, 2018)	17,755	17,724
Additional paid-in capital	93,396,120	93,815,185
Accumulated deficit	(42,832,987)	(80,397,343)
Current year income/(loss)	(4,306,752)	37,564,356
Accumulated other comprehensive loss	(347,597)	(326,171)
<b>Total stockholders' equity</b>	<b>45,926,539</b>	<b>50,673,751</b>
<b>Total liabilities and stockholders' equity</b>	<b>60,823,183</b>	<b>69,977,576</b>

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.



## Universal Biosensors, Inc.

## Consolidated Condensed Statements of Comprehensive Income/(Loss) (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	AS	AS	AS	AS
<b>Revenue</b>				
Revenue from products	1,311,924	227,649	3,606,286	1,131,319
Revenue from services	101,233	47,007,376	1,784,228	59,593,955
Total revenue	1,413,157	47,235,025	5,390,514	60,725,274
<b>Operating costs &amp; expenses</b>				
Cost of goods sold	726,530	186,515	1,996,189	1,055,534
Cost of services	96,157	217,313	545,937	644,508
Total cost of goods sold & services	822,687	403,828	2,542,126	1,700,042
<b>Contribution from products &amp; services</b>	590,470	46,831,197	2,848,388	59,025,232
<b>Other operating costs &amp; expenses</b>				
Product support	12,574	8,750	41,956	202,899
Depreciation and amortization expenses	182,284	451,481	605,513	1,519,375
Research and development	1,175,165	2,759,664	4,312,185	9,452,609
General and administrative	1,599,851	1,360,040	5,810,226	5,110,134
Total operating costs & expenses	2,969,874	4,579,935	10,769,880	16,285,017
Profit/(loss) from operations	(2,379,404)	42,251,262	(7,921,492)	42,740,215
<b>Other income/(expense)</b>				
Interest income	223,054	175,643	695,208	365,542
Financing costs	0	(734,946)	0	(2,118,069)
Research and development tax incentive income	437,516	0	1,764,463	0
Exchange gain	874,253	183,395	1,124,075	412,768
Other	38,016	(9,758)	30,994	(8,498)
Total other income/(expense)	1,572,839	(385,666)	3,614,740	(1,348,257)
Net income/(loss) before tax	(806,565)	41,865,596	(4,306,752)	41,391,958
Income tax benefit/(expense)	0	0	0	0
Net income/(loss)	(806,565)	41,865,596	(4,306,752)	41,391,958
<b>Earnings per share</b>				
Basic net income/(loss) per share	(0.00)	0.24	(0.02)	0.23
Average weighted number of shares—basic	177,546,854	176,859,637	177,455,083	176,620,235
Diluted net income/(loss) per share	(0.00)	0.24	(0.02)	0.23
Average weighted number of shares—diluted	177,546,854	177,329,518	177,455,083	177,096,693
<b>Other comprehensive gain/(loss), net of tax:</b>				
Foreign currency translation reserve	(6,774)	(31,291)	(21,426)	(36,525)
Reclassification for gain/(loss) realized in net income/(loss)	0	0	0	0
Other comprehensive loss	(6,774)	(31,291)	(21,426)	(36,525)
Comprehensive gain/(loss)	(813,339)	41,834,305	(4,328,178)	41,355,433

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.



## Universal Biosensors, Inc.

## Consolidated Condensed Statements of Changes in Stockholders' Equity and Comprehensive Income/(Loss) (Unaudited)

	Ordinary shares		Additional Paid- in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income/(Loss)	Total Stockholders' Equity
	Shares	Amount				
	AS	AS	AS	AS	AS	AS
<b>Balances at January 1, 2019</b>	177,243,520	17,724	93,815,185	(42,832,987)	(326,171)	50,673,751
Net income/(loss)	0	0	0	(4,306,752)	0	(4,306,752)
Exercise of stock options issued to employees	303,334	31	3,369	0	0	3,400
Other comprehensive loss	0	0	0	0	(21,426)	(21,426)
Stock option expense/(credit)	0	0	(422,434)	0	0	(422,434)
<b>Balances at September 30, 2019</b>	177,546,854	17,755	93,396,120	(47,139,739)	(347,597)	45,926,539
<b>Balances at July 1, 2019</b>	177,546,854	17,755	93,377,674	(46,333,174)	(340,823)	46,721,432
Net income/(loss)	0	0	0	(806,565)	0	(806,565)
Other comprehensive income	0	0	0	0	(6,774)	(6,774)
Stock option expense/(credit)	0	0	18,446	0	0	18,446
<b>Balances at September 30, 2019</b>	177,546,854	17,755	93,396,120	(47,139,739)	(347,597)	45,926,539
<b>Balances at January 1, 2018</b>	176,498,550	17,650	93,450,721	(80,397,343)	(301,709)	12,769,319
Net income/(loss)	0	0	0	41,391,958	0	41,391,958
Exercise of stock options issued to employees	503,334	50	(50)	0	0	0
Other comprehensive loss	0	0	0	0	(36,525)	(36,525)
Stock option expense/(credit)	0	0	228,224	0	0	228,224
<b>Balances at September 30, 2018</b>	177,001,884	17,700	93,678,895	(39,005,385)	(338,234)	54,352,976
<b>Balances at July 1, 2018</b>	176,498,550	17,650	93,627,763	(80,870,981)	(306,943)	12,467,489
Net income/(loss)	0	0	0	41,865,596	0	41,865,596
Exercise of stock options issued to employees	503,334	50	(50)	0	0	0
Other comprehensive loss	0	0	0	0	(31,291)	(31,291)
Stock option expense/(credit)	0	0	51,182	0	0	51,182
<b>Balances at September 30, 2018</b>	177,001,884	17,700	93,678,895	(39,005,385)	(338,234)	54,352,976

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.



## Universal Biosensors, Inc.

## Consolidated Condensed Statements of Cash Flows (Unaudited)

	Nine Months Ended September 30,	
	2019	2018
	AS	AS
<b>Cash flows from operating activities:</b>		
Net income/(loss)	(4,306,752)	41,391,958
Adjustments to reconcile net income/(loss) to net cash provided by operating activities:		
Depreciation and amortization expenses	871,342	1,680,323
Share based payments expense	(422,434)	228,224
Gain on fixed assets disposal	9,386	8,498
Unrealized foreign exchange gains	(2,825,545)	(442,639)
Financing costs—amortization of warrants	0	104,096
Change in assets and liabilities:		
Inventory	(144,414)	180,850
Accounts receivables	49,244,598	(505,149)
Prepayment and other assets	(1,297,373)	(42,249,234)
Income tax payable	(4,352,564)	0
Deferred revenue	(5,820,320)	0
Employee entitlements	(374,550)	(321,814)
Accounts payable and accrued expenses	(461,530)	789,318
Net cash provided by operating activities	30,119,844	864,431
<b>Cash flows from investing activities:</b>		
Proceeds from sale of property, plant and equipment	16,496	2,582
Purchases of property, plant and equipment	(94,769)	(308,669)
Acquisition of assets	(10,169,456)	0
Net cash used in investing activities	(10,247,729)	(306,087)
<b>Cash flows from financing activities:</b>		
Borrowing costs	0	(256,410)
Proceeds from stock options exercised	3,400	0
Net cash provided by/(used in) financing activities	3,400	(256,410)
Net increase in cash, cash equivalents and restricted cash	19,875,515	301,934
Cash, cash equivalents and restricted cash at beginning of period	12,133,378	29,495,227
Effect of exchange rate fluctuations on the balances of cash held in foreign currencies	2,813,629	1,970,220
<b>Cash, cash equivalents and restricted cash at end of period</b>	<b>34,822,522</b>	<b>31,767,381</b>

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.



**Universal Biosensors, Inc.**

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

**Organization of the Company**

We are a specialist medical diagnostics company focused primarily on the research, development and manufacture of in vitro diagnostic test devices for consumer and professional point-of-care use. In addition, we own, manage and operate a hemostasis laboratory.

Key aspects of our strategy for increasing shareholder value include:

- executing on our business activities, including undertaking research and development activities, manufacturing products and providing development and support services including providing laboratory services;
- extending and demonstrating the broader application of our technology and seeking to enter into collaborative, strategic or distribution arrangements with other life sciences companies or other industry participants with respect to specific tests or specific fields;
- participating in healthcare markets across the globe; and
- identifying and pursuing related opportunities for growth.

Our plan of operations over the remainder of the fiscal year ending December 2019 is to:

- seek to enter into collaborative, strategic or distribution arrangements with other life sciences companies or other industry participants with respect to the development and commercialization of specific tests or specific fields;
- manufacture products;
- undertake research and development work;
- provide the necessary post-market support for our customers and partners;
- provide laboratory services for our customers and partners;
- demonstrate the broader application of our technology platform for markets with significant commercial potential; and
- identify, investigate and evaluate inorganic growth opportunities within the overall strategic initiatives.

We have rights to an extensive patent portfolio, with certain patents owned by UBS and a number licensed to UBS by LifeScan and other third-party licensors. The Company's first global strategic partnership was established with LifeScan with respect to diabetes care. The Company developed a blood glucose product with LifeScan ("OneTouch Verio®"). During 2018, LifeScan gave notice and exercised its right to "convert" its obligation to pay quarterly service fees to UBS (the "LifeScan Conversion"). Accordingly, we have not received any further quarterly service fees beyond 2018 and we do not expect to receive any further revenues from LifeScan unless we enter into a new agreement with LifeScan in the future. In October 2018, Platinum Equity acquired LifeScan, Inc. from Johnson & Johnson. Unless otherwise noted, references to "LifeScan" in this document are references collectively or individually to LifeScan, Inc., and/or LifeScan Europe, a division of Cilag GmbH International.

We have, worked with Siemens Healthcare Diagnostics, Inc. ("Siemens") since 2012 in relation to a range of products for the point-of-care coagulation testing market, pursuant to a collaboration agreement with Siemens (the "Collaboration Agreement"). The first such product developed with Siemens, the Xprecia Stride™ Coagulation Analyzer, received CE mark approval on December 9, 2014 and US Food and Drug Administration ("FDA") approval on October 4, 2016. The Xprecia Stride™ Coagulation Analyzer is now available in the United States, Europe, the Middle East, Africa, Asia Pacific, Latin America and Canada. Under the terms of a supply agreement with Siemens (the "Supply Agreement"), UBS is the manufacturer of test strips for this product for Siemens. The Collaboration Agreement was terminated on September 18, 2019. On September 9, 2019, we entered into certain binding term sheets with Siemens (the "Siemens Term Sheets") and on September 18, 2019, we entered into a commercial and distribution agreement with Siemens (the "Siemens Distribution Agreement") and a supply agreement with Siemens (the "Siemens Supply Agreement" and together with the Siemens Term Sheets and the Siemens Distribution Agreement the "2019 Siemens Agreements"). Pursuant to the 2019 Siemens Agreements the Company agreed to acquire certain assets of Siemens (the "Siemens Acquisition"). Pursuant to the terms of the 2019 Siemens Agreements, among other things:

- Siemens has committed to order a certain minimum amount of Xprecia Stride™ strips from UBI over the subsequent 42 months, subject to certain conditions; and
- The Company has the right to pursue partnership and distribution opportunities for point-of-care coagulation products outside of our arrangement with Siemens, which we believe will allow us to access new global markets and market segments, including the hospital point-of-care segment that was previously exclusive to Siemens under the Siemens Collaboration Agreement.



**Universal Biosensors, Inc.**

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

The Company intends to undertake an open market (or “on-market”) buyback of up to 10% of its outstanding equity securities over the 12 months following October 14, 2019 (the “Buyback”). Any securities purchased pursuant to the Buyback would be purchased at the Company’s sole discretion and funded from existing cash reserves. The Company would only buy back securities at such times and in such circumstances as the Company considers beneficial to the efficient capital management of the Company. The Buyback and the terms thereof are dependent upon market conditions, volumes and other relevant factors and there is no assurance that the Company will undertake the Buyback or purchase any of its outstanding equity securities pursuant to the Buyback.

**Interim Financial Statements**

The accompanying unaudited consolidated condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”) and with the instructions to Form 10-Q and Article 10 of Regulation S-X for interim financial information. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the nine months ended September 30, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019. The accompanying unaudited consolidated condensed financial statements should be read in conjunction with the financial statements and footnotes thereto as of and for the year ended December 31, 2018, included in the Annual Report on Form 10-K of Universal Biosensors, Inc. filed with the U.S. Securities and Exchange Commission (the “SEC”) on February 22, 2019 (the “Annual Report”).

The year-end consolidated condensed balance sheets data as at December 31, 2018 was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP.

**Basis of Presentation**

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

**Summary of Significant Accounting Policies**

*Principles of Consolidation*

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

*Use of Estimates*

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





**Universal Biosensors, Inc.**

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

***Cash, Cash Equivalents and Restricted Cash***

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. The Company maintains cash and restricted cash, which includes tenant security deposits and credit card security deposits. As of September 30, 2019, the Company has not realized any losses in such cash accounts and believes it is not exposed to any significant risk of loss.

***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 their fair value.

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

Cash and cash equivalents and accounts receivable consist of financial instruments that potentially subject the Company to concentration of credit risk to the extent of the amount recorded on the consolidated condensed balance sheets. The Company's cash and cash equivalents are primarily invested with one of Australia's 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 consolidated condensed balance sheets. The Company has not experienced any losses on its deposits of cash and cash equivalents. The Company has not identified any collectability issues with respect to receivables.

***Derivative Instruments and Hedging Activities***

*Derivative financial instruments*

The Company may use derivative financial instruments to hedge its foreign exchange exposure 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 unrealized gain or loss on the derivative financial instrument is recognized directly in equity. When the forecast transaction subsequently results in the recognition of a non-financial asset or non-financial liability, the associated cumulative gain or loss is removed from equity and included in the initial cost or other carrying amount of the non-financial asset or liability.



**Universal Biosensors, Inc.**

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

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

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

*Derivative Instruments and Hedging Activities*

In determining fair value, we utilize valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as consider our own and counterparty credit risk. For periods ended September 30, 2019 and December 31, 2018, we did not have any assets or liabilities that utilize Level 3 inputs. The valuation of our foreign exchange derivatives are based on the market approach using observable market inputs, such as forward rates and incorporate non-performance risk (the credit standing of the counterparty when the derivative is in a net asset position, and the credit standing of the Company when the derivative is in a net liability position). Our derivative assets are categorized as Level 2. The fair value methodologies described as Level 2 and 3 inputs are defined elsewhere in these notes to the consolidated condensed financial statements.

*Fair Value of Financial Instruments*

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

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

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

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

***Inventory***

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



**Universal Biosensors, Inc.**

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

	<b>Nine Months Ended September 30,</b>	<b>Year Ended December 31,</b>
	<b>2019</b>	<b>2018</b>
	<b>\$</b>	<b>\$</b>
Raw materials	246,656	302,056
Work in progress	597,477	442,410
Finished goods	413,587	0
	1,257,720	744,466

**Receivables**

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

	<b>Nine Months Ended September 30,</b>	<b>Year Ended December 31,</b>
	<b>2019</b>	<b>2018</b>
	<b>\$</b>	<b>\$</b>
Accounts receivable	964,963	50,209,561
Allowance for doubtful debts	0	0
	964,963	50,209,561

**Property, Plant, and Equipment—net**

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, include normal services, and do not include items of a capital nature.

The Company receives Commonwealth of Australia grant monies under grant agreements to support its development activities (refer section on “Government grants”), including in connection with the purchase of plant and equipment. Plant and equipment is presented net of the government grant. The grant monies are recognized against the acquisition costs of the related plant and equipment as and when the related assets are purchased.

**Impairment of Long-Lived Assets**

The Company reviews its capital assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. In performing the review, the Company estimates undiscounted cash flows from products under development that are covered by these patents and licenses. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than the carrying amount of the asset. If the evaluation indicates that the carrying value of an asset is not recoverable from its undiscounted cash flows, an impairment loss is measured by comparing the carrying value of the asset to its fair value, based on discounted cash flows. Impairment of long-lived-assets as at September 30, 2019 was \$2,574,709 (December 31, 2018: \$2,574,709).



**Universal Biosensors, Inc.**

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

**Government grants**

UBS was awarded a grant from the Commonwealth of Australia under the Next Generation Manufacturing Investment Programme up to a maximum grant amount of A\$575,000 payable over a three-year period commencing from January 1, 2017. The grants are paid upon achievement of pre-agreed milestones. The milestones generally relate to UBS placing purchase orders, commissioning upgrades and validating the equipment. Amongst other reasons, the Commonwealth of Australia may terminate the grant agreement for breach of the agreement by UBS or for failure to undertake the required programme. Under these circumstances, the Commonwealth of Australia may require UBS to repay some or the entire grant. The Company continues to undertake the project funded by the Commonwealth of Australia.

An amount of A\$271,318 and A\$89,500 were received under this grant in November 2017 and June 2018, respectively. UBS believes that the likelihood of being required to repay grant funding is remote because the Company continues to comply with the grant agreement.

**Other Liabilities**

Other liabilities represent marketing support payment due to one of our partners and is payable in US currency. The total amount of marketing support payment to be paid by the Company is US\$2,048,602. These amounts will be paid once supporting documentation has been provided to the Company.

**Research and Development**

Research and development expenses consist of costs incurred to further the Group’s research and product 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	AS	AS	AS	AS
Research and development expenses	1,175,165	2,759,664	4,312,185	9,452,609

**Income Taxes**

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

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

Pursuant to the new U.S. tax reform rules, UBI is subject to regulations addressing Global Intangible Low-Taxed Income (“GILTI”) effective in 2018. The GILTI rules are new provisions of the U.S. tax code enacted as a part of tax reform legislation in the U.S. passed in December 2017. Mechanically, the GILTI rule functions as a global minimum tax for all U.S. shareholders of controlled foreign corporations (“CFCs”) and applies broadly to certain income generated by a CFC. The Company can make an accounting policy election to either: (1) treat GILTI as a period cost if and when incurred; or (2) recognize deferred taxes for basis differences that are expected to reverse as GILTI in future years. The Company has elected to treat GILTI as a period cost.



**Universal Biosensors, Inc.**

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

At December 31, 2018 the Company has nil (A\$10,993,737 at December 31, 2017) of accumulated tax losses available for carry forward against future earnings, which under Australian tax laws do not expire but may not be available under certain circumstances. The Company also has A\$3,374,776 (A\$11,048,336 at December 31, 2017) of non-refundable R&D tax offset as at December 31, 2018. The R&D Tax offset is a non-refundable tax offset, which assists to reduce a company’s tax liability. Once the liability has been reduced to zero, any excess offset may be carried forward into future income years. UBI has U.S. tax losses available for carry forward against future earnings of nil as at December 31, 2018 (US\$1,011,321 as of December 31, 2017). Pursuant to the U.S. Federal Tax Reform, the effective tax rate of UBI has been reduced from 34% to 21%. The deferred tax benefit based on this new rate for UBI is nil. HRL has Canadian tax losses available for carry forward against future earnings of CAD\$738,848 and CAD\$668,043 as at December 31, 2018 and 2017, respectively.

We are subject to income taxes in the United States, Canada and Australia. Tax returns up to and including the 2018 financial year have been filed in all these jurisdictions.

**Asset Retirement Obligations**

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

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

ARO for the period ended September 30, 2019 and year ended December 31, 2018 was A\$2,600,000.

**Australian Goods and Services Tax (“GST”) and Canadian Harmonized Sales Tax (“HST”)**

Revenues, expenses and assets are recognized net of the amount of associated GST and HST, unless the GST and HST 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 and HST receivable or payable. The net amount of GST and HST recoverable from, or payable to, the taxation authority is included with other receivables or payables in the consolidated condensed balance sheets.

**Revenue Recognition**

**A. Significant accounting policy**

We recognize revenue from all sources, other than those received from LifeScan as outlined below, based on the provisions of ASC 606 Revenue from Contracts with Customers.

Revenue is measured based on a consideration specified in a contract with a customer. The Company recognizes revenue when it satisfies a performance obligation by transferring control over a product or service to a customer.

The modified retrospective method has been used in adopting the guidance of ASC 606. There has been no change in accounting principle and the financial statements have not been affected by the application of the guidance in ASC 606.



**Universal Biosensors, Inc.**

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

During the 2018 financial year, LifeScan effected the LifeScan Conversion. As a result of the LifeScan Conversion, beyond the 2018 financial year, the Company will no longer receive any quarterly service fees from LifeScan. Since we will no longer be receiving any substantial revenues from LifeScan beyond the 2018 financial year, the LifeScan contract is deemed to be completed hence ASC 606 is not applied to revenues from LifeScan. The Company notes that there was an underpayment of quarterly services fees of A\$164,577 relating to prior years, the sum of which has been accrued in the previous quarter. This amount was received in the current quarter.

In relation to revenues from LifeScan, we recognized revenues from all sources based on the provisions of the U.S. SEC’s Staff Accounting Bulletin No. 104 and ASC 605 Revenue Recognition.

The Company’s LifeScan revenue represented provision of services.

Revenue from services is recognized when a persuasive evidence of an arrangement exists, services have been rendered, the price is fixed or determinable, and collectability is reasonably assured.

**B. Nature of goods and services**

The following is a description of products and services from which the Company generates its revenue.

<u>Products and services</u>	<u>Nature, timing of satisfaction of performance obligations, and significant payment terms</u>
Point-of-care coagulation test	The Company recognizes revenue from sales of products at the time title of goods passes to the customer and the customer assumes the risks and rewards of ownership. The performance obligation is satisfied at a point in time when the products are shipped to the customer. The customer pays the Company within 60 days from receipt of invoice. The transaction price is fixed.
Coagulation testing services	These are services performed by HRL. Revenue is recognized when the testing services undertaken on behalf of the customer have been completed by HRL. The performance obligation is satisfied at a point in time when the tests are completed and the results are forwarded to the customer. The customer pays HRL generally within 30 days from receipt of invoice. The transaction price is fixed.
Quarterly service fees	Quarterly service fees are based on the number of strips sold by LifeScan which falls within a valid claim of certain LifeScan patents. It is payable to us as an ongoing reward for our services and efforts to enhance the product. Revenue from quarterly services fees is recognized as revenue from services when the four basic criteria for revenue recognition are met. Quarterly service fees are billed on a quarterly basis and paid within 45 days of receipt of invoice. The transaction price is fixed. As further discussed herein, during the 2018 financial year, LifeScan effected the LifeScan Conversion. As a result of this, beyond the 2018 financial year, the Company will no longer receive any quarterly service fees from LifeScan. The Company notes that there was an underpayment of quarterly services fees of A\$164,577 relating to prior years, the sum of which was accrued in the quarter ended June 30, 2019 and received during the current quarter.



**Universal Biosensors, Inc.**

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

**C. Disaggregation of revenue**

In the following table, revenue is disaggregated by major product and service line, and timing of revenue recognition.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	A\$	A\$	A\$	A\$
<b>Major product/service lines</b>				
Xprecia Stride™ strips	1,311,924	227,649	3,606,286	1,131,319
Lump sum service fees	0	42,164,868	0	42,164,868
Quarterly service fees	0	4,420,358	164,577	16,445,552
Coagulation testing services	101,233	422,150	916,412	983,535
Other services	0	0	703,239	0
	<u>1,413,157</u>	<u>47,235,025</u>	<u>5,390,514</u>	<u>60,725,274</u>
<b>Timing of revenue recognition</b>				
Products and services transferred at a point in time	1,413,157	47,235,025	5,390,514	60,725,274
Services transferred over time	0	0	0	0
	<u>1,413,157</u>	<u>47,235,025</u>	<u>5,390,514</u>	<u>60,725,274</u>

**D. Contract balances**

The following table provides information about receivables, contract assets, and contract liabilities from contracts with customers.

	Nine Months Ended September 30,	
	2019	2018
	A\$	A\$
Receivables	964,963	4,902,417
Contract assets	0	0
Contract liabilities:		
- Current	0	2,356,583
- Non-current	0	3,463,737

Receivables represent the Company's right to consideration that is unconditional. The contract assets primarily relate to the Company's right to consideration for work completed but not billed at the reporting date. The contract assets are transferred to the receivables when the rights become unconditional. The contract liabilities primarily relate to the advance consideration received from Siemens for contract research and development, for which transfer of control occurs, and therefore revenue is recognized when the deliverables are met.

Significant changes in the contract assets and the contract liabilities balances during the period are as follows.

	Nine Months Ended September 30,	
	2019	2018
	A\$	A\$
Contract assets	0	0
Contract liabilities		
- Current	0	2,356,583
- Non-current	0	3,463,737
	<u>0</u>	<u>5,820,320</u>

The Company met one of its milestones pursuant to the Siemens Collaboration Agreement in January 2019 therefore revenue of A\$658,675 was recognized in Q1 2019 when this deliverable was met. The remainder of the milestones previously received but deferred was repaid in September 2019 when the Siemens Collaboration Agreement was terminated.



**Universal Biosensors, Inc.**

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

***E. Transaction price allocated to the remaining performance obligations***

These were nil as at September 30, 2019.

*Interest income*

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

*Research and development tax incentive income*

Research and development tax incentive income is recognized when there is reasonable assurance that the income will be received, the relevant expenditure has been incurred, and the consideration can be reliably measured.

The research and development tax incentive is one of the key elements of the Australian Government's support for Australia's innovation system and is supported by legislative law primarily in the form of the Australian Income Tax Assessment Act 1997 as long as eligibility criteria are met. Generally speaking, an entity which is an R&D entity involved in eligible R&D activities may claim research and development tax incentive income as follows:

- (1) as a 43.5% refundable tax offset if aggregate turnover (which generally means an entity's total income that it derives in the ordinary course of carrying on a business, subject to certain exclusions) of the entity is less than A\$20,000,000, or
- (2) as a 38.5% non-refundable tax offset if aggregate turnover of the entity is more than A\$20,000,000.

In accordance with SEC Regulation S-X Article 5-03, the Company's research and development tax incentive income has been recognized as non-operating income as it is not indicative of the core operating activities or revenue producing goals of the Company.

Management has assessed the Company's research and development activities and expenditures to determine which activities and expenditures are likely to be eligible under the tax incentive regime described above. At each period end management estimates the refundable tax offset available to the Company based on available information at the time. This estimate is also reviewed by external tax advisors on an annual basis.

In the nine months ended September 30, 2019 there is reasonable assurance that the aggregate turnover of the Company for the year ending December 31, 2019 will be less than A\$20,000,000 and accordingly A\$1,764,463 has been recorded as a research and development tax incentive income for the nine months ended September 30, 2019. The Company will review its forecasted aggregate turnover on a quarterly basis to determine if the R&D tax offsets are refundable or captured as part of the current year income tax computation.

***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 UBI and UBS is AUD or A\$ for all years presented. The functional currency of HRL is CAD\$ for all years presented.

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

*Transactions and balances*

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





**Universal Biosensors, Inc.**

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

The Company has recorded foreign currency transaction gains of A\$874,253 and A\$183,395 for the three months ended September 30, 2019 and 2018, respectively and A\$1,124,075 and A\$412,768 for the nine months ended September 30, 2019 and 2018, respectively.

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

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

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

***Commitments and Contingencies***

Liabilities for loss contingencies, arising from claims, assessments, litigation, fines, and penalties and other sources are recorded when it is probable that a liability has been incurred and the amount of the assessment can be reasonably estimated. Contingent consideration as at September 30, 2019 was A\$2,222,551 (equivalent to US\$1,500,000) and nil as at December 31, 2018. The Company has agreed to pay US\$1,500,000 to Siemens by January 31, 2020 upon the execution of a license agreement in connection with the Siemens acquisition. This will enable UBI to use Siemens proprietary reagent which will allow UBI to access markets in certain jurisdictions. Purchase commitments contracted for as at September 30, 2019 is A\$520,982 (December 31, 2018: A\$941,864).

***Patent and License Costs***

Legal and maintenance fees incurred for patent application costs have been charged to expense and reported in general and administrative 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 testing activities on behalf of the Company. Depending on the timing of payments to the service providers and the level of service provided, the Company records prepaid or accrued expenses relating to these costs.

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

***Leased Assets***

All of the Company's leases for the periods ending September 30, 2019 and December 31, 2018 are considered operating leases. The costs of operating leases are charged to the consolidated condensed statements of comprehensive income on a straight-line basis over the lease term.

**Universal Biosensors, Inc.****Notes to Consolidated Condensed Financial Statements (Unaudited)****Stock-based Compensation**

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

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

*(a) Stock Option Plan*

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

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

In accordance with ASC 718, the fair value of the option grants was estimated on the date of each grant using the Trinomial Lattice model.

No options have been issued by the Company since January 1, 2018.

Stock option activity during the current period is as follows:

	Number of shares	Weighted average exercise price A\$
Balance at December 31, 2018	15,153,884	0.63
Granted	0	0.00
Exercised	(303,334)	0.01
Lapsed	(12,274,100)	0.64
Balance at September 30, 2019	<u>2,576,450</u>	<u>0.61</u>

The number of options exercisable as at September 30, 2019 and 2018 was 2,544,286 and 7,208,775, respectively. The total stock compensation income/(expense) recognized in the consolidated condensed statements of comprehensive income/(expense) was (A\$18,446) and (A\$51,182) for the three months ended September 30, 2019 and 2018, respectively and A\$422,434 and (A\$228,224) for the nine months ended September 30, 2019 and 2018, respectively.

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

As of September 30, 2019, there was A\$684 of unrecognized compensation expense related to unvested share-based compensation arrangements under the Employee Option Plan. This expense is expected to be recognized over the vesting years as follows:

Fiscal Year	A\$
2019	684
2020	0
2021	0
	<u>684</u>

The aggregate intrinsic value for all options outstanding as at September 30, 2019 and 2018 was zero.

*(b) Restricted Share Plan*

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

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

	Number of shares	Weighted average issue price A\$
Balance at December 31, 2018	311,246	0.28
Granted	0	0.00
Release of restricted shares	(113,546)	0.28
Balance at September 30, 2019	<u>197,700</u>	<u>0.27</u>

*Employee Benefit Costs*

The Company contributes 9.5% of each employee's salary to standard defined contribution superannuation funds on behalf of all UBS employees. 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 have reached the statutory retirement age. Whilst the Company has a third party default superannuation fund, it permits UBS employees to choose an approved and registered superannuation fund into which the contributions are paid. Contributions are charged to the consolidated condensed statements of comprehensive income as they become payable.

*Registered Retirement Savings Plan and Deferred Sharing Profit Plan*

The Company provides eligible HRL employees a retirement plan. The retirement plan includes a Registered Retirement Savings Plan ("RRSP") and Deferred Profit Sharing Plan ("DPSP"). The RRSP is voluntary and the employee contributions are matched by the Company up to a maximum of 5% based on their continuous years of service and placed into the DPSP. The Company contributes 1% to 2% of the employee's base earnings towards the DPSP. The DPSP contributions are vested immediately.

*Benefit Plan*

The Company provides eligible HRL employees a Benefit Plan. In general, the Benefit Plan includes extended health care, dental care, basic life insurance, basic accidental death and dismemberment, and disability insurance.



**Universal Biosensors, Inc.**

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

**Net Income/(Loss) per Share and Anti-dilutive Securities**

Basic and diluted net income/(loss) per share is presented in conformity with ASC 260 – Earnings per Share. Basic and diluted net income/(loss) per share has been computed using the weighted-average number of common shares outstanding during the period. Diluted net income/(loss) per share is calculated by adjusting the basic net income/(loss) per share by assuming all dilutive potential ordinary shares are converted.

**Total Comprehensive Income/(Loss)**

The Company follows ASC 220 – Comprehensive Income. Comprehensive income/(loss) 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/(loss).

The tax effect allocated to each component of other comprehensive loss is as follows:

	Before-Tax Amount AS	Tax (Expense)/ Benefit AS	Net-of-Tax Amount AS
<b><u>Nine Months Ended September 30, 2019</u></b>			
Foreign currency translation reserve	21,426	0	21,426
Reclassification for gains realised in net income	0	0	0
Other comprehensive loss	<u>21,426</u>	<u>0</u>	<u>21,426</u>
<b><u>Nine Months Ended September 30, 2018</u></b>			
Foreign currency translation reserve	36,525	0	36,525
Reclassification for gains realised in net income	0	0	0
Other comprehensive loss	<u>36,525</u>	<u>0</u>	<u>36,525</u>

**Business combinations**

Business combinations are accounted for using the acquisition method of accounting. Acquisition cost is measured as the aggregate of the fair value at the date of acquisition of the assets given, equity instruments issued or liabilities incurred or assumed. Acquisition related costs are expensed as incurred (except for those costs arising on the issue of equity instruments which are recognized directly in equity). Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are measured at fair value on the acquisition date. Goodwill is measured as the excess of the acquisition cost, the amount of any non-controlling interest and the fair value of any previous UBI equity interest in the acquiree, over the fair value of the identifiable net assets acquired.

**Recent Accounting Pronouncements**

(a) Recent issued accounting standards not yet adopted

ASU No.2016-02, “Leases”

On February 25, 2016, the FASB issued ASU 2016-02, its new standard on accounting for leases. ASU 2016-02 introduces a lessee model that brings most leases on the balance sheet and eliminates the requirement in current U.S. GAAP for an entity to use bright-line tests in determining lease classification. The standard also requires lessors to increase the transparency of their exposure to changes in value of their residual assets and how they manage that exposure.

The new guidance will be effective for public business entities for annual periods beginning after December 15, 2018, and interim periods therein. Early adoption is permitted. The Company has deferred the adoption of this standard as is allowable for an Emerging Growth Company.



**Universal Biosensors, Inc.**

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

ASU No. 2017-12, "Targeted Improvements to Accounting for Hedging Activities"

On August 28, 2017, the FASB issued ASU 2017-12, which amends the hedge accounting recognition and presentation requirements in ASC 815.2. The FASB's objectives in issuing the ASU are to (1) improve the transparency and understandability of information conveyed to financial statement users about an entity's risk management activities by better aligning the entity's financial reporting for hedging relationships with those risk management activities and (2) reduce the complexity of and simplify the application of hedge accounting by preparers.

For public business entities, the ASU is effective for fiscal years beginning after December 15, 2018, and interim periods therein; however, early adoption by all entities is permitted upon its issuance. The Company has deferred the adoption of this standard as is allowable for an Emerging Growth Company.

(b) Recently adopted accounting pronouncements

ASU No. 2016-18, "Restricted Cash"

On November 17, 2016, the FASB issued ASU 2016-18, which amends ASC 230 to add or clarify guidance on the classification and presentation of restricted cash in the statement of cash flows. For public business entities, the guidance is effective for fiscal years beginning after December 15, 2017, including interim periods therein. For all other entities, it is effective for fiscal years beginning after December 15, 2018, and interim periods thereafter. Early adoption is permitted for all entities. The Company has adopted this guidance from January 1, 2018 and it has not had a material impact on the Company's consolidated financial statements.

ASU No. 2018-05, "Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118."

On March 13, 2018, the FASB issued ASU 2018-05. This Financial Reporting Alert contains responses to frequently asked questions about how an entity should account for the tax effects of the new tax reform legislation in accordance with ASC 740, Income Taxes. This ASU is effective upon issuance and the adoption of this guidance has not had a material impact on the Company's consolidated financial statements.

ASU No. 2018-09, "Codification Improvements"

The FASB issued ASU 2018-09 on July 16, 2018. The ASU's amendments "clarify, correct errors in, or make minor improvements to the Codification." This ASU is effective upon issuance and the adoption of this guidance has not had a material impact on the Company's consolidated financial statements.

ASU No. 2014-09, "Revenue from Contracts with Customers"

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, Revenue from Contracts with Customers (Topic 606), which provides companies with a single revenue recognition model for recognizing revenue from contracts with customers. The core principle of the new standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. There are two permitted transition methods under the new standard, the full retrospective method or the modified retrospective method. The new standard is effective for annual reporting periods beginning after December 15, 2017. The Company has adopted this guidance from January 1, 2019 and it has not had a material impact on the Company's consolidated financial statements.

UBI has selected the modified retrospective method where the effect of applying the standard is recognized at the date of initial application, without restating previous years.



**Universal Biosensors, Inc.**

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

***Related Party Transactions***

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

In September 2011, we entered into a non-exclusive license agreement with SpeedX Pty Ltd (“SpeedX”) pursuant to which SpeedX granted us a license to use its proprietary MNAzyme technology in the field of molecular diagnostics. Under the agreement we make milestone payments totaling A\$500,000 to SpeedX if certain specified targets are achieved, and royalty payments ranging from 5% to 15% of that portion of our sales and licensing revenues arising from SpeedX technology or products incorporating SpeedX technology.

The license agreement and the obligation to pay royalties continues until SpeedX’s patent rights have expired, lapsed, are found to be invalid or are rejected. The agreement will terminate by mutual agreement or by one party for breach or insolvency of the other. SpeedX may also terminate the license agreement if the research and development on a first licensed product is not completed by UBS within 7 years (subject to certain exceptions), and UBS may terminate if it determines that it does not wish to proceed with further commercialization of SpeedX’s technology.

Mr. Denver is a director of SpeedX and up until August 7, 2017 was a director of the Company. Mr. Denver continued to provide services to the Company in an advisory capacity between October 1, 2017 and June 30, 2018.

The agreement with SpeedX was terminated without costs borne by either party by mutual agreement of both parties on March 29, 2019.

Mr. Coleman is a Non-Executive Chairman of the Company and Executive Chairman of Viburnum Funds Pty Ltd. Viburnum Funds Pty Ltd, as an investment manager for its associated funds, holds a beneficial interest and voting power over approximately 19% of our shares.

An employee of Viburnum Funds Pty Ltd has on occasions been seconded to Universal Biosensors to assist the Company on strategic matters. During these periods Viburnum Funds Pty Ltd continues to pay all the salary entitlements of the seconded person. Universal Biosensors is solely responsible for the reimbursement of certain expenditures such as travel and rental whilst the employee is on secondment. The total expenditure reimbursed by the Company to Viburnum Funds Pty Ltd as at September 30, 2019 and 2018 was A\$12,365 and A\$21,716, respectively.

***Borrowings***

The Company repaid its borrowings in November 2018.

***Athyrium Credit Agreement***

On December 19, 2013 (“Closing Date”), UBI and its wholly owned subsidiary, UBS (together UBI and UBS, the “Transaction Parties”) entered into a credit agreement with Athyrium Opportunities Fund (A) LP (“Athyrium A”), as administrative agent (the “Administrative Agent”) and as a lender, and Athyrium Opportunities Fund (B) LP (“Athyrium B”) as a lender (Athyrium A and Athyrium B together with any other lenders party thereto from time to time, the “Lenders”) for a secured term loan of up to US\$25 million, which was amended on January 30, 2015 (“Credit Agreement”). Of this amount, US\$15 million had been drawn at December 31, 2013 with a further US\$10 million available to be drawn down on or before July 31, 2015, if UBS satisfied certain conditions precedent relating to product revenues.

The credit agreement was amended again on December 29, 2017 (“Amendment”). Subject to the terms of the Amendment, the Amendment modified the Credit Agreement to (i) extend the maturity date to July 1, 2019 (“Maturity Date”), (ii) add the Borrower’s wholly owned subsidiary, Hemostasis Reference Laboratory, Inc. (“HRL”), as a guarantor of the Borrower’s obligations under the Credit Agreement and (iii) subject to the prior written consent of the Lenders in their sole discretion, permit UBI to repurchase shares in an aggregate amount up to US\$2,000,000 within 12 months after the date Lenders provide any such consent. In connection with the Amendment, UBI agreed to pay a fee of US \$200,000 to the Lenders and to reimburse certain expenses of the Lenders incurred in connection with the Amendment. The fee of US\$200,000 was paid in January 2018.



**Universal Biosensors, Inc.**

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

The term loan was voluntary prepaid in November 2018 and a Deed of Release was executed in December 2018 releasing all the Transaction Parties securities and obligations under the term loan. The term loan bore interest at 10.5% per annum payable in cash quarterly in arrears over the term, and as otherwise described in the Credit Agreement. A default interest rate of 13% per annum applied during the existence of a default under the Credit Agreement. The term loan under the Credit Agreement was secured by substantially all of UBI, UBS' and HRL's assets. UBI and HRL (together with any future subsidiaries) guaranteed all of UBS's obligations under the term loan.

Voluntary prepayments of the term loans were not permitted prior to the second anniversary of the Closing Date, except in the event of a change of control of a Transaction Party. After the second anniversary, UBS could make voluntary repayments in minimum principal amounts of US\$2,500,000 together with interest, plus a prepayment premium commencing at 15% of the principal of such prepayment due and payable on the applicable date and reducing pro-rata on a monthly basis until the Maturity Date. Since UBS repaid the loan prior to its Maturity Date, it paid a prepayment premium of US\$62,500.

As further described below, pursuant to the Credit Agreement, UBI issued to the Lenders warrants entitling the holder to purchase up to an aggregate total of 4.5 million shares of UBI's common stock in the form of CDIs at a price of A\$1.00 per share (the "Exercise Price"), which represents a 117% premium over the closing price of UBI's common stock on December 19, 2013. The warrants are immediately exercisable and have a term of seven years.

**Warrants**

Pursuant to the Credit Agreement, UBI issued to the Lenders warrants entitling the holder to purchase up to an aggregate total of 4.5 million shares of UBI's common stock in the form of CDIs at a price of A\$1.00 per share (the "Exercise Price"), which represents a 117% premium over the closing price of UBI's common stock on December 19, 2013. The warrants are immediately exercisable and have a term of seven years.

The warrants may be exercised at any time until December 19, 2020, in whole or in part in minimum multiples of 500,000 shares of common stock. The holder of the warrants can pay the Exercise Price in cash or it has the right to pay all or a portion of the Exercise Price by making a cashless exercise, therefore reducing the number of shares of common stock the holder would otherwise be issued.

The warrant is subject to adjustments in the event of certain issuances by UBI, such as bonus issues, pro rata (rights) issues and reorganizations (e.g., consolidation, subdivision).

The Company assessed that the warrants are not liabilities within scope of ASC 480-10-25. The warrants are legally detachable from the loan and separately exercisable and as such meet the definition of a freestanding derivative instrument pursuant to ASC 815.

However, the scope exception in accordance with ASC 815-10-15-74 applies to warrants and it meets the requirements of ASC 815 that would be classified in stockholders' equity. Therefore, the warrants were initially accounted for within stockholders' equity, and subsequent changes in fair value will not be recorded. The fair value of the warrant was estimated using the Trinomial Lattice model.

The debt issuance costs were recorded as deferred issuance costs and are amortized as interest expense, using the effective interest method, over the term of the loan pursuant to ASC 835-30-35-2.

The warrants issued in December 2013 had a grant fair value of US\$815,655 and are included in equity.



**Universal Biosensors, Inc.**

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

**Restricted Cash**

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the consolidated condensed balance sheets that sum to the total of the same such amounts shown in the consolidated statements of cash flows.

	Nine Months Ended September 30, 2019 AS	Year Ended December 31, 2018 AS
Cash and cash equivalents	34,485,732	11,797,789
Restricted cash - current assets	16,790	15,589
Restricted cash - non-current assets	320,000	320,000
	34,822,522	12,133,378

Restricted cash maintained by the Company in the form of term deposits is as follows:

	Nine Months Ended September 30, 2019 AS	Year Ended December 31, 2018 AS
Collateral for facilities (a) - current assets	16,790	15,589
Collateral for facilities (b) - non-current assets	320,000	320,000
	336,790	335,589

- (a) Represents bank guarantee of CDN\$15,000 as security deposit on HRL’s credit card
- (b) Represents bank guarantee of A\$250,000 for commercial lease of UBS’ premises and security deposit on Company’s credit cards of A\$70,000

Interest earned on the restricted cash for the three months ended September 30, 2019 and 2018 were A\$1,653 and A\$18,500, respectively and for the nine months ended September 30, 2019 and 2018 were A\$5,246 and A\$53,420, respectively.

**Acquisition of Assets from Siemens**

As discussed in more detail in “Notes to Consolidated Condensed Financial Statements (Unaudited) – Organization of the Company”, on September 18, 2019 we entered into certain definitive agreements with Siemens modifying our commercial relationship relating to coagulation products. As part of this arrangement, we agreed on a total consideration of US\$13,000,000 of which US\$11,000,000 was paid on September 23, 2019. The consideration paid relates primarily to the settlement of the prepaid milestones and acquisition of intangible assets. The transaction did not involve any liabilities being assumed and we have allocated the cost of the assets on the basis of their relative fair values.

*(a) Acquisition related costs*

These were nil. Legal expense incurred during the period is mainly relating to the settlement of the dispute between the Company and Siemens rather than asset acquisition and as such have been expensed.



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

The Company has agreed to pay US\$1,500,000 to Siemens by January 31, 2020 upon the execution of a license agreement. This will enable UBI to use Siemens proprietary reagent which will allow UBI access to markets in certain jurisdictions. A further US\$500,000 will be payable by January 1, 2026 if an intermediate product of the Siemens proprietary reagent is supplied by Siemens and if UBI chooses to use this intermediate product.

*(c) Identifiable assets acquired*

Total identifiable assets acquired are as follows:

	A\$
Intangible assets - distribution rights <sup>1</sup>	12,013,658
Inventory	368,840
Total identifiable assets acquired	12,382,498
Deferred income tax liability on intangible assets <sup>1</sup>	4,358,338
	16,740,836
Less: Deferred income tax liability on intangible assets	4,358,338
Contingent consideration	2,213,042
Consideration paid in September 2019	<u>10,169,456</u>

1. Total Intangible assets recognized in balance sheet A\$16,371,996

*(d) Measurement of fair values*

The fair value of the distribution rights acquired has been based on the amount paid. Inventory has been valued at net realizable value.

**Intangible Assets**

The intangible assets, having finite useful lives, are amortized over their estimated useful lives. Finite life intangible assets are amortized over the shorter of their contractual or useful economic lives. The intangible assets comprise of distribution rights and are amortized on a straight-line basis over 10 years. The amortization expense of the intangible assets was A\$32,896 for the quarter ended September 30, 2019.

	Nine Months Ended September 30,	Year Ended December 31,
	2019	2018
	A\$	A\$
Intangible assets - gross	16,371,996	0
Less accumulated amortization	(32,896)	0
Total intangible assets - net	<u>16,339,100</u>	<u>0</u>

**Impairment of Intangible Assets**

Intangible assets with an indefinite life are tested for impairment at least annually and when there is an indication of impairment.



**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 most recent Annual Report on 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, as amended (the “Exchange Act”) 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”, “intends”, “may”, “assumes”, “illustration”, and similar expressions constitute forward-looking statements, although not all forward-looking statements contain such identifying words.*

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

**Results of Operations**

*Analysis of Consolidated Revenue*

As discussed in “Notes to Consolidated Condensed Financial Statements (Unaudited) – Organization of the Company”, during 2018, LifeScan effected the LifeScan Conversion. Accordingly, we will not receive any further quarterly service fees beyond 2018 and we do not expect to receive any further revenues from LifeScan unless we enter into a new agreement with LifeScan in the future. As a result of this and despite sales of the Xprecia Stride™ strips increasing, our total revenue decreased by 97% and 91%, respectively, during the three and nine months ended September 30, 2019, compared to the same periods in the previous financial year.

On September 9, 2019, we entered into binding term sheets, and on September 18, 2019, we entered into certain definitive agreements, in each case with Siemens and including the Distribution Agreement, modifying our commercial relationship relating to coagulation products (the term sheets together with the definitive agreements, the “Agreements”). The Agreements restore our commercial relationship and provide for cooperation between UBI and Siemens to retain and grow the incumbent user base on a non-exclusive basis. Siemens will support this with a minimum Xprecia Stride Strip purchase guarantee over 42 months on favorable payment terms, and manufacturing assistance which will enable a reduction in manufacturing costs. The Agreements further enable us to pursue partnership and distribution opportunities for our products outside of our agreements with Siemens, which we believe will allow us to access new global markets and market segments, including the hospital point-of-care segment that was previously exclusive to Siemens. The Agreements also provide UBI with increased control over the pricing for the analyzers and strips it sells. The Agreements further provide UBI with ongoing access to Siemens’ proprietary reagent necessary for strip manufacturing (subject to conditions being fulfilled by Siemens), across certain global markets and market segments and now including patient self-test (with the exception of any product that comprises lapidated recombinant human tissue factor which is useful for automated prothrombin time based testing and is marketed or sold (i) in multi-test packages, or (ii) single test packages, and which is not a single test PT product). Finally, the Agreements preserve value created from UBI and Siemens’ previous development spending for UBI’s sole benefit while ceasing UBI’s development spending obligations with respect to Siemens, providing us with control over our development activities.



*Revenue from Products*

The financial results of the PT-INR test strips for the Xprecia Stride™ Coagulation Analyzer we manufactured and sold to Siemens during the respective periods are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	AS	AS	AS	AS
Revenue from products	1,311,924	227,649	3,606,286	1,131,319
Cost of goods sold	(726,530)	(186,515)	(1,996,189)	(1,055,534)
Production margin	585,394	41,134	1,610,097	75,785

The movement in revenues is primarily volume driven. Management is of the view that revenues increased by 476% and 219%, respectively during the three and nine months ended September 30, 2019 compared to the same periods in the previous financial year as a result of Siemens purchase order volatility during the period. The production margin from the sale of our PT-INR strips has improved with higher throughput.

*Revenue from Services*

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

- Product enhancement – a quarterly service fee based on the number of strips sold by LifeScan which falls within a valid claim of certain LifeScan patents is payable to us as an ongoing reward for our services and efforts to enhance the product (as noted elsewhere herein, commencing in the 2019 financial year, UBI will no longer receive these quarterly service fees from LifeScan due to the LifeScan Conversion);
- Contract research and development – we undertake contract research and development on behalf of our customers and partners;
- Lump sum service fees – this one-off fee is calculated by multiplying the LifeScan quarterly service fees for the 2018 financial year by two;
- Other services – calibration services provided by HRL and other ad-hoc services provided on an agreed basis according to our customers and partners requirements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	AS	AS	AS	AS
Revenue from services:				
Lump sum service fees	0	42,164,868	0	42,164,868
Quarterly service fee	0	4,420,358	164,577	16,445,552
Other services	101,233	422,150	1,619,651	983,535
	101,233	47,007,376	1,784,228	59,593,955
Cost of services	(96,157)	(217,313)	(545,937)	(644,508)
Net margin	5,076	46,790,063	1,238,291	58,949,447

*Quarterly service fee* - Whilst we no longer receive the quarterly service fees due to the LifeScan Conversion, the Company notes that there was an underpayment of quarterly services fees of A\$164,577 relating to prior years, the sum of which had been accrued in the previous quarter ended June 30, 2019.



*Other services* - Other services represents coagulation testing services performed by HRL, Siemens related research and development milestone achieved during the first quarter and other ad hoc services undertaken for our partners.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	A\$	A\$	A\$	A\$
Coagulation testing services	101,233	178,452	916,412	363,667
Contract research and development	0	0	658,675	0
Other	0	243,698	44,564	619,868
	<u>101,233</u>	<u>422,150</u>	<u>1,619,651</u>	<u>983,535</u>

Coagulation testing services for the nine month period ended September 30, 2019 increased as a result of marketing and delivery initiatives undertaken by HRL. There was a decline in coagulation testing services for the three month period ended September 30, 2019 due to the Company's completion of a project during the first half of 2019. This revenue has not been replaced during the current quarter resulting in a decline in revenue. During the first quarter we delivered on a milestone under the Siemens Collaboration Agreement and recognized revenue of US\$500,000 (equivalent to A\$658,675). Other services represent ad-hoc services provided to our customers and partners.

*Contribution from Products & Services*

The net contribution from our products and services is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	A\$	A\$	A\$	A\$
Lump sum service fees	0	42,164,868	0	42,164,868
Quarterly service fees	0	4,420,358	164,577	16,445,552
Manufacturing contribution	585,394	41,134	1,610,097	75,785
Other services	5,076	204,837	1,073,714	339,027
Contribution from products & services	<u>590,470</u>	<u>46,831,197</u>	<u>2,848,388</u>	<u>59,025,232</u>

The decrease in period to period total contributions from products and services reflected in the table above is primarily a result of the Company not receiving any further quarterly service fees from LifeScan in 2019 due to the LifeScan Conversion. The Company notes that there was an underpayment of quarterly services fees of A\$164,577 relating to prior years, the sum of which had been accrued in the previous quarter ended June 30, 2019.

The manufacturing contribution has increased due to increased sales of PT-INR strips and as a result of our investment in scale up projects which has improved efficiency and yields. Manufacturing operations have the flexibility to expand in order to support volume increases on the Siemens contract.

Contribution from other services increased over the nine month period primarily as a result of increase in revenue generated by HRL and achievement of a milestone.

*EBITDA*

EBITDA is earnings before interest, taxes, depreciation and amortization. EBITDA is a non-GAAP measurement. Management uses EBITDA because it believes that such measurements are widely accepted financial indicators used by investors and analysts to analyze and compare companies on the basis of operating performance and that these measurements may be used by investors to make informed investment decisions, including our ability to generate earnings sufficient to service our debt, and enhances our understanding of our financial performance and highlights operational trends. These measures are not in accordance with, or an alternative for, generally accepted accounting principles in the United States (GAAP). The most comparable GAAP measure is net earnings from continuing operations. Consolidated EBITDA should not be considered in isolation or as a substitution for analysis of our results as reported under GAAP.



EBITDA for the respective periods and a reconciliation of net income to EBITDA is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	AS	AS	AS	AS
Net income/(loss)	(806,565)	41,865,596	(4,306,752)	41,391,958
Interest income	(223,054)	(175,643)	(695,208)	(365,542)
Interest expense	0	606,166	0	1,741,825
Amortization	32,896	0	32,896	0
Depreciation - cost of goods sold & services	84,814	7,007	265,829	160,948
Depreciation - other operating costs & expenses	149,388	451,481	572,617	1,519,375
<b>EBITDA</b>	<b>(762,521)</b>	<b>42,754,607</b>	<b>(4,130,618)</b>	<b>44,448,564</b>

The decrease in EBITDA for all periods are primarily as a result of the Company not receiving any further quarterly service fees from LifeScan due to the LifeScan Conversion.

*Product Support*

Product support relates to post-market technical support provided by us to Siemens for the Xprecia Stride™ Coagulation Analyzer.

Product support for the respective periods are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	AS	AS	AS	AS
Product support	12,574	8,750	41,956	202,899

We expect product support expenditure to decrease over time.

*Depreciation and Amortization Expenses*

Depreciation of fixed assets is based on a straight line basis over the useful life of property, plant and equipment. Depreciation is allocated to cost of goods sold and research and development based on output. The decline in depreciation for all periods is due to fixed assets with a written down value of A\$2,574,709 being written off as December 31, 2018 as its carrying value was no longer supported by future revenues streams.

Depreciation for the respective periods charged to other operating costs and expenses is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	AS	AS	AS	AS
Research and development expenses	116,175	410,326	462,829	1,391,294
General and administrative expenses	33,128	41,096	109,526	126,901
Product support depreciation	85	59	262	1,180
Depreciation	149,388	451,481	572,617	1,519,375

Amortization expenses on intangible assets acquired in September 2019 pursuant to the Siemens Acquisition for the three and nine month period ended September 30, 2019 was A\$32,896.



*Research and Development Expenses*

Total research and development expenses for the respective periods are as follows:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
	<u>AS</u>	<u>AS</u>	<u>AS</u>	<u>AS</u>
Research and development expenses	<u>1,175,165</u>	<u>2,759,664</u>	<u>4,312,185</u>	<u>9,452,609</u>

Research and development expenditure principally reflects the effort required in product development of the tests we are developing. Research and development expenditure decreased by 57% and 54%, respectively during the three and nine months ended September, 2019 compared to the same periods in the previous financial year.

The decrease in year-to-date research and development expenses was a result of all proprietary coagulation product research and development spending being suspended in the fourth quarter of 2018 and scaling back of research and development obligations relating to Siemens projects since March 2019 pursuant to the Term Sheet Agreement we executed with Siemens on February 8, 2019.

Research and development expenditure also include separation payments made to certain staff during the first half of the year as part of a management initiative to reduce expenditures. Whilst this represented a cost during the period, the overall research and development expenditure for the year ended December 31, 2019 is expected to decrease as a result of the decline in headcount.

While we have a degree of control as to how much we spend on research and development activities in the future, we cannot predict with certainty what it will cost to complete our individual research and development programs successfully or when or if they will be commercialized. The timing and cost of any program is dependent upon a number of factors including achieving technical objectives, which are inherently uncertain, and subsequent regulatory approvals. We do however have project plans in place for all our development programs which we use to plan, manage and assess our projects. As part of this procedure, we also undertake commercial assessments of such projects to optimize outcomes and make go no-go decisions.

In addition, our business strategy contemplates that we may enter into collaborative arrangements with third parties for one or more of our non-blood glucose programs. In the event that we are successful in securing such third party collaborative arrangements, the third party may direct the research and development activities and may contribute towards all or part of the cost of these activities, both of which will influence our research and development expenditure. With the termination of the Collaboration Agreement with Siemens, we no longer undertake any research and development activities for Siemens.

Research and development expenses are related to the development of new technologies and products based on the electrochemical cell platform.

The Company conducts research and development activities to build an expanding portfolio of product-based revenues and cash flows and increase the value of UBI's core technology assets. Research is focused on demonstrating technical feasibility of new technology applications. Development activity is focused on turning these technology platforms into commercial-ready products and represents the majority of the Company's research and development expenses.

Research and development expenses consist of costs associated with research activities, as well as costs associated with our product development efforts, including pilot manufacturing costs. Research and development expenses include:

- consultant and employee related expenses, which include consulting fees, salaries 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.

*General and Administrative Expenses*

General and administrative expenses currently consist principally of salaries and related costs, including stock option expense, for personnel in executive, business development, finance, accounting, information technology and human resources functions. Other general and administrative expenses include depreciation, repairs and maintenance, insurance, facility costs not otherwise included in research and development expenses, consultancy fees and professional fees for legal including legal services and maintenance fees incurred for patent applications, audit and accounting services. General and administrative expenses increased by 18% and 14%, respectively for the three and nine months ended September 30, 2019 compared to the same periods in the previous financial year.

The increase was primarily due to legal and consultant fees incurred as part of contract negotiations supporting customer relationship management and partner development.

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
	<u>AS</u>	<u>AS</u>	<u>AS</u>	<u>AS</u>
General and administrative expenses	<u>1,599,851</u>	<u>1,360,040</u>	<u>5,810,226</u>	<u>5,110,134</u>

*Interest Income*

Interest income increased by 27% and 90%, respectively during the three and nine months ended September 30, 2019 when compared to the same periods in the previous financial year. The increase in interest income is generally attributable to the higher amount of funds available for investment.

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
	<u>AS</u>	<u>AS</u>	<u>AS</u>	<u>AS</u>
Interest income	<u>223,054</u>	<u>175,643</u>	<u>695,208</u>	<u>365,542</u>

*Financing Costs*

In December 2013, UBS accessed new capital via a US\$25,000,000 loan facility of which US\$15,000,000 was drawn in December 2013. The term loan was fully repaid in November 2018. The breakdown of the financing costs is as follows:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
	<u>AS</u>	<u>AS</u>	<u>AS</u>	<u>AS</u>
Interest expense	<u>0</u>	<u>606,166</u>	<u>0</u>	<u>1,741,825</u>
Warrants expense	<u>0</u>	<u>36,226</u>	<u>0</u>	<u>104,096</u>
Other debt issuance costs	<u>0</u>	<u>92,554</u>	<u>0</u>	<u>272,148</u>
	<u>0</u>	<u>734,946</u>	<u>0</u>	<u>2,118,069</u>

Interest expense relates to applicable interest of 10.5% levied on the loan. The debt issuance costs were recorded as deferred issuance costs and are amortized as interest expense, using the effective interest method, over the term of the loan.



*Research and development tax incentive income*

In the nine months ended September 30, 2019 there is reasonable assurance that the aggregate turnover of the Company for the year ending December 31, 2019 will be less than A\$20,000,000 and accordingly A\$437,516 and A\$1,764,463 has been recorded as a research and development tax incentive income for the three and nine months ended September 30, 2019.

*Exchange gain*

Exchange gain for the respective periods are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	A\$	A\$	A\$	A\$
Exchange gain	874,253	183,395	1,124,075	412,768

Foreign exchange gains and losses arise from the settlement of foreign currency transactions that are translated into the functional currency using the exchange rates prevailing at the dates of the transactions and from the translation at period-end exchange rates of monetary assets and liabilities denominated in foreign currencies.

**Critical Accounting Estimates and Judgments**

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

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

(a) Revenue Recognition

Revenue is measured based on a consideration specified in a contract with a customer. The Company recognizes revenue when it satisfies a performance obligation by transferring control over a product or service to a customer.

(b) Stock-Based Compensation

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

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

*Share Price and Exercise Price at Valuation Date*

With the exception of ZEPOs, the exercise price of the options granted has been determined using the closing price of our common stock trading in the form of CDIs on ASX at the time of grant of the options. The exercise price of ZEPOs is nil. The ASX is the only exchange upon which our securities are quoted.





*Volatility*

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

*Time to Expiry*

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

*Risk Free Rate*

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

(c) Income Taxes

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

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

(d) Impairment of Long-Lived Assets

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

(e) Warrants

In connection with our US\$15 million loan facility, we issued to the Lenders warrants entitling the holder to purchase up to an aggregate total of 4.5 million shares of UBI’s common stock in the form of CDIs at a price of A\$1.00 per share. The fair value of the warrants to purchase common stock is estimated using the Trinomial Lattice model. Each of the inputs to the Trinomial Lattice model is discussed below.

*Exercise Price at Valuation Date*

The exercise price of the warrants has been determined as stated in the Credit Agreement. For further details, see Notes to Consolidated Condensed Financial Statements—*Summary of Significant Accounting Policies – Borrowings – Athyrium Credit Agreement*.

*Volatility*

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



*Time to Expiry*

The warrants have a term of seven years.

*Risk Free Rate*

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

(f) Research and development tax incentive income

Research and development tax incentive income is recognized when there is reasonable assurance that the income will be received, the relevant expenditure has been incurred, and the consideration can be reliably measured. The research and development tax incentive is one of the key elements of the Australian Government's support for Australia's innovation system and is supported by legislative law primarily in the form of the Australian Income Tax Assessment Act 1997 as long as eligibility criteria are met.

Management has assessed the Company's research and development activities and expenditures to determine which activities and expenditures are likely to be eligible under the tax incentive regime described above. At each period end management reviews the aggregate turnover of the Company to determine if the research and development tax incentive income should be recorded and based on this information and other available information at the time estimates the refundable tax offset available to the Company. This estimate is also reviewed by external tax advisors on an annual basis.

(g) Acquisition Accounting

Accounting for assets on acquisition requires an assessment of the existence, fair value and expected useful economic lives of separate intangible assets at the date of acquisition. The value attributed together with the assessment of useful economic lives determines future amortization charges.

Accounting for deferred contingent acquisition consideration is based on estimates of future performance of the acquired assets over the contractual period. If the future results of these assets differs from the forecast used for these calculations, there may be a material change in the value of these deferred liabilities which would be recorded in the consolidated statements of comprehensive income/(loss).

(h) Carrying value of Intangible Assets

The Company assesses the carrying value of intangible assets annually, or whenever there is an indication of impairment. Identifying indicators or impairment requires judgments to be made as to the prospects and value drivers of the individual assets.



**Financial Condition, Liquidity and Capital Resources**

*Net Financial Assets*

Our net financial assets position is shown below:

	<u>Nine Months Ended</u> <u>September 30,</u> <u>2019</u> <u>AS</u>	<u>Year Ended</u> <u>December 31,</u> <u>2018</u> <u>AS</u>
<b>Financial assets:</b>		
Cash and cash equivalents	34,485,732	11,797,789
Accounts receivables	964,963	50,209,561
Total financial assets	35,450,695	62,007,350
<b>Debt:</b>		
Short term secured loan	0	0
Long term secured loan	0	0
Total debt	0	0
<b>Net financial assets</b>	<b>35,450,695</b>	<b>62,007,350</b>

Since inception, we have financed our business primarily through the issuance of equity securities, funding from strategic partners, government grants and rebates (including the research and development tax incentive income), cash flows generated from operations, and the loan discussed below.

On December 19, 2013 we entered into the Credit Agreement which was amended in January 2015 and on December 29, 2017 with Lenders for a US\$25,000,000 secured term loan. A first tranche loan of US\$15,000,000 was drawn on December 2013 and we elected not to draw down the additional US\$10,000,000. The term loan was repaid in November 2018. The term loan had a maturity date of July 1, 2019 and bore interest at 10.5% per annum. Interest payments were due quarterly over the term of the term loan and, other than as described elsewhere herein, we were not required to make payments of principal for amounts outstanding under the term loan until the Maturity Date. Subject to certain exceptions, the term loan was secured by substantially all of our assets, including our intellectual property. For further details, see Notes to Consolidated Financial Statements—*Summary of Significant Accounting Policies – Borrowings – Athyrium Credit Agreement*.

The decline in our net financial assets position is primarily a result of the acquisition of assets from Siemens pursuant to the Siemens Acquisition, payment of GILTI taxes, legal and specialist consultant fees incurred as part of contract negotiations, separation payments made to our staff and working capital maintenance generally.

We believe we have sufficient cash and cash equivalents to fund our operations for at least the next twelve months. Liquidity risk is the risk that the Company may encounter difficulty meeting obligations associated with financial liabilities. The Company manages liquidity risk through the management of its capital structure. The purpose of liquidity management is to ensure that there is sufficient cash to meet all the financial commitments and obligations of the Company as they come due. In managing the Company’s capital, management estimates future cash requirements by preparing a budget and a multi-year plan for review and approval by the Board. The budget is reviewed and updated periodically and establishes the approved activities for the next twelve months and estimates the costs associated with those activities. The multi-year plan estimates future activity along with the potential cash requirements and is based upon management’s assessment of current progress along with the expected results from the coming years’ activity. Budget to actual variances are prepared and reviewed by management and are presented on a regular basis to the Board of Directors.

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

We regularly review all our financial assets for impairment. There were no impairments recognized as at September 30, 2019 or for the year ended December 31, 2018.

*Derivative Instruments and Hedging Activities*

In determining fair value, we utilize valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as consider our own and counterparty credit risk. At September 30, 2019 and December 31, 2018, we did not have any assets or liabilities that utilize Level 3 inputs. The valuation of our foreign exchange derivatives is based on the market approach using observable market inputs, such as forward rates, and incorporates non-performance risk (the credit standing of the counterparty when the derivative is in a net asset position, and the credit standing of the Company when the derivative is in a net liability position). Our derivative assets are categorized as Level 2.



200GTTVj9J@rxM6&gt;

We had no derivatives or outstanding contracts in place through the period ended September 30, 2019 and for the year ended December 31, 2018.

*Measures of Liquidity and Capital Resources*

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

	<u>Nine Months Ended September 30,</u> <u>2019</u> <u>AS</u>	<u>Year Ended December 31,</u> <u>2018</u> <u>AS</u>
Cash and cash equivalents	34,485,732	11,797,789
Working capital (current assets less current liabilities)	31,376,651	50,830,568
Ratio of current assets to current liabilities	4.97 : 1	4.85 : 1
Shareholders' equity per common share	0.26	0.29

The movement in cash and cash equivalents and working capital during the above periods was primarily due to the receipt of the lump sum service fee of US\$ 31,503,880 from LifeScan on February 18, 2019 offset by acquisition of assets from Siemens pursuant to the Siemens Acquisition during September 2019.

We have not identified any collection issues with respect to receivables.

*Summary of Cash Flows*

	<u>Nine Months Ended September 30,</u> <u>2019</u> <u>AS</u>	<u>2018</u> <u>AS</u>
Cash provided by/(used in):		
Operating activities	30,119,844	864,431
Investing activities	(10,247,729)	(306,087)
Financing activities	3,400	(256,410)
Net increase in cash, cash equivalents and restricted cash	19,875,515	301,934

Our net cash provided by operating activities for all periods represents receipts offset by payments for our research and development projects including efforts involved in establishing and maintaining our manufacturing operations and general and administrative expenditure. We also serviced our long term secured loan during 2018 prior to it being fully repaid in November 2018. An increase in operating cash flows primarily resulted from the receipt of the lump sum service fee of US\$ 31,503,880 from LifeScan pursuant to the LifeScan Conversion on February 18, 2019 offset by working capital maintenance generally.

Our net cash used in investing activities for all periods is primarily for the purchase of various equipment and for the various continuous improvement programs we are undertaking. Additionally, during September 2019, the Company acquired certain assets from Siemens pursuant to the Siemens Acquisition.



**Off-Balance Sheet Arrangement**

The future minimum lease payments under non-cancellable operating leases (with initial or remaining lease terms in excess of one year) as of September 30, 2019 are:

	AS
Less than 1 year	652,691
1 – 3 years	933,497
3 – 5 years	3,867
More than 5 years	0
<b>Total minimum lease payments</b>	<b><u>1,590,055</u></b>

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

This off-balance sheet arrangement is not reasonably likely to have a material impact on financial condition, changes in financial condition, results of operations, or liquidity.

**Segments**

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

We operate predominantly in one geographical area, being Australia.

The Company's material long-lived assets are all based in Australia.



**Item 3 Quantitative and Qualitative Disclosures About Market Risk**

As a “smaller reporting company”, we are not required to provide the information called for by this Item.



**Item 4. Controls and Procedures**

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

*Changes in Internal Control over Financial Reporting.* During the fiscal quarter ended September 30, 2019, there were no changes in the Company's internal control over financial reporting identified in connection with the evaluation referred to above in this Item 4 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**PART II****Item 1 Legal Proceedings**

None.

**Item 1A Risk Factors**

In addition to the other information discussed in this report, the factors described in Part I, Item 1A. "Risk Factors" in our 2018 Annual Report on Form 10-K filed with the SEC on February 22, 2019 should be considered as they could materially affect our business, financial condition or future results. There have not been any significant changes with respect to the risks described in our 2018 Form 10-K, but these are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may adversely affect our business, financial condition or operating results.

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

There has been no sale of equity securities by the Company or purchase of equity securities by the Company, or by an affiliated purchaser on behalf of the Company, since December 31, 2018.

**Item 3 Defaults Upon Senior Securities**

None.

**Item 4 Mine Safety Disclosures**

Not applicable.

**Item 5 Other Information****Termination of a Material Definitive Agreement**

As discussed in "Notes to Consolidated Condensed Financial Statements (Unaudited) – Organization of the Company", the Collaboration Agreement between the Company and Siemens was terminated on September 18, 2019. Under the terms of the Collaboration Agreement we collaborated with Siemens on the development of coagulation-related test strip products. The Collaboration Agreement was terminated in connection with the entrance of the Company into the 2019 Siemens Agreements which were previously disclosed on our Current Report on Form 8-K filed on August 22, 2019 (Item 1.01 of which is incorporated by reference herein), on our Current Report on Form 8-K filed on September 9, 2019 (Item 1.01 of which is incorporated by reference herein), and on Current Report on Form 8-K filed on September 23, 2019 (Item 1.01 of which is incorporated by reference herein).

**Item 6 Exhibits**

Exhibit No	Description	Location
10.23	<a href="#">Siemens and Universal Biosensors Definitive Agreements executed on September 18, 2019</a> Portions of the exhibit have been omitted in the exhibit index of the SEC filing with which the redacted exhibit is filed or incorporated by reference	Filed herewith
31.1	<a href="#">Rule 13a-14(a)/15d-14(a) Certification (Interim Principal Executive Officer)</a>	Filed herewith
31.2	<a href="#">Rule 13a-14(a)/15d-14(a) Certification (Principal Financial Officer)</a>	Filed herewith
32	<a href="#">Section 1350 Certificate</a>	Furnished herewith
101	The following materials from the Universal Biosensors, Inc. Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Condensed Balance Sheets, (ii) the Consolidated Condensed Statements of Comprehensive Income/(Loss), (iii) the Consolidated Condensed Statements of Changes in Stockholder's Equity and Comprehensive Income/(Loss), (iv) the Consolidated Condensed Statements of Cash Flows and (v) the Notes to Consolidated Condensed Financial Statements	Filed herewith





**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: November 4, 2019

By: /s/ Salesh Balak  
Salesh Balak  
Interim Principal Executive Officer

Date: November 4, 2019

By: /s/ Salesh Balak  
Salesh Balak  
Principal Financial Officer



**Exhibit 10.23**

\*Certain identified information has been excluded from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed. The redacted confidential portions of the exhibit are marked by [\*\*\*].

**COMMERCIAL & DISTRIBUTION AGREEMENT**

between

**Siemens Healthcare Diagnostics Inc.**

and

**Universal Biosensors Pty Ltd.**

This Commercial and Distribution Agreement, dated as of September 18, 2019 (the “Distribution Agreement”) is between Siemens Healthcare Diagnostics Inc., incorporated in California and whose registered office is at 511 Benedict Avenue, Tarrytown, New York 10591 (“SHDI”) and Universal Biosensors Pty Ltd. (“UBI”), whose registered office is at 1 Corporate Avenue, Rowville, Victoria 3178, Australia, (collectively, “UBI” and together with SHDI, the “Parties”).

**Background**

WHEREAS, on September 9, 2011, UBI and SHDI entered into a Collaboration Agreement and a Letter Agreement, on September 20, 2012 a Supplemental Agreement, on December 12, 2014 a Xprecia Stride Letter Agreement, and subsequent various amendments to the Collaboration Agreement (such amendments together with the Collaboration agreement collectively, the “Collaboration Agreement”) under which, among other things, UBI and SHDI agreed to collaborate together on UBI’s development of a Stride Strip Product to be used in conjunction with an associated Stride Instrument for SHDI to sell in the hospital point-of-care coagulation market subject to the terms and conditions set forth in the Supply Agreement;

WHEREAS, on September 9, 2011, UBI and SHDI entered into a Collaboration Agreement and a Letter Agreement, on September 20, 2012 a Supplemental Agreement, on December 12, 2014 a Xprecia Stride Letter Agreement, and subsequent various amendments to the Collaboration Agreement (collectively, the “Collaboration Agreement”); and whereas on September 20, 2012, SHDI and UBI entered into a Supply Agreement (the “Supply Agreement,” and collectively with the Collaboration Agreement, the “Agreements”);

WHEREAS, the Parties now wish to amend the commercial relationship between the Parties and enter into this Distribution Agreement whereby, among other commercial terms, SHDI shall provide UBI with Stride Instruments as described herein after the execution of this Distribution Agreement (the “Execution Date”) for UBI to distribute; and

WHEREAS, [\*\*\*].

Now, THEREFORE, in consideration of the mutual promises, the Parties hereto agree as follows:

**ARTICLE 1 DEFINITIONS**

“**Execution Date**” shall mean the date of execution of this Agreement.



“**Field**” shall have the meaning given in Exhibit 1 attached.

[\*\*\*]

[\*\*\*]

“**Prime Instruments**” shall mean the handheld analyzer developed by UBI and manufactured for SHDI (also often referred to as the Prime reader or meter) [\*\*\*].

“**Prime Product**” shall mean collectively the Prime Instrument, the Prime Strip Product, and any Prime Product Accessories.

“**Prime Strip Product**” shall mean [\*\*\*].

[\*\*\*]

“**Specifications**” shall mean [\*\*\*].

“**Stride Instruments**” shall mean the handheld analyzer developed by UBI and manufactured for SHDI (also often referred to as the Stride reader or meter) that is capable of reading and reporting results for Stride Strip Products and contains the XPRECIA STRIDE brand name.

“**Stride Strip Product**” shall mean a PT/INR strip product manufactured by UBI for SHDI and containing the XPRECIA STRIDE brand name.

“**Stride Product**” shall mean collectively the Stride Instrument, Stride Strip Product, and any Stride Product Accessories, including LQC kits (as defined below).

“**Territory**” shall mean global territory, unless otherwise explicitly stated.

All currency in this Distribution Agreement is in United States Dollars, unless otherwise explicitly stated.



Other terms are defined below:

**ARTICLE 2 DISTRIBUTION ARRANGEMENT BETWEEN THE PARTIES**

**2.1 Distribution Rights**

SHDI hereby relinquishes its exclusive right to commercialize and distribute the Stride Product and Prime Product, and all components thereof individually or collectively, to the professional Point of Care market segment, except SHDI retains non-exclusive distribution and other rights set forth in the Agreements only to the extent necessary to fulfill existing contracts for the Stride Product [\*\*\*]. SHDI relinquishes all distribution and other rights to the Stride Product and the Prime Product, and all components thereof individually or collectively, under the Agreements for all applicable markets upon the Execution Date. For the avoidance of doubt, the rights transferred to UBI pursuant to this Distribution Agreement include, among other things, any rights and/or obligations necessary to seek regulatory registration and approval with respect to the Stride Product, the Prime Product, or any other product, and all components thereof individually or collectively, in jurisdictions whether or not the Stride Product or Prime Product is currently sold there, or where additional or further regulatory registrations and/or approvals are or become necessary, which rights shall include but not be limited to: (i) disclosing any information necessary to the relevant regulatory entity, (ii) completing and submitting any required documentation related to the registration and approval, and (iii) any other action UBI shall determine in its sole discretion is necessary with respect to seeking such registration or approval. [\*\*\*].

SHDI agrees to comply with the following obligations to enable UBI to fulfill its role as a distributor:

**2.2 SHDI's Distribution Arrangement Obligations**

- (a) Within five (5) days of the Execution Date, SHDI shall send a letter to [\*\*\*] stating that that SHDI consents to [\*\*\*] manufacturing any brand of instruments for UBI [\*\*\*]. UBI acknowledges that SHDI is not responsible for [\*\*\*] agreement to UBI's manufacturing terms.
- (b) After the [\*\*\*], Siemens is no longer responsible for any Stride Instruments and/or alternative instrument (excluding the Stride Instruments described in 2.2(d) below) that [\*\*\*] manufactures for UBI, and SHDI will not be involved in any relationship going forward between UBI and [\*\*\*], although Siemens will provide any necessary support to UBI and [\*\*\*] to the extent it is able to do so.
- (c) Within five (5) days of the Execution Date, SHDI shall provide to UBI in writing the information listed and as agreed to in Exhibit 2 to this Distribution Agreement.
- (d) [\*\*\*]. Except as for matters directly related to actions mandated by the SHDI quality/regulatory system or by regulatory authorities, SHDI shall in no way discourage its customers from using the Stride Product or any components thereof.
- (e) SHDI hereby appoints UBI exclusively to distribute and receive payment for approximately [\*\*\*] Stride Instruments, which shall come in the manufacturer's final box packaging, that are currently in SHDI's inventory. UBI may distribute the Stride Instruments directly or through



UBI-appointed distributors. Projected inventory is subject to changes based upon [\*\*\*]. The final inventory amount shall be contained on Exhibit 2. For each instrument less than [\*\*\*] provided by SHDI, SHDI shall pay to UBI [\*\*\*] per instrument for each instrument. For each instrument less than [\*\*\*] provided by SHDI, SHDI shall pay to UBI [\*\*\*] per instrument for each instrument.

- (f) SHDI shall provide UBI the Stride Instruments referenced above in Section 2.2(d) as follows:
  1. UBI shall place purchase orders in writing at times to be determined solely by UBI, such purchase orders shall in no case be for fewer than [\*\*\*].
  2. After receipt of such written purchase order, SHDI shall have no longer than [\*\*\*] (the "Lead Time") to deliver the order to the country of destination designated by UBI, provided that any additional time required to clear customs in any jurisdiction that requires such clearance shall not be included in the [\*\*\*].
  3. All purchase orders to be delivered to a facility designated by UBI. SHDI shall ship Stride Instruments to UBI in increments of [\*\*\*] at a time pursuant to the installment schedule determined by the Parties and at UBI's cost to a designated facility of UBI's choosing. The address of such designated facility to be provided to SHDI within [\*\*\*] from the Execution Date of the Agreement or with the first purchase order whichever is sooner.
  4. [\*\*\*].
  5. After the end of [\*\*\*], SHDI shall ship any remaining Stride Instruments as described in Section 2.2(d) to the designated UBI facility.
- (g) In addition to UBI's right to sell, market, and distribute Stride Instruments, [\*\*\*], SHDI hereby appoints UBI to market and sell to customers the Stride Strip Products, including those bearing Siemens' brand, directly or through UBI-appointed distributors in connection with the sale by UBI or any partner of its choosing, of the Stride Instruments as set forth in clause (d) above. UBI can also sell non-Siemens branded strips that are compatible with the Stride Instrument in connection with the Stride Instruments referenced in clause (d) above at its discretion, [\*\*\*]. [\*\*\*].
- (h) UBI shall have the right to use the SHDI brand in connection with its sales, distribution, and marketing of Stride Products, or any components thereof, [\*\*\*]. [\*\*\*], provide service and support for the distribution and sale of all Stride Products, or any components thereof, to SHDI customers. [\*\*\*]. For the avoidance of doubt, UBI may sell non-Siemens branded strips to any customers who are still using Siemens-branded instruments [\*\*\*]. During all times that UBI is selling the Stride Product, UBI will adhere to the current arrangement in terms of quality assurance.
- (i) During the [\*\*\*], SHDI will make available to UBI for purchase an adequate number (which number shall be determined between the Parties) of [\*\*\*] for the Stride Product which have been sold by UBI. If SHDI is unable to continue supplying UBI with [\*\*\*] beyond [\*\*\*], SHDI will assist UBI in its efforts to establish uninterrupted supply of [\*\*\*] beyond [\*\*\*] with the supplier of [\*\*\*]. [\*\*\*].



- (j) SHDI will support UBI in its efforts to identify and appoint distributors [\*\*\*]. [\*\*\*].
- (k) SHDI to collaborate with UBI on customer transition as may be agreed between the Parties' designated marketing and sales representatives.
- (l) SHDI shall purchase at least [\*\*\*] during [\*\*\*] at the contractually stated strip price contained in Exhibit 2. SHDI shall make a [\*\*\*] prepayment for such [\*\*\*] to UBI in cash to a bank account specified by UBI on or before [\*\*\*]. This amount shall be applied by UBI against all invoices delivered by UBI to SHDI for [\*\*\*] after the Execution Date of this Distribution Agreement. After the [\*\*\*] is fully deducted from invoices payable by SHDI to UBI, SHDI will make payment on any invoices for Stride Strip Product purchases delivered by UBI to SHDI in cash promptly upon receipt thereof.
- (m) SHDI's commitment to purchase [\*\*\*] shall terminate when SHDI has completed payment for [\*\*\*] at the contractually stated strip price contained in Exhibit 2, which in any event shall occur no later than the end of [\*\*\*]. The Parties acknowledge that SHDI may have contractual commitments that extend beyond [\*\*\*]. In such circumstances, the Parties agree to discuss in good faith how to manage such customers and reach an amicable outcome for the Parties and the applicable customer, including Siemens shall have the option to purchase additional [\*\*\*] at the contractual price contained herein for a reasonable time beyond [\*\*\*].
- (n) [\*\*\*] shall have a minimum shelf life of [\*\*\*] when received by SHDI. SHDI shall provide a [\*\*\*] forecast of anticipated [\*\*\*] purchasing needs with only [\*\*\*] of such forecast binding on the Parties.

**2.3 UBI's Distribution Arrangement Obligations**

- (a) UBI represents that it (with its principals and employees) possesses the technical know-how, resources, infrastructure, and ability to sell the Stride Instruments manufactured by or for SHDI and intends to sell the Stride Instruments and Stride Strip Products described in section 2.2. (e) on the terms set forth herein and in the Territory independently and not through a sales agent or other representative of any third-party other than SHDI.
- (b) SHDI is desirous of having UBI sell the Stride Instruments in such Territory on the terms and conditions set forth herein.

**2.4 UBI's Stride Strip Product Supply Obligations**

UBI's supply of Stride Strip Products is controlled by the Parties' Supply Agreement which remains in effect except as otherwise modified. In the event there is a conflict between this Distribution Agreement and the Supply Agreement, this Distribution Agreement shall control and prevail.



**2.5 Failure to Supply Event to Enforce Bank Guarantee**

If UBI fails to deliver to SHDI the full quantity of [\*\*\*] requested by Siemens to be delivered in such month, to the extent such Purchase Order is submitted by SHDI with sufficient lead-time as set forth in Section 4.1 of the Supply Agreement, is consistent with Siemens' forecasts, which forecasts shall have been delivered to and accepted by UBI as of the terms of the Supply Agreement, and does not exceed UBI's supply commitment; and except to the extent such failure or delay is caused by Force Majeure or by SHDI's failure or delay in delivering any applicable [\*\*\*] in sufficient quantity necessary to produce the quantity of such [\*\*\*] requested, *then*, UBI will endeavor to advise SHDI in advance of any inability to make full and timely delivery of [\*\*\*] which SHDI has ordered. UBI has an opportunity to cure such failed supply within [\*\*\*], assuming opportunity to cure is not deemed futile. If the supply issue is not cured within [\*\*\*], a Failure to Supply Event has occurred and SHDI shall be entitled to enforce the Bank Guarantee (defined below) attached hereto as Exhibit 3. For the avoidance of doubt, Section 1.12 of the Parties' Supply Agreement is not replaced by this Section and shall still be binding on the Parties.

**ARTICLE 3 MANUFACTURING CHANGE REQUESTS BY UBI**

UBI shall at all times retain all manufacturing rights with respect to the Stride Strip Product, including all rights to subcontract its manufacturing and/or relocate its manufacturing facility and/or change its strip manufacturing procedures ("Manufacturing Changes"). [\*\*\*]. [\*\*\*]. The Parties shall negotiate in good faith to resolve any issues with Manufacturing Changes.

**3.1 Manufacturing Process and Calibrations**

UBI intends to implement a master lot/working lot calibration process, and shall seek SHDI's prior review and approval, which approval or denial shall not be unreasonably withheld or delayed and shall be delivered no later than three (3) months after any such request by UBI.

**3.2 Manufacturing Process and Shelf Life**

UBI intends to implement [\*\*\*] expiration extensions providing at least [\*\*\*] shelf life for the [\*\*\*] and shall seek SHDI's prior review and approval, which approval or denial shall be delivered no later than [\*\*\*] from such request by UBI. [\*\*\*].

**3.3 Last-Time Buy**

SHDI may make a last time buy by [\*\*\*]. Last time buy means the last purchase by SHDI which may consist of quantities of [\*\*\*] higher than forecasted volumes due to SHDI's requirement to provide the [\*\*\*] to the end of its life cycle. Such quantities to be agreed to by the Parties and shall be within the production capacity of UBI.

**ARTICLE 4 PRODUCT REGISTRATION**

SHDI commits to maintain any required and already obtained regulatory product registrations for the [\*\*\*] in countries where SHDI currently generates revenue from sales of the Stride Product. [\*\*\*], UBI is responsible for any product registrations for any non-Siemens branded Stride Instrument or alternative instrument. The Parties shall designate representatives to coordinate such filings between the Parties [\*\*\*].



**4.1 Re-registration**

UBI acknowledges that a UBI Manufacturing Change may require SHDI to re-register the Stride Product in certain jurisdictions, which may involve additional resource commitments and expenses for SHDI. At least [\*\*\*] prior to implementing any Manufacturing Change, the Parties shall discuss UBI's proposed Manufacturing Change(s), and if: (i) the aggregate of all such reasonable registration related costs incurred by SHDI over the [\*\*\*] for the Manufacturing Change(s) would exceed [\*\*\*] and (ii) SHDI does not withhold approval pursuant to Article 3 above, UBI will reimburse Siemens for any reasonable registration related expenses incurred and documented by Siemens that exceed [\*\*\*] and/or UBI may propose other solutions for the Parties to consider and negotiate in good faith. [\*\*\*].

**ARTICLE 5 OPERATIONS**

**5.1 Acceptance of Stride Instrument Supplied by SHDI**

- (a) All orders for the Stride Instrument that SHDI receives from UBI are subject to acceptance by SHDI. UBI will place orders and place delivery schedules with SHDI for its requirements in accordance with the agreed upon Lead Time. SHDI's Lead Time may be amended from time to time upon no less than [\*\*\*] days prior written notice from SHDI to UBI so that adequate inventory is maintained, and only upon agreement of all Parties. UBI should attempt, as a matter of course, to determine the availability of [\*\*\*] before making any binding commitment to supply to customers.
- (b) SHDI will use commercially reasonable efforts to fill the accepted orders as promptly as practicable, subject, however, to any delays caused by other orders or requirements, transportation conditions, labor or material shortages, governmental restrictions or embargo, strikes, riots, fires, acts of God, or any other cause beyond the reasonable control of SHDI. In all cases SHDI will endeavor to advise UBI in advance of any inability to make full and timely delivery of any Stride Instruments which UBI has ordered.

**5.2 Delivery**

- (a) All Stride Instruments ordered by UBI shall be packed for shipment and storage in accordance with SHDI's standard commercial practices, provided that SHDI packages, labels, stores, and supplies shall be in compliance and in accordance with: (i) all applicable local, state, federal and national laws, regulation, rules, guidelines and procedures, including but not limited to the U.S. Federal Food, Drug and Cosmetic Act, as amended, and the regulations issued thereunder; (ii) applicable standards relating to current good manufacturing practices for the type of Stride Instrument furnished hereunder promulgated by any governmental authority having jurisdiction over the manufacture and sale of such products, in the form of laws, statutes, regulations, or guidance documents; and (iii) the Stride Instrument product Specifications. SHDI shall bear all costs associated with label printing, labeling, and packaging of the Stride Instrument.
- (b) [\*\*\*]. Accordingly, UBI agrees to properly disclose and appropriately reflect the credit or reduction in price in any costs claimed or charges made to Medicare, Medicaid or other federal or state health insurance programs which reimburse the products and require such disclosure.





200GWTTVj9T%@q66^

**5.3 Acceptance of Stride Instruments**

- (a) UBI shall inspect all shipments of Stride Instruments received from SHDI for conformity with its orders. UBI shall notify SHDI and the carrier if any of the Stride Instruments are damaged, missing or not in conformity with UBI’s order (“Non-Conforming”), as soon as possible, and no later than eight (8) calendar days after receipt of the Stride Instruments. UBI’s failure to do so will be deemed a waiver of any such claims, except in the case of latent defects not discoverable by normal incoming inspection procedures. The Stride Instrument will be held by UBI at UBI’s risk.
- (b) Upon receipt of UBI’s notification that any Stride Instrument is Non-Conforming, SHDI may elect to inspect the Stride Instrument. If SHDI agrees that the Stride Instrument is Non-Conforming and that such defect or Non-Conformity is attributable to SHDI shall replace or correct such Stride Instrument or if replacement is not possible, SHDI shall reimburse UBI, as UBI’s sole remedy.
- (c) Unless SHDI has expressly authorized or permitted the return of any Stride Instrument Products hereunder, SHDI shall not be obligated to accept from UBI any Stride Instruments returned, nor to make any exchange thereof.
- (d) Except in the case of damage or defect attributable to SHDI as notified to SHDI pursuant to this Article 5 or warranty claims, UBI shall not make any claims against SHDI for any Non-Conforming Stride Instruments.

**ARTICLE 6 OUTSTANDING PAYMENT OBLIGATIONS**

As promptly as practicable after the Execution Date, (i) UBI shall extinguish [\*\*\*] of outstanding purchase orders related to the Collaboration Agreement and (ii) SHDI shall extinguish [\*\*\*] that was paid to UBI pursuant to Section 3.2 of the Supply Agreement.

**ARTICLE 7 BUSINESS DEVELOPMENT SUPPORT**

SHDI will support UBI in good faith in the establishment of an agreement with another partner, [\*\*\*]. Such support will include, but is not limited to, [\*\*\*]. [\*\*\*]. [\*\*\*].

**ARTICLE 8 UBI PERFORMANCE GUARANTEE**

A performance guarantee [\*\*\*] shall be held in a UBI bank account with Commonwealth Bank of Australia, [\*\*\*]. SHDI shall be under no obligation to deliver the Stride Instruments referenced herein in section 2.2(d), (e), and (f), until SHDI’s receipt of a fully-effectuated Bank Guarantee from UBI. In the event that this Distribution Agreement is terminated due to a breach of this Distribution Agreement by UBI, (such breach either not disputed by UBI or admitted by UBI or breach finally determined in accordance with the dispute resolution procedures in Article 14 of the Supply Agreement) or due to UBI’s insolvency as set forth in Section 17.1(b), the Bank Guarantee shall survive such termination.



**ARTICLE 9 [\*\*\*]**

**9.1 [\*\*\*]**

[\*\*\*]. [\*\*\*]. [\*\*\*]. [\*\*\*]. [\*\*\*]. [\*\*\*]. [\*\*\*]. [\*\*\*].

**9.2 [\*\*\*]**

[\*\*\*].

**ARTICLE 10 TERM**

This Distribution Agreement shall commence on the Execution Date and shall continue in full force and effect until [\*\*\*], unless extended by mutual written agreement by the Parties' or their authorized representatives, unless sooner terminated as provided herein.

**ARTICLE 11 INTELLECTUAL PROPERTY LICENSES**

**11.1 [\*\*\*]**

- (a) [\*\*\*]. [\*\*\*].
- (b) [\*\*\*]. [\*\*\*].
- (c) [\*\*\*].
- (d) [\*\*\*].
- (e) [\*\*\*]. [\*\*\*]. [\*\*\*].
- (f) [\*\*\*]. [\*\*\*].

**11.2 [\*\*\*]**

- (a) [\*\*\*]. [\*\*\*]. [\*\*\*]. [\*\*\*]:  
  - [\*\*\*]. [\*\*\*]. [\*\*\*]. [\*\*\*]. [\*\*\*]. [\*\*\*]. [\*\*\*]. [\*\*\*].

**ARTICLE 12 CONFIDENTIALITY**

**12.1 Parties' Confidential Information**

- (a) This Distribution Agreement, its terms, and the negotiations leading to this agreement are confidential. No Party shall disclose or cause to be disclosed this Distribution Agreement, the terms of this agreement, or any drafts or communications relating to the negotiation of this Agreement to any person not a Party to this Distribution Agreement without the written consent of all Parties. Notwithstanding anything contained within this Section 12, each Party may share this Distribution Agreement, its terms, and any drafts or the negotiations leading to this Agreement, with its respective lawyers, advisors, consultants, accountants and auditors on a need to know basis provided these individuals agree to use and maintain the information in a confidential manner consistent with the provisions contained in this Agreement.



- (b) The parties acknowledge that, as a result of this Distribution Agreement, each may become acquainted with the confidential or proprietary data (“Confidential Information”) of the other party, including data concerning a party’s services, products, business methods, financial information, projections, technology, databases, customer, distributors, supplier, and employee information, Trade Secrets (as defined below), and other information the secrecy of which is valued by the disclosing party. The receiving party shall: (i) hold the disclosing party’s Confidential Information in strict confidence; (ii) refrain from disclosing Confidential Information to any third parties or to its own employees or consultants other than those who need to know the Confidential Information, who are aware of the confidential nature of the Confidential Information, and who have a confidentiality obligation to the receiving party; and (iii) use the Confidential Information only as authorized under this Agreement.
- (b) Notwithstanding anything to the contrary in this Agreement, the receiving party will have no obligation with respect to any Confidential Information which: (i) is already known to the receiving party without any confidentiality undertaking (as evidenced by reasonable supporting documentation in existence as of the date of receipt of the Confidential Information); (ii) is or becomes publicly known through no fault of the receiving party; (iii) is developed by the receiving party independently of the Confidential Information (as evidenced by reasonable supporting documentation); (iv) is approved for release in writing by disclosing party; (v) is required to be disclosed by law or in connection with a request of a court or governmental agency, *provided*, however, that the receiving party will provide the disclosing party with at least ten calendar days’ advance written notice prior to disclosure to permit the disclosing party to obtain a protective order or other similar relief; or (vi) is, to the receiving party’s knowledge, rightfully received from a third party having no secrecy or confidentiality obligation to the disclosing party.
- (c) The receiving party’s obligations under this Distribution Agreement will apply to Confidential Information during the term of this Agreement; provided, however, that for any Confidential Information constituting a trade secret as defined under the California Uniform Trade Secrets Act (“Trade Secret”), as now in force or hereafter amended, or any similar successor law, the receiving party’s obligations will continue to apply to the Confidential Information, [\*\*\*], for so long as the Confidential Information continues to constitute a Trade Secret.
- (d) All documents and other tangible materials embodying Confidential Information (including reports, marketing materials, and other work product prepared by receiving party based wholly or partly on Confidential Information), irrespective of media, will be, at the disclosing Party’s option, promptly returned to the disclosing Party or destroyed by the receiving party (such destruction to be certified by the receiving party) upon thirty (30) calendar days’ notice by the disclosing party.
- (e) In the event either Party desires to disclose the existence of this Agreement or the terms of this Agreement to any third-party not authorized herein, the Party desiring to disclose such information, shall request permission from the other Party in writing. The confidentiality obligations set forth in this Article 12 continue beyond the termination or expiration of this Distribution Agreement.



**ARTICLE 13 Facilities, Books and Records**

**13.1 Audit Rights**

- (a) SHDI (or a third party retained by SHDI) shall be entitled to conduct an audit of UBI upon reasonable prior notice, to ensure UBI's performance under this Agreement or any related agreement, *provided* that SHDI shall not be entitled to conduct more than one (1) audit every year.
- (b) SHDI can conduct an audit of UBI if SHDI has obtained good faith information which indicates that UBI:
  - (i) may have breached any of its obligations, representations or warranties under this Agreement; or
  - (ii) may have good cause to terminate the Agreement in accordance with this Distribution Agreement.
- (c) UBI agrees to fully cooperate in any audit to which it may be subject and agrees to keep and make available in the case of audit, books and records relating to its obligations under this Distribution Agreement.
- (d) UBI agrees to make available its facilities and warehouses available for audit and inspection pursuant to the terms in this Article.
- (e) UBI's failure to comply with this Article shall constitute a material breach for purposes of this Agreement. Notwithstanding any other provision or this Agreement, the rights of SHDI hereunder shall be specifically enforceable in any court of competent jurisdiction.

**ARTICLE 14 OTHER OBLIGATIONS OF THE PARTIES**

**14.1 Insurance**

The Parties shall procure and maintain in full force and effect during the term of this Distribution Agreement valid insurance policies, through an insurance carrier possessing at least an A.M. Best Rating of "A-", in connection with its activities as contemplated hereby, which policies shall provide for appropriate insurance in a reasonable amount of coverage, but in no event less than the following limits:

- (a) [\*\*\*].
- (b) [\*\*\*]. [\*\*\*]. [\*\*\*]. [\*\*\*].

**14.2 Compliance with Applicable Law**

- (a) The Parties shall comply with the U.S. Foreign Corrupt Practices Act, U.S. and non-U.S. anti-bribery and anti-corruption laws, the Anti-Kick Back law, and all other laws, rules and regulations applicable to this Agreement and to all transactions and activities contemplated by or to be performed hereunder.
- (b) The Parties shall perform their duties under this Distribution Agreement in compliance with all applicable laws and regulations and conduct themselves in a manner that will reflect favorably at all times on the other Party and the Stride Product, and not engage in any deceptive, misleading, or unethical practice that might have a commercially detrimental effect on same.
- (c) UBI shall provide immediate notification to SHDI upon discovery of any potential violation of SHDI Business Conduct Guidelines attached hereto and fully incorporated herein, the U.S. Foreign Corrupt Practices Act, any U.S. or non-U.S. anti-bribery and anti-corruption laws, the Anti-Kick Back law, or any other laws, rules and regulations applicable to this Agreement. Further, UBI shall cooperate with SHDI in any investigation regarding such potential violations.



- (d) The Parties agree to fully comply with the requirements set forth by any applicable legislation in the Territory. [\*\*\*]. [\*\*\*].
- (e) UBI shall be responsible for its own taxes incurred, and Siemens shall be responsible for its own taxes incurred, whether in the Territory or any other country, now or hereafter imposed with respect to the transactions contemplated hereunder.

**14.3 SDHI Business Conduct Guidelines**

- (a) UBI has read and understands the SHDI Supplier Code of Conduct, attached hereto as Exhibit 4, and agrees to comply with this program with respect to its obligations under this Distribution Agreement, and such guidelines are incorporated herein.

**ARTICLE 15 RECALLS**

If SHDI decides to institute a recall of any Stride Instrument from the marketplace (“Product Recall”), whether mandated by local governmental authorities, or instituted by voluntary action, or to undertake any other form of Field Corrective Action (“FCA”) with respect to any Stride Instrument or any component thereof (including software) for safety checks or modifications or, as applicable, installation of appropriate upgrades, software fixes, or related items, then upon notification by SHDI, UBI shall implement the Product Recall (or FCA) as instructed by SHDI. UBI shall inform its customers of the Stride Instrument and end users of the Product Recall (or FCA) in a timely manner and in accordance with the instructional materials provided by SHDI. All reasonable out-of-pocket costs associated with the Product Recall including without limitation, the cost of parts required for such activities and the associated labor costs shall be borne by the party responsible for the Product Recall. Irrespective of the case of the Product Recall, the Parties shall fully cooperate with each other in implementing and managing the Product Recall. If necessary, UBI shall reasonably comply with all medical vigilance or post-market surveillance requirements applicable in the Territory for Product-related corrective actions of the type contemplated herein. [\*\*\*].

**ARTICLE 16 Additional Obligations of the Parties/Representations and Warranties**

**16.1 Additional Obligations of UBI**

- (a) [\*\*\*], UBI shall remove the branding on Siemens’ Stride and Prime Products described in section 2.2(d) that have not been sold to or placed [\*\*\*] to customers (and may replace it with branding of UBI’s choice) and may remove certain packaging and replace batteries for Siemens’ Stride and Prime Products. [\*\*\*], UBI shall not modify the Stride Products, including packaging, labeling, inserts or instructions, apart from batteries, for use, in any way without the prior written consent of SHDI.
- (b) UBI shall store and distribute the Stride Products while containing SHDI and/or XPRECIA STRIDE and/or STRIDE brand in accordance with the conditions shown on the Product’s labeling.
- (c) UBI shall transfer to end customers as soon as reasonably possible all information provided by SHDI and only to the extent such information is in fact provided by SHDI at SHDI’s cost and is necessary for the safe use of the Stride Instrument, including instructions for use, material safety data sheets, customer bulletins and other mandatory safety related documents.



- (d) UBI shall communicate all technical support bulletins to the designated recipient(s) at UBI as they become available. Information contained in technical support bulletins are written specifically for use by qualified support staff and shall be considered confidential and not communicated to third parties without consent from SHDI.
- (e) UBI agrees to provide to its customers a UBI warranty, a copy of which shall also be provided to SHDI for its records.
- (g) UBI shall, subject to applicable data protection laws, make available to SHDI upon request all documentation and information related to performance of this Agreement.

**16.2 Additional Obligations of SHDI**

- (a) SHDI, or its manufacturing partner, shall manufacture, package, label, store, and supply Stride Products in compliance and in accordance with: (i) all applicable local, state, federal and national laws, regulation, rules, guidelines and procedures, including but not limited to the U.S. Federal Food, Drug and Cosmetic Act, as amended and the regulations issued there under; (ii) applicable standards relating to current good manufacturing practices for the type of Stride Products furnished hereunder promulgated by any governmental authority having jurisdiction over the manufacture and sale of such Stride Products, in the form of laws, statutes, regulations, or guidance documents; and (iii) the Stride Products Specifications. [\*\*\*].
- (b) SHDI shall notify UBI immediately in writing should SHDI become aware of any defect or condition which may render any of the Stride Products in violation of the Food, Drug and Cosmetic Act or any other applicable law.
- (c) SHDI shall notify the appropriate federal, state and local authorities of any customer complaints or other occurrences regarding the Stride Products which are required to be so reported in accordance with SHDI compliant procedures as contained in the Parties' Quality Agreement. SHDI shall be responsible for evaluating all complaints regarding the Stride Products. For complaints from SHDI's customers, SHDI shall be responsible for responding to the complaint(s). For UBI customers, UBI shall forward customer complaints to Siemens and Siemens shall provide the results of its applicable evaluation to UBI to inform UBI's response to its customer(s). If a customer complaint is related to the Stride Strip Product, UBI is responsible for evaluating the complaint.

**16.3 SHDI Representations and Warranties**

- (a) [\*\*\*]. The provisions of the warranty provided by SHDI and attached hereto ("SHDI Warranty") are UBI's sole and exclusive remedy in respect of any claim for Stride Products, but excluding the Stride Strip Products, defect or breach of warranty.
- (b) To the extent any nonperformance of the Stride Product is caused by the nonperformance of the Stride Strip Product, SHDI representations and warranties shall not apply.
- (c) SHDI represents and warrants that: (i) it has the full right, power, and corporate authority to enter into this Agreement and to make the promises set forth in this Agreement and there are no outstanding agreements, assignments or encumbrances in existence inconsistent with the provisions of this Agreement; (ii) no actions are threatened or pending before any court or governmental authority or other tribunal relating to the Stride Product that would affect SHDI's ability to perform its obligations hereunder; (iii) the Stride Product will not contain



any material other than those specifically listed in the Product specification; (iv) the Stride Product and SHDI's manufacturing processes and methods do not infringe on the intellectual rights of any third party, and; (v) its employees, agents or representatives performing services or supplying products, parts, or raw materials in connection with the Stride Product and/or this Agreement, are not now nor have ever been: (a) convicted of a criminal offense related to health care; or (b) excluded, debarred, or otherwise ineligible for participation in a U.S. "Federal health care program" as defined in 42 U.S.C. '1320a-7b(f) (or any applicable successor statutory section) or in any other government payment program. SHDI hereby further certifies that it will immediately notify UBI upon its receipt of any indication, whether or not official, that SHDI, its employees, agents or representatives performing services or supplying products, parts, or raw materials in connection with the Stride Product and/or this Agreement, shall be excluded from any U.S. Federal health care program, as defined above, for any reason during the Term.

- (d) OTHER THAN AS EXPRESSLY SET FORTH IN THIS AGREEMENT AND THE SUPPLY AGREEMENT, THE PARTIES EACH HEREBY DISCLAIM ALL WARRANTIES, EXPRESS AND IMPLIED, IN CONNECTION WITH THIS AGREEMENT AND THE PRODUCTS, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, CLEAR TITLE, OR NON-INFRINGEMENT. NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, THE ENTIRE LIABILITY OF EITHER PARTY IN RELATION TO ANY PRODUCTS AND / OR ANY ASSOCIATED ADVICE OR SERVICES, WHETHER BY REASON OF ANY REPRESENTATION (UNLESS FRAUDULENT) OR ANY IMPLIED WARRANTY, CONDITION OR OTHER TERM OR ANY DUTY AT COMMON LAW (INCLUDING TORT AND NEGLIGENCE) OR UNDER THE AGREEMENT SHALL NOT EXCEED THE PRICE OF THE RELEVANT PRODUCTS.
- (e) SHDI specifically warrants to UBI that the Stride Product as of the date of shipment to UBI or its designee and until expiration of the Product's label expiration date: (a) conform to the applicable Specifications and claims made by SHDI for the Stride Products; (b) comply with all legal standards; and (c) are free from defects in design, workmanship and materials.

**ARTICLE 17 TERMINATION**

**Section 17.1 Right to Terminate**

- (a) Either party may terminate this Agreement in writing with immediate effect if the other party neglects or fails to perform, observe, or correct a material breach of its obligations under this Agreement to the non-breaching party within thirty (30) calendar days of written notice indicating the nature of the breach. The non-breaching party may terminate this Agreement immediately upon notice to the breaching party if the material breach triggering such termination is not curable.
- (b) This Agreement may be terminated by either party with immediate effect if a regulatory authority of competent jurisdiction has determined the other Party shall be subject to insolvency or bankruptcy proceedings or the other Party has initiated insolvency and/or bankruptcy proceedings. In the event that UBI becomes insolvent during [\*\*\*] and has not fulfilled its [\*\*\*] obligations equal to [\*\*\*], then SHDI may seek from UBI reimbursement of the outstanding monetary amount equal to the volume [\*\*\*] that have not been supplied, whether or not this Distribution Agreement has already terminated.



- (c) This Agreement may be terminated by either Party with immediate effect if the other party consolidates, merges or sells all or substantially all of its assets to a direct competitor of the other Party without the other Party’s prior written consent, or assigns or attempts to assign this Agreement without the other Party’s prior written consent.
- (d) Any post-termination rights of a Party as contained in the Parties’ Supply Agreement are incorporated herein.
- (e) [\*\*\*]. [\*\*\*].

**17.2 Applicability of Terms After Termination**

- (a) In the event of a breach of this Agreement by UBI where UBI does not dispute such breach, UBI shall, at SHDI’s request:
  - (i) [\*\*\*]
  - (ii) [\*\*\*]
  - (iii) [\*\*\*].
- (b) Applicability of Terms after Termination:
  - (i) In the event of termination or expiration, this Agreement shall, remain applicable to any orders for Products which UBI has previously placed with SHDI. In the event that termination occurs due to UBI’s breach, SHDI shall fill UBI’s previously orders solely at SHDI’s discretion.

**Article 18 Limitation on Liability/Indemnification**

**18.1 Limitation on Liability**

Except as provided in the Bank Guarantee, in no event shall either Party’s liability hereunder exceed the actual loss or damage sustained by the other party, up to the purchase price of the Products giving rise to such loss or damage during the year in which the loss or damage occurred. **NEITHER PARTY SHALL BE LIABLE FOR ANY LOSS OF USE, REVENUE OR ANTICIPATED PROFITS, COST OF SUBSTITUTE PRODUCTS OR SERVICES, LOSS OF STORED, TRANSMITTED OR RECORDED DATA, OR FOR ANY INDIRECT, INCIDENTAL, UNFORESEEN, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT OR THE SALE OR USE OF THE PRODUCTS.** This provision does not affect third party claims for personal injury arising as a result of a Party’s negligence or, or a Party’s indemnification obligations for third-party claims to the extent set out in this Agreement. **THE FOREGOING IS A SEPARATE, ESSENTIAL TERM OF THIS AGREEMENT AND SHALL BE EFFECTIVE UPON THE FAILURE OF ANY REMEDY, EXCLUSIVE OR NOT.**

**18.2 UBI Indemnification**

UBI’s indemnification obligations under the Collaboration Agreement Section 17.2 are incorporated herein. UBI will also defend and otherwise hold harmless SHDI from any third-party claim, loss, damage, or liability (“Third-Party Claim”) that is due to: (i) UBI’s misrepresentations or omissions





with respect to the Products; (ii) UBI's failure to perform any covenants of UBI in this Agreement; and (iii) UBI's violation of law. Notwithstanding the foregoing, in no event will UBI's indemnification obligations apply to any Third-Party Claim caused by SHDI's acts or omissions.

**18.3 SHDI Indemnification**

SDHI's indemnification obligations under the Collaboration Agreement Section 17.1 are incorporated herein. SHDI will also defend and otherwise hold harmless UBI from any Third-Party Claim that is due to: (i) SHDI's misrepresentations or omissions with respect to [\*\*\*]; (ii) SHDI's failure to perform any covenants of SHDI in this Agreement; and (iii) SHDI's violation of law. Notwithstanding the foregoing, in no event will SHDI's indemnification obligations apply to any Third-Party Claim caused by UBI's acts or omissions.

**18.4 Indemnification Procedures**

If either Party believes that it may be entitled to indemnification under this Agreement (an "Indemnified Party"), it shall give written notice to the Party obligated to indemnify it (an "Indemnifying Party") with reasonable promptness upon becoming aware of any Third-Party Claim or other facts upon which a claim for indemnification will be based. Such notice shall set forth such information with respect thereto as is then reasonably available to the Indemnified Party. The Indemnifying Party shall have the right to control the defense of any such Third-Party Claim, including the selection and management of counsel reasonably satisfactory to the Indemnified Party. The Indemnified Party shall cooperate in such defense and make available all records, materials and witnesses reasonably requested by the Indemnifying Party in connection therewith at the Indemnifying Party's expense. If the Indemnifying Party shall have assumed the defense of the Third-Party Claim with counsel reasonably satisfactory to the Indemnified Party, the Indemnifying Party shall not be liable to the Indemnified Party for any legal or other expenses (other than for reasonable costs of investigation) subsequently incurred by the Indemnified Party in connection with the defense thereof. The Indemnifying Party shall not be liable for any Third-Party Claim settled without its consent, which consent shall not be unreasonably withheld or delayed. The Indemnifying Party shall obtain the written consent of the Indemnified Party prior to ceasing to defend, settling or otherwise disposing of any Third-Party Claim if as a result thereof the Indemnified Party would become subject to injunctive or other equitable relief or if the Indemnified Party may reasonably object to such disposition of such Third-Party Claim based on an adverse effect on the Indemnified Party.

**18.5 Indemnification of Infringement Claims**

[\*\*\*]. [\*\*\*]. [\*\*\*]. [\*\*\*]. [\*\*\*]. [\*\*\*]. [\*\*\*].

**Section 18.6 Dispute Resolution**

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



The provisions set forth in this Article 18 shall survive the termination or expiration of this Distribution Agreement.

**ARTICLE 19 INTERPRETATION AND ENFORCEMENT**

**Section 19.1 Notices**

All notices required under this Agreement shall be sent by registered or recorded delivery air mail letter, postage pre-paid and return receipt requested, or by a reputable international courier providing proof of delivery, and shall be deemed duly given on the day on which the notice is received, unless otherwise expressly specified herein.

Notices shall be addressed:

In the case of SHDI, to:

Siemens Healthcare Diagnostics Inc.  
Attn.: Head of Point of Care, Laboratory Diagnostics ]  
Address: 2 Edgewater Drive, Norwood, MA 02062

or to such other person or address as SHDI may from time to time furnish to UBI.

With a copy to:

Siemens Healthcare Diagnostics Inc.  
Legal Department  
Attn.: General Counsel  
511 Benedict Avenue  
Tarrytown, NY 10591

In the case of UBI, to:

UBI Name: Universal Biosensors Pty, Ltd.  
Attn.: Chief Financial Officer  
Address: 1 Corporate Avenue Rowville VIC 3178

or to such other person or address as UBI may from time to time furnish to SHDI.

**19.2 UBI Not Agent or Legal Representative**

In fulfilling its obligations under this Agreement, each party will be acting as an independent contractor. Nothing contained in this Agreement will be construed to place the Parties in a relationship of employee and employer, joint venturers, or principal and agent. Neither Party is authorized to assume or undertake any obligation of any kind, express or implied, on behalf of the other Party. Each Party will control and be responsible for its own business operations, insurance, and the compensation, wages, taxes, withholding, benefits, and conditions of employment of its personnel. Without limiting the generality of the foregoing, the Parties specifically acknowledge that each Party is acting as an independent entity hereunder and not as a sales agent or other representative of the other Party. This Agreement does not authorize or appoint either Party as the agent or legal representative of the other Party for any purpose whatsoever. Neither Party is granted any right or authority, and the Parties hereby expressly disclaim any right or authority and agrees not to represent to any Party a right or authority, to create or assume any obligation or responsibility, express or implied, on behalf of or in the name of the other Party or to bind the other Party in any manner.



**19.3 Entire Agreement**

This Distribution Agreement, including the Supply Agreement, including the Exhibits hereto which are incorporated as an integral part of this Distribution Agreement, constitutes the entire agreement and understanding of the Parties relating to the subject matter hereof, and supersedes all prior agreements, oral or written, and all negotiations, conversations or discussions heretofore had between SHDI and UBI related to this Distribution Agreement. No modification of or amendment to this Distribution Agreement, nor any waiver of any rights under this Distribution Agreement, will be effective unless set forth in writing signed by authorized representatives of both Parties.

**19.4 Assignment**

- (a) UBI shall not, either in whole or in part, assign any rights, duties or obligations under this Agreement or subcontract any part or all of UBI's obligations hereunder to any third party without the express prior written approval of SHDI, which shall not be unreasonably withheld or delayed. Irrespective of SHDI's approval, UBI remains solely responsible for the proper selection and supervision of its assignees and subcontractors.
- (b) Without prejudice to SHDI's discretion to grant such approval or not, SHDI will in no case grant such approval unless the third party enters into an agreement with UBI whereby such third party agrees to be bound by compliance provisions at least equivalent to those required by this Agreement.
- (c) SHDI may assign this Agreement at its discretion provided it gives UBI at least thirty (30) days prior written notice.

**19.5 No Implied Waiver**

The failure of either Party at any time to require performance by the other Party of any provision hereof shall not affect in any way the full right to require such performance at any time thereafter. Furthermore, the waiver by either Party of a breach of any provision hereof shall not be taken or held to be a waiver of the provision itself.

**19.6 Controlling Law**

The validity, interpretation and performance of this Agreement shall be controlled, governed, enforced and construed in accordance with the substantive laws of New York without regard to its provisions on conflicts of law. The United Nations Convention on Contracts for the International Sale of Goods (CISG) shall not apply.

**19.7 Dispute Resolution**

The Parties agree that any dispute arising under or relating to the Parties' rights and obligations under this Distribution Agreement shall be resolved in accordance with Article 14 of the Parties' Supply Agreement.

**19.8 Severability**

In the event that any provision of this Distribution Agreement is adjudicated invalid, illegal or unenforceable, such adjudication will not affect the validity, legality or enforceability of any other provision of this Distribution Agreement. The Parties shall replace the invalid, illegal or unenforceable provision by a valid, legal and enforceable provision which economically best meets the intention of the Parties.



**19.9 Force Majeure**

The obligations of either Party to perform under this Distribution Agreement shall be excused during each period of delay caused by matters such as strikes, shortages of power or raw material, government orders or acts of God, which are reasonably beyond the control of the Party obligated to perform.

**19.10 Counterparts**

This Distribution Agreement shall be executed in two (2) or more counterparts in the English language, and each such counterpart shall be deemed an original hereof. In case of any conflict between the English version and any translated version of this Agreement, the English version shall govern.

**Dated: September 18, 2019**

**Siemens Healthcare Diagnostics Inc.**

By: /s/ Vivek Mehrotra  
 Name: Vivek Mehrotra  
 Title: Head Finance POC

By: /s/ Christoph Pedain  
 Name: Christoph Pedain  
 Title: Head POC

**UBI:**

By: /s/ Craig Coleman  
 Name: Craig Coleman  
 Title: Director

By: /s/ Satesh Balak  
 Name: Satesh Balak  
 Title: CFO

List of Exhibits:

- Exhibit 1: Definition of Field for Distribution License
- Exhibit 2: SHDI Information, including Pricing Information
- Exhibit 3: Bank Guarantee
- Exhibit 4: Supplier/Distributor Code of Conduct
- Exhibit 5: [\*\*\*]



200GWTTVj9VWG%46}

**EXHIBIT 1**

**Definition of Field for Distribution License**

“Field” shall mean [\*\*\*]. [\*\*\*]. [\*\*\*].

[\*\*\*].



**EXHIBIT 5**

[\*\*\*]

[\*\*\*]. [\*\*\*]. [\*\*\*]. [\*\*\*].

[\*\*\*]. [\*\*\*]. [\*\*\*]. [\*\*\*]. [\*\*\*].

[\*\*\*].

[\*\*\*]. [\*\*\*]. [\*\*\*].

[\*\*\*].

[\*\*\*].

[\*\*\*].

[\*\*\*].

[\*\*\*]. [\*\*\*]. [\*\*\*].

[\*\*\*]. [\*\*\*].



\*Certain identified information has been excluded from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed. The redacted confidential portions of the exhibit are marked by [\*\*\*].

**CONFIDENTIAL SETTLEMENT AND TERMINATION AGREEMENT**

This Confidential Settlement and Termination Agreement, dated as of September 18, 2019, consistent with and as structured on the agreed upon Settlement Term Sheet, executed on September 8, 2019 (the "Settlement Term Sheet"), attached hereto (the "Settlement Agreement") is entered into by and between Universal Biosensors, Inc. and Universal Biosensors Pty Ltd (collectively, "UBI"), on the one hand, and Siemens Healthcare Diagnostics Inc. ("SHDI"), on the other hand (each a "Party" and together the "Parties").

**WHEREAS**, on September 9, 2011, UBI and SHDI entered into a Collaboration Agreement and a Letter Agreement, on September 20, 2012 a Supplemental Agreement, on December 12, 2014 a Xprecia Stride Letter Agreement, and subsequent various amendments to the Collaboration Agreement (collectively, the "Collaboration Agreement") under which UBI and SHDI agreed to, among other things, collaborate together on UBI's development of a PT/INR test strip and associated reader (the PT/INR test strip and the associated reader shall hereinafter be collectively referred to as the "Stride Product"), for UBI to modify the test strip and develop certain additional coagulation-related test strips and a second reader (collectively, the "Prime Product"), and for SHDI to obtain regulatory approval, commercialize, market, and sell in the hospital point-of-care coagulation market the Stride Product and the Prime Product, subject to the terms and conditions set forth in the Collaboration Agreement; and

**WHEREAS**, on September 20, 2012, SHDI and UBI entered into a Supply Agreement addressing, among other things, UBI's sale and SHDI's purchase of certain products from UBI pursuant to the Collaboration Agreement (the "Supply Agreement," and collectively with the Collaboration Agreement, the "Agreements"); and



**WHEREAS**, since 2018, SHDI and UBI have been engaged in a dispute regarding their respective obligations under the Collaboration Agreement and Supply Agreement; and

**WHEREAS**, on November 12, 2018, pursuant to section 14.1 of the Collaboration Agreement, UBI filed a request for non-binding mediation under the International Institute for Conflict Prevention & Resolution Mediation Procedure (the “Mediation”); and

**WHEREAS**, during the course of the Mediation, each Party alleged certain respective claims and defenses against the other Party; and each Party denies the allegations/claims asserted by the other Party; and

**WHEREAS**, as set forth herein, the Parties now desire to amicably resolve the disputes encompassed in the Mediation without resort to arbitration on those disputes, as well as any and all other disputes between the Parties that could potentially arise out of, concern, or relate in any way to the Agreements and/or the parties’ relationship created by the Agreements (the “Disputes”);

**NOW THEREFORE**, in consideration of the recitals set forth above and the promises made in this Settlement Agreement, and for other good and valuable consideration, the receipt and the legal sufficiency of which is hereby acknowledged, and intending to be legally bound, the Parties agree as follows:

1. Payment. UBI shall pay to SHDI Eleven Million United States Dollars (\$11,000,000.00 USD) [\*\*\*], mutual termination of the Collaboration Agreement, and for other just and adequate consideration as set forth in this Settlement Agreement, as follows:

a) Eleven Million Dollars (\$11,000,000.00 USD) shall be paid by UBI to SHDI, Point of Care Business (the “Settlement Payment”) not later than five (5) days after the execution of this Settlement Agreement (the date of execution of this Settlement Agreement shall be referred to as the “Execution Date”) by wire transfer to the following bank account:

[\*\*\*]





2. Market Rights. In consideration of the terms contained in this Settlement Agreement, and upon SHDI's receipt of the Settlement Payment, SHDI relinquishes its exclusive right to commercialize and distribute UBI's Stride and Prime Products to the professional Point of Care market segment, except SHDI retains certain non-exclusive distribution and other rights as agreed to by the Parties [\*\*\*], and except as otherwise may be agreed to by the Parties in any subsequent distribution arrangement. For the avoidance of doubt, the rights transferred to UBI pursuant to this Settlement Agreement include, among other things, any rights and/or obligations necessary to seek regulatory registration and approval in jurisdictions whether or not the Stride or Prime Product is currently sold there, or where additional or further regulatory registrations and/or approvals are or become necessary. [\*\*\*].

3. UBI's Release. In consideration of the terms contained in this Settlement Agreement, and upon SHDI's receipt of the Settlement Payment, with respect to events from the beginning of time to the date of this Settlement Agreement, UBI, on behalf of itself, its predecessors, parents, successors, affiliates, subsidiaries, assigns, beneficiaries, heirs, agents, officers, directors, shareholders, employees, attorneys, and representatives, and all persons acting by, through, under, or in concert with them, and each of them (the "UBI Releasers"), fully release and forever discharge SHDI, together with its respective predecessors, parents, successors, affiliates, subsidiaries, assigns, beneficiaries and heirs, and all of its respective current and former directors, officers, employees, insurers, agents, attorneys, and representatives (the "SDHI Releasees"), from all known and unknown claims, liabilities, obligations, promises, agreements, controversies, damages, actions, causes of action, debts, judgments, suits, rights, demands, fees, and expenses



(including attorney's fees and costs actually incurred), of any nature whatsoever, whether in law or in equity, whether based on contract, statute, regulation, tort or otherwise, whether or not apparent or yet to be discovered, under or related to the Agreements or any transactions thereunder, their negotiation, execution, performance, any breaches thereof, or their termination, or the relationship between the Parties created by the Agreements, but excluding any claims relating to the enforcement of this Settlement Agreement, which are expressly reserved. To the extent that California or other law may be applicable, the UBI Releasors hereby agree that the provisions of Section 1542 of the Civil Code of the State of California and all similar federal or state laws, rights, rules or legal principles of any other jurisdiction which may be applicable hereto, to the extent they apply to any of the matters released herein, are hereby knowingly and voluntarily waived and relinquished by the UBI Releasors, to the fullest extent that such rights and benefits pertaining to the matters released herein may be waived, and the UBI Releasors hereby agree and acknowledge that this waiver is an essential term of this release, without which the release provided to the UBI Releasees by SHDI Releasors (each defined below) would not have been given. This release shall not affect UBI's indemnification obligations under Section 17.2 of the Collaboration Agreement with respect to third party claims which may be raised against SHDI by third parties after the Execution Date and during [\*\*\*], and further, does not affect any of UBI's ongoing obligations under the Parties' Supply Agreement, which remains in effect except as otherwise modified.

4. SHDI's Release. In consideration of the terms contained in this Settlement Agreement, and upon SHDI's receipt of the Settlement Payment, with respect to events from the beginning of time to the date of this Settlement Agreement, SHDI, on behalf of itself, its predecessors, parents,



successors, affiliates, subsidiaries, assigns, beneficiaries, heirs, agents, officers, directors, shareholders, employees, attorneys, and representatives, and all persons acting by, through, under, or in concert with them, and each of them (the "SDHI Releasers"), fully release and forever discharge UBI, together with its respective predecessors, parents, successors, affiliates, subsidiaries, assigns, beneficiaries and heirs, and all of its respective current and former directors, officers, employees, insurers, agents, attorneys, and representatives (the "UBI Releasees"), from all known and unknown claims, liabilities, obligations, promises, agreements, controversies, damages, actions, causes of action, debts, judgments, suits, rights, demands, fees, and expenses (including attorney's fees and costs actually incurred), of any nature whatsoever, whether in law or in equity, whether based on contract, statute, regulation, tort or otherwise, whether or not apparent or yet to be discovered, under or related to the Agreements or any transactions thereunder, their negotiation, execution, performance, any breaches thereof, or their termination, or the relationship between the Parties created by the Agreements, but excluding any claims relating to the enforcement of this Settlement Agreement, which are expressly reserved. To the extent that California or other law may be applicable, the SDHI Releasers hereby agree that the provisions of Section 1542 of the Civil Code of the State of California and all similar federal or state laws, rights, rules or legal principles of any other jurisdiction which may be applicable hereto, to the extent they apply to any of the matters released herein, are hereby knowingly and voluntarily waived and relinquished by the SDHI Releasers, to the fullest extent that such rights and benefits pertaining to the matters released herein may be waived, and the SDHI Releasers hereby agree and acknowledge that this waiver is an essential term of this release, without which the release provided to the SDHI Releasees by the UBI Releasers would not have been given. This release shall not affect SHDI's indemnification obligations under Section 17.1 of the Collaboration Agreement with respect to third party claims which may be raised



against UBI by third parties after the Execution Date and during [\*\*\*], and further, does not affect any of SHDI's ongoing obligations under the Parties' Supply Agreement, which remains in effect except as otherwise modified.

5. Supply Agreement. The Parties agree that the Supply Agreement shall remain in effect except as otherwise modified herein or in a separate writing signed by the Parties subsequent to or contemporaneous with the Execution Date.

6. Collaboration Agreement. The Parties agree that the Collaboration Agreement shall be terminated upon the Execution Date, with no further obligations owing by either Party under it, except that, as set forth herein, each Party's indemnification obligations in Sections 17.1 and 17.2 of the Collaboration Agreement shall survive.

7. Confidentiality. This Settlement Agreement, its terms, and the negotiations leading to this Settlement Agreement are confidential. No Party shall disclose or cause to be disclosed the Settlement Term Sheet or this Settlement Agreement, the terms of those agreements, or any communications relating to the negotiation of those agreements to any person not a Party to those agreements without the written consent of all Parties. Notwithstanding anything contained within this Section 7, each Party may share the Settlement Term Sheet and this Settlement Agreement, their terms, and the negotiations leading to those agreements, with its respective lawyers, advisors, consultants, accountants and auditors on a need to know basis provided these individuals agree to use and maintain the information in a confidential manner consistent with the provisions contained in this Settlement Agreement.

8. Public Announcements. The Parties agree to consult with each other reasonably and in good faith with respect to the text and timing of press releases related to this Settlement Agreement and any other subject matter related to this Settlement Agreement, prior to the issuance thereof, except that



a Party may issue such press releases and/or disclosures as it determines are reasonably necessary to comply with applicable law (including disclosure requirements of the U.S. Securities and Exchange Commission or with the requirements of any stock exchange on which securities issued by a Party or its Affiliates are traded). In the event of a public announcement that a Party determines is necessary or prudent to comply with applicable law, to the extent practicable under the circumstances, the Party making such announcement shall use commercially reasonable efforts to provide the other Party with a copy of the proposed text of such announcement sufficiently in advance of the scheduled release to afford such other Party a reasonable opportunity to review and comment upon the proposed text.

9. Representations. The Parties hereto each represent and warrant that:

- a) it is legally entitled and authorized to settle the claims being released herein;
- b) it is authorized to bind the persons and entities on whose behalf it is releasing the claims described herein;
- c) it has made no assignment or other transfer of any interest that it has in the claims being released pursuant to this Settlement Agreement; and
- d) it has read and fully understands the provisions of this Settlement Agreement to such Party's satisfaction; and
- e) it is represented by counsel, or alternatively, had an opportunity to consult with legal counsel of its choosing before executing this Settlement Agreement.

10. Attorneys' Fees. Each Party is responsible for its own legal fees and costs incurred through the Execution Date.



11. Entire Agreement. This Settlement Agreement is the complete agreement between the Parties regarding the matters described herein, there being no prior or other contemporaneous agreement or promise of any kind that modifies, supplements or alters it, except as may be otherwise set forth herein. This Settlement Agreement supersedes all previous communications, negotiations, representations or agreements (whether oral or written) that may have been made between the Parties, including but not limited to the Settlement Term Sheet and all prior settlement term sheets with the exception of the Standstill Agreement Extension dated as of August 15, 2019, but only until [\*\*\*] is received by SHDI, at which time the Standstill Agreement Extension shall be replaced as well. This Settlement Agreement shall be binding upon and shall inure to the benefit of the Parties and each of their respective successors and assigns.

12. Governing Law. This Settlement Agreement shall be governed by, interpreted under, and enforced in accordance with the laws of the State of New York, without regard to the principles of conflicts of laws.

13. Counterparts. This Settlement Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

14. Execution. A photocopy of the fully executed original of this Settlement Agreement shall be deemed to be an original for any and all purposes.

**IN WITNESS WHEREOF**, the Parties, each intending to be legally bound hereby, have caused this Settlement Agreement to be executed, on their own or through their respective duly authorized officers.

Dated: September 18, 2019



UNIVERSAL BIOSENSORS PTY LTD

Print Name: Salesh Balak  
Print Title: CFO  
Signature: /s/ Salesh Balak

UNIVERSAL BIOSENSORS, INC.

Print Name: Craig Coleman  
Print Title: Director  
Signature: /s/ Craig Coleman

SIEMENS HEALTHCARE DIAGNOSTICS INC.

Print Name: Vivek Mehrotra  
Print Title: Head Finance POC  
Signature: /s/ Vivek Mehrotra

SIEMENS HEALTHCARE DIAGNOSTICS INC.

Print Name: Christoph Pedain  
Print Title: Head POC  
Signature: /s/ Christoph Pedain



**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, Salesh Balak, certify that:

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

Date: November 4, 2019

/s/ Salesh Balak

Salesh Balak  
Interim Principal Executive Officer  
Universal Biosensors, Inc.





**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, Salesh Balak, certify that:

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

Date: November 4, 2019

/s/ Salesh Balak

Salesh Balak  
Principal Financial Officer  
Universal Biosensors, Inc.



**Exhibit 32**

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

In connection with the quarterly report of Universal Biosensors, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2019, 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 4<sup>th</sup> day of November, 2019.

/s/ Salesh Balak  
 \_\_\_\_\_  
 Salesh Balak  
 Interim Principal Executive Officer

/s/ Salesh Balak  
 \_\_\_\_\_  
 Salesh Balak  
 Principal Financial Officer

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