



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

FORM 10-K

Annual Report Pursuant To Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2019

OR

Transition Report Pursuant To Section 13 or 15(d) of the Securities Exchange Act of 1934

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)

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

Not Applicable
(Zip Code)

Securities registered pursuant to Section 12(b) of the Act: None

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

Title of each class
Shares of Common Stock, par value US\$0.0001 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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 or a smaller reporting company or an emerging growth company. See definitions 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 Act). Yes No

The approximate aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant was A\$22,307,806 (equivalent to US\$15,644,464) as of June 30, 2019.

There were 177,571,854 shares of the registrant’s common stock, par value US\$0.0001 per share, outstanding as of February 20, 2020.

Certain information contained in the registrant’s definitive Proxy Statement for the 2020 annual meetings of stockholders, to be filed not later than 120 days after the end of the fiscal year covered by this report, is incorporated by reference into Part III hereof.

Information contained on pages F-2 through F-43 of our Annual Report to Stockholders for the fiscal year ended December 31, 2019 (our “2019 Annual Report”) is incorporated by reference in our response to Items 7, 7A, 8 and 9A of Part II.

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Unless otherwise noted, references on this Form 10-K 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 its wholly owned Canadian operating subsidiary, Hemostasis Reference Laboratory Inc. (“HRL”). Our principal place of business is located at 1 Corporate Avenue, Rowville, Victoria 3178, Australia. Our telephone number is +61 3 9213 9000. Unless otherwise noted, all references in this Form 10-K 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.



FORWARD-LOOKING STATEMENTS

This Form 10-K, together with other statements and information publicly disseminated by us, contains certain forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 and include this statement for purposes of complying with these safe harbor provisions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our, our customers and partners’ or our industry’s actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. All statements, other than statements of historical facts, are forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our business and product development strategies;
- our expectations with respect to collaborative, strategic or distribution arrangements;
- our expectations with respect to the timing and amounts of revenues from our customers and partners;
- our expectations with respect to the services we provide to, and the development projects we undertake for, our customers and partners;
- our expectations with respect to regulatory submissions, clearances, market launches of products we develop or are involved in developing;
- our expectations with respect to sales of products we develop or are involved in developing and the quantities of such products to be manufactured by us;
- our expectations with respect to our research and development programs, the timing of product development and our associated research and development expenses;
- the ability to protect our owned or licensed intellectual property; and
- our estimates regarding our capital requirements, the sufficiency of our cash resources, our debt repayment obligations and our need for additional financing.

The words “anticipates,” “believes,” “continue,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “projects,” “should,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Form 10-K. The forward-looking statements included in this Form 10-K do not guarantee our future performance, and actual results could differ from those contemplated by these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. We undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in cautionary statements throughout this Form 10-K, particularly those set forth in section “Item 1A - Risk Factors.” However, new factors emerge from time to time and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Except to the extent required by applicable law or regulation, we do not undertake to update or revise any forward-looking statements.



PART I

ITEM 1. BUSINESS.

The following discussion and analysis should be read in conjunction with our financial statements and related notes included elsewhere in this Form 10-K. This discussion and analysis contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth in the section entitled "Item 1A—Risk Factors" and elsewhere in this Form 10-K.

Business overview

We are specialists in the design and development of electrochemical cells (strips) used in conjunction with point of use devices that are used in various industries such as healthcare (point of care), food and drink and agriculture.

We were incorporated in the State of Delaware on September 14, 2001 and our shares of common stock in the form of CHESSE Depository Interests ("CDIs") have been quoted on the Australian Securities Exchange ("ASX") since December 13, 2006. Our securities are not currently traded on any other public market. Our wholly owned subsidiary and primary operating vehicle, Universal Biosensors Pty Ltd ("UBS") was incorporated as a proprietary limited company in Australia on September 21, 2001. UBS conducts our primary research, development and manufacturing activities in Melbourne, Australia. A subsidiary of UBS, Hemostasis Reference Laboratory Inc. ("HRL") was incorporated in British Columbia, Canada on November 30, 2016. HRL conducts coagulation testing and calibration services for products we manufacture as well as for other customers in Hamilton, Canada.

Our principal place of business is 1 Corporate Avenue, Rowville, Victoria 3178, Australia. Our principal telephone number in Australia is +61 3 9213 9000. HRL's principal place of business is 15(H) Wing, Second Floor, 711 Concession Street, Hamilton, Ontario and its registered office is 310-318 Homer Street, Vancouver, British Columbia V6B 2V2, Canada. We also maintain a website at www.universalbiosensors.com and HRL maintains a website at www.hemostasislab.com. The information contained in, or that can be accessed through, our websites is not incorporated by reference into, and does not constitute a part of this Form 10-K.

We have rights to an extensive patent portfolio, with certain patents owned by UBS and a number licensed to UBS by LifeScan, Inc. 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 are using our electrochemical cell technology platform to develop point of use devices for a number of different markets.

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 on December 9, 2014 and US Food and Drug Administration ("FDA") clearance 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 may 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.

We are required to file a Form 10-K as a result of UBI being registered under the U.S. Securities and Exchange Act of 1934, as amended.

Our Strategy

We are specialists in the design and development of electrochemical cells (strips) used in conjunction with point of use devices that are used in various industries such as healthcare (point of care), food and drink and agriculture. In addition, we own, manage and operate a hemostasis laboratory. Key aspects of our strategy for generating shareholder value include:

- executing on our existing business activities, including undertaking research and development activities for our customers and partners, manufacturing products and providing development and support services including providing laboratory services, to our customers and partners;
- 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; and
- identifying and pursuing related opportunities for growth.

Plan of Operations for the Remainder of the Fiscal Year Ending December 2020

Our plan of operations over the remainder of the fiscal year ending December 2020 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 for our customers and partners;
- provide the necessary post-market support for our customer and partner;
- 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.

Description of our business

We are specialists in the design and development of electrochemical cells (strips) used in conjunction with point of use devices that are used in various industries such as healthcare (point of care), food and drink and agriculture. In addition, we own, manage and operate a hemostasis laboratory.

Industry background

We operate in the high growth, point-of-care segment of the global in vitro diagnostics (IVD) industry and other industries where point of use devices are used. A large proportion of clinical diagnostics has historically been performed by trained personnel at dedicated or centralized testing sites including hospital laboratories and commercial pathology laboratories. Significant interest has developed in techniques and technologies that allow testing to be performed “on-the-spot” (in real time at the patient’s side). Point-of-care testing can be further divided into consumer self-testing or testing of patients by one of a variety of medical or laboratory professionals in locations such as clinics, physician’s office laboratories and emergency departments. While not all tests are suited to being performed at the point-of-care, we believe our electrochemical cell technology and other technologies could be a suitable platform for adapting a number of relevant central laboratory tests to a point-of-care format. UBI continues to focus on the diagnostic POC market and is now exploring the opportunities this technology offers of speed, ease of use, reliability, accuracy at a low cost in alternative industries.



Point of use tests in development and partnering strategy

We are also working to demonstrate the broader application of our technology platform for markets with significant commercial potential. To date, we have developed a blood glucose test with LifeScan and a coagulation Prothrombin Time International Normalized Ratio (“PT-INR”) test with Siemens, both of which are now sold by LifeScan and Siemens, respectively. Building upon the success of these globally launched products, the Company continues to focus on the point-of-use market and in addition is now exploring opportunities this technology offers of speed, ease of use, reliability and accuracy at a low cost.

Principal Products and Services

UBS is the manufacturer and distributor of PT-INR coagulation test strips and the distributor of the Siemens’ Xprecia Stride™ Coagulation Analyzer. HRL conducts coagulation testing and calibration services. UBS also conducts research and development to demonstrate the broader application of its technology platform.

Facilities

UBS leases approximately 5,000 square meters of office, research and development and manufacturing facilities at 1 Corporate Avenue, Rowville in Melbourne, Australia. UBS has had ISO 13485 certification continuously at that site since May 2007. The lease for 1 Corporate Avenue expires on March 31, 2022 with an option to renew the lease for two further terms of three years each.

HRL leases approximately 482 square meters of office and laboratory facilities at 15(H) Wing, Second Floor, 711 Concession Street, Hamilton, Ontario. As part of the acquisition of the assets of the Hemostasis Reference Laboratory business in December 2016, HRL was transferred ISO 13485:2003 and ISO 13485 certification, which has been held continuously at the site since May 15, 2014 and July 2011, respectively. The lease for 711 Concession Street expires on January 31, 2021. Either HRL or its landlord can terminate the lease early by giving 6 months’ notice.

Raw materials

Raw materials essential to our business are purchased worldwide in the ordinary course of business from numerous suppliers. In general, these materials are available from multiple sources. Certain of our products in development may be more reliant on sole sources of supply. We seek to enter into long term contracts of supply with respect to these materials and intend to develop mitigation strategies, which may include development work to enable substitute materials to be used.

Distribution

UBI and Siemens are responsible for the sales and distribution of the Xprecia Stride™ product.

Regulatory clearances

In all major territories of the world, regulatory clearances are required prior to marketing diagnostic tests. The regulatory clearance requirements vary from country to country and product to product, however, regulatory clearances typically require a satisfactory “technical dossier”, which provides the regulatory bodies with details of the design and previous testing of the product including safety and efficacy data as well as the details of the conduct of trials which show the suitability for use of the product at the point of use. Regulators also require demonstration of continuing compliance with an appropriate quality management system. There is no common international regulatory body and we, or our relevant customer or partner or distributor, would be required to submit for clearance to sell in each of the major jurisdictions in which we or our relevant customers and partners seeks to market products. For example, for Europe, a designated “Notified Body” assesses the quality system and product technical dossier, whereas in the United States, the Food and Drug Administration, or “FDA”, is the regulatory body responsible for the examination of the design and performance of the device and for assessment of our quality system.

In the case of point of use tests, there are often additional requirements that a manufacturer must meet such as an examination of certain aspects affecting test suitability for non-laboratory professional users. In Europe, certain codified standards describe the requirements of tests whilst in the United States, tests to be used by non-laboratory professionals must gain CLIA waiver status under the United States Clinical Laboratory Improvement Amendments (“CLIA”) of 1988. Amongst other clearances, we also require clearance for export of medical devices from the Therapeutics Goods Administration, or “TGA”, in Australia, for all products under our name.



The importance and duration of all our patents, trademarks and licenses

We rely on a combination of patent, copyright, trademark and trade secret laws, as well as confidentiality agreements, to establish and protect our proprietary rights which in the aggregate we believe to be of material importance to us in the operation of our business. Our continued success depends to a large extent on our ability to protect and maintain our owned and licensed patents and patent applications, copyright, trademark and trade secrets.

Our point of use tests in development draw upon an extensive portfolio of patents and patent applications as well as know-how either owned by UBS or licensed to UBS. We patent the technology, inventions and improvements that we consider important to the development of our business.

We rely on the owned patent applications and the patents and patent applications licensed to us in the manufacture of the point of use tests being developed by us and to enable us to grant rights to our customers and partners to commercialize products that we may develop.

Our owned and licensed patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends upon the type of patent, the scope of its coverage and the availability of legal remedies in the country. We maintain the owned and licensed patents and patent applications that we consider most significant by virtue of their importance to our platform.

We intend to continue to file and prosecute patent applications when and where appropriate to attempt to protect our rights in our proprietary technologies.

Pursuant to our License Agreement with LifeScan, LifeScan is responsible for prosecution and maintenance of the patents and patent applications licensed to us by them. In the event that LifeScan elects not to proceed with the prosecution of a patent application licensed to us by them or discontinues the payment of fees, we have the right to assume and continue at our own expense the prosecution of any such patent or patent applications.

Our ability to build and maintain our proprietary position for our technology and products will depend on our success in obtaining effective claims and those claims being enforced once granted and, with respect to intellectual property licensed to us, the licensee's success in obtaining effective claims and those claims being enforced once granted. The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Some countries in which we or our customers or partners may seek approval to sell point of use tests that we have been involved in developing, may fail to protect our owned and licensed intellectual property rights to the same extent as the protection that may be afforded in the United States or Australia. Some legal principles remain unresolved and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States, the United Kingdom, the European Union, Australia or elsewhere. In addition, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or in interpretations of patent laws in the United States, the United Kingdom, the European Union, Australia or elsewhere may diminish the value of our intellectual property or narrow the scope of our patent protection.

Trademarks

It is anticipated that we may brand products that we manufacture and distribute as part of our strategy. In such a case our intention is to own our brands applied to those products. We have filed trademark applications in significant markets in accordance with that strategy.

Seasonality

We do not expect sales of our products and services to be materially impacted by seasonality.

The practices of the registrant and the industry (respective industries) relating to working capital items.

The nature of the Company's business requires it to maintain sufficient levels of inventory to meet contractually agreed delivery requirements of its customers. Significant amounts of inventory are not retained by the Company as it does not have to meet rapid delivery requirements. The Company provides its customers with payment terms prevalent in the industry. The Company does not provide extended payment terms to its customers.



Dependence on single customer

In 2018, we received a significant portion of our revenue from LifeScan. All revenue from products was recognized in connection with the manufacture of the test strips for Siemens' Xprecia Stride™ Coagulation Analyzer. Commencing in the 2019 financial year, we have no longer received and will no longer receive any revenue from LifeScan due to the LifeScan Conversion.

	Years Ended December 31,	
	2019	2018
	AS	AS
Home country - Australia	3,677,486	490,962
Foreign countries		
- U.S.A.	1,437,998	1,428,350
- Germany	4,785,384	1,603,817
- Switzerland	235,945	66,084,950
- Canada	296,183	238,056
- Other	155,451	101,817
Total - foreign countries	6,910,961	69,456,990
Total income	10,588,447	69,947,952
% of total income derived from - LifeScan	2%	94%
- Siemens	53%	3%
- Other	45%	2%

We did not have any significant backlog orders as of December 31, 2019 and 2018.

Competitive conditions of our business

The coagulation testing market is dominated by PT-INR testing, which represents around 70% of this market. Roche is currently the largest player in the point-of-care professional PT-INR testing market. Roche has a well established brand recognition, sales and marketing force, and has significant resources available to support its product.

Core to our business strategy is the extension of our intellectual property platform to enable other tests currently done in the central laboratory to be migrated to the point of use settings. Our belief is that much testing done in the central lab can be more efficiently and profitably performed at the point of use. With the exception of blood glucose testing, most point-of-care testing is currently conducted in professional settings. The healthcare professional has a choice and can request tests from a central laboratory, or services provider, or choose to have the test performed at the point-of-care. Thus we face competition not just from other companies active in the point of use space, but also the providers of testing who operate in centralized settings. Further our belief is that self-service, home, point of use testing can be more efficient and at lower cost to the healthcare system and directly involve the patient in their medical information collection and healthcare decision making.

Employees

At February 20, 2020, the total number of employees we had was 55 of which 39 were full time employees in our facilities, spanning production, engineering, operations, quality and regulatory, research and development and administration.

Available Information

We are required to file a Form 10-K as a result of UBI as a result of UBI being registered under the U.S. Securities and Exchange Act of 1934, as amended.



We file annual and quarterly reports, proxy statements and other information with the SEC, copies of which are available on ASX. Our public filings (including our Annual Report on Form 10-K and proxy statement) are also available at the website maintained by us at <http://universalbiosensors.com> and the SEC at <http://www.sec.gov>.

We provide without charge to each person solicited by the Proxy Statement a copy of our Annual Report on Form 10-K, including our financial statements but excluding the exhibits to Form 10-K other than Exhibit 13. The Annual Report includes a list of the exhibits that were filed with the Form 10-K, and we will furnish a copy of any such exhibit to any person who requests it upon the payment of our reasonable expenses in providing the requested exhibit. For further information, please contact our Company Secretary at companysecretary@universalbiosensors.com or 1 Corporate Avenue, Rowville VIC 3178 Australia.

Our Corporate Governance Statement issued in accordance with ASX Listing Rule 4.10.3 reporting compliance against the ASX Corporate Governance Principles and Recommendations is available at <http://www.universalbiosensors.com/Investor-Centre/Corporate-Governance.aspx>.



ITEM 1A. RISK FACTORS.

Investing in our shares or CDIs involves a high degree of risk. Before you invest in our shares or CDIs, you should understand the high degree of risk involved. You should carefully consider the following risks and other information in this Form 10-K, including our financial statements and related notes appearing elsewhere in this Form 10-K, before you decide to invest in our shares or CDIs. If any of the events described below actually occurs, our business, financial condition and operating results could be harmed. In such an event, the market price of our CDIs would likely decline and you could lose part or all of your investment.

As a result of the LifeScan Conversion, no further revenues are expected from LifeScan unless a new agreement is in place. Without significant new revenue streams pursuant to the development of new products and/or establishing new partnerships, our results of operations will be materially adversely affected.

Following the LifeScan Conversion, if the Company is unable to secure similarly significant revenues from new customers and/or relationships with new strategic partners, we expect this will severely and adversely affect our financial results, business and business prospects and the future of our research and development activities. Amongst other things, it would seriously restrict or eliminate our ability to develop and commercialize our own tests and our ability to grant further sublicenses, which would restrict or eliminate our commercialization opportunities.

If any of our key contracts are terminated, or if counterparties to our key contracts do not meet their performance obligations under those contracts, our business would be severely harmed and development and commercialization opportunities restricted or eliminated.

The License Agreement with LifeScan imposes material obligations on us. LifeScan may terminate the License Agreement if we fail to use commercially reasonable efforts to commercialise and fail to provide evidence of our compliance within 90 days of written notice, are liquidated or wound up, or are in persistent and material breach of our obligations and fail to remedy the breach within 90 days of written notice requiring us to do so. If we were to breach the License Agreement and LifeScan were to validly terminate the agreement in response, it would severely and adversely affect our financial results, business and business prospects and the future of our research and development activities. Amongst other things, it would seriously restrict or eliminate our ability to develop and commercialize our own tests and our ability to grant further sublicenses, which would restrict or eliminate our commercialization opportunities. If the License Agreement was terminated, any sublicense under the License Agreement previously granted by us to a third party that is in effect immediately prior to such termination (which would include licenses granted to Siemens under the Collaboration Agreement) would survive termination as a direct license from LifeScan to such sublicensee, provided certain conditions are met, including that the sublicensee is not in material breach of any provision of the License Agreement and agrees to be bound to the terms of the License Agreement with respect to the applicable sublicense field.

The Collaboration Agreement with Siemens was terminated on September 18, 2019. Pursuant to the terms of the 2019 Siemens Agreements, while there is a mutual release of all pre-existing claims from both parties, UBI is committed to the supply of a fixed number of Xprecia Stride™ strips to Siemens till March 18, 2023, backed by US\$5 million bank guarantee provided by UBI. In the event UBI is not able to supply the required number of Xprecia Stride™ strips to Siemens, UBI will forfeit a portion of the bank guarantee.

Our sales and marketing strategy may be unsuccessful in growing the Xprecia Stride™ share of the Coagulation testing market and/or transitioning its existing customer base from Siemens.

Further to the terms of the 2019 Siemens Agreements, Siemens will assist UBI in appointing distributors to continue growing the Xprecia Stride™ market share and transitioning its existing customer base. Nonetheless, existing customers may choose not to purchase Xprecia Stride™ strips and instrument from UBI following the expiration of their current contracts with Siemens. Without the continuation of supply to existing Xprecia Stride™ customers, the manufacturing of Xprecia Stride™ strips is likely to result in an operating loss to the extent that there are fixed overhead costs that do not vary with production volume. We also do not have an established sales and marketing force and any efforts to find customers and distributors and sell the Xprecia Stride™ product may be futile.

Our products may not be successful in the marketplace.

Our success and the success of products that we are involved in developing is ultimately dependent on the level of continued market acceptance and sales of those products. Continued market acceptance will depend on, amongst other things, the ability to provide and maintain evidence of safety, efficacy and cost effectiveness of the products, the advantages and profile over competing products, the level of support from clinicians, the relative convenience and ease of use, cost-effectiveness compared to other products, the availability of reimbursement from national health authorities, the timing of regulatory clearances and market introduction and the success of marketing and sales efforts by our customers and partners. Additionally, it is difficult to determine the market opportunity for new technologies and our estimates may not accurately reflect the actual demand in the target markets or new competitive product introductions may disrupt current market conditions and decrease our commercial opportunities and impact on our revenue.



Our commercial opportunity will be reduced or eliminated if the size of the market opportunity is less than we expect or if our competitors develop and commercialize products that are safer, more effective, more convenient, less expensive, or reach markets sooner or are marketed better than products that we are involved in developing or are currently being marketed by our partners.

The coagulation test strips for the Xprecia Stride™ Coagulation Analyzer which we developed with Siemens were first released in Europe in December 2014. Sales of the product have remained comparatively low relative to initial expectations and accordingly we have a limited track record of market acceptance of the product. Revenue derived from this product is likely to remain conservative in 2020 given the uncertainty of customer transition from Siemens and our ability to attract new customers and distributors. Further, there can be no guarantee this product, or any of the other products in development, will gain market share in a timely fashion (or at all). Competitors such as Roche Diagnostics have well established brand recognition, sales and marketing forces, product development programs and have significant resources available to support their products.

Likewise, we cannot be sure that any other products we are involved in developing will be successful in the marketplace or will secure and maintain adequate market share.

Our ability to be or maintain profitability in the future will be adversely affected if any of the products that we are involved in developing fail to achieve or maintain market acceptance or compete effectively in the market place. It may render prior development efforts unproductive and worthless and would reduce or eliminate our revenues from product sales and/or manufacturing and may have a material adverse effect on our business and financial position.

Deviations from expected results of operations and/or expected cash requirements could adversely affect our financial condition and results of operations.

Our principal current sources of liquidity are the cash received from the LifeScan Conversion, earnings from Xprecia Stride™ strip sales, along with cash flows from operations and existing cash and cash equivalents. These are sufficient to fund our operating needs and capital requirements for at least the next twelve months, based on current assumptions regarding the amount and timing of such expenditures and anticipated cash flows. Any significant deviation in actual results from our expected results of operations, any significant deviation in the amounts or timing of material expenditures from current estimates, or other significant unanticipated expenses could have a material adverse effect on our financial condition and/or may result in the need for debt or equity financing.

Our business strategy may involve entering into collaborative arrangements with other companies and there is a risk that we will not be able to enter into collaborative arrangements with respect to our products.

Our business strategy has historically involved demonstrating the broader application of our technology platform for a number of different products/technologies and then entering into collaborative arrangements, licensing agreements, strategic alliances or distribution arrangements for these products/technologies. We have not established any internal product sales and marketing capacity and to achieve commercial success we must enter into and maintain successful arrangements with others to sell, market and distribute products that we are involved in developing.

While we are currently developing our own products, we may not be able to enter collaborative or distribution arrangements with respect to certain of our products/technologies. We may have to change strategy, delay, reduce the scope of or eliminate some or all of our development programs or liquidate some or all of our assets or seek to raise additional capital. As a result, we may not be able to pursue what we consider to be worthwhile commercial opportunities and significant monies and management time invested may be rendered unproductive and worthless. Our inability to enter collaborative or strategic arrangements would thus have a material adverse effect on our business and financial position.



Entering into collaborative arrangements with respect to our products will expose us to risks and uncertainties related to those collaborations and partners thereto.

To the extent we complete development of our products and are able to enter into additional collaborative or strategic arrangements with respect to such products, we will be exposed to risks and uncertainties related to those arrangements. We may be required to relinquish important rights such as marketing and distribution rights and the customer or partner will generally make the key decisions on product choice, regulatory clearances, product launch, product manufacture and marketing and promotion. Decisions made by our partner with respect to the commercialization of the products we develop with them will significantly affect the extent and timing of revenues to us. Collaborative arrangements, licensing agreements or strategic or distribution arrangements will subject us to a number of risks, including the risk that:

- our partner may choose not to launch new products we develop, may choose to launch the products in a limited number of jurisdictions, may delay the launch of products, may undertake only limited sales and marketing efforts to commercialize the products, all of which would have a material adverse effect on our business and financial position;
- our partner may experience financial difficulties or may significantly change its business strategy;
- our partner may not perform as required; a partner could independently move forward with a competing product developed either independently or in collaboration with others, including our competitors; and
- the collaborative arrangements are terminated or allowed to expire.

Allegedly defective design or the manufacture of allegedly defective products could potentially expose us to substantial costs, write-offs, regulatory actions and reputational damage.

Allegedly defective designs or manufacture of allegedly defective products exposes us to the risk of product liability claims and product recalls. Any such claims have the potential to result in substantial costs, write-offs and potential delays in our shipment of product to customers, decreased demand for products and services, loss of revenue and cash flow, reputational damage, costs of related litigation, increases in our insurance premiums and increased scrutiny by regulatory agencies, claims by our customers and may trigger the dissolution of partnerships or collaborative relationships. The occurrence of certain of these events may trigger action by government regulatory agencies including for example, warning, recalls and fines or penalties. While we will seek to mitigate our loss by obtaining appropriate insurances and appropriate contractual protections, if we are unable to maintain our insurance at an acceptable cost or on acceptable terms with adequate coverage, or negotiate appropriate contractual protections or otherwise protect against potential product liability claims, we will be exposed to significant liabilities. Recalls would harm our business and compromise the performance of our obligations to our customers and would have a material adverse effect on our business and financial results and may result in claims by our customers or partners and may trigger the dissolution of partnerships or collaborative relationships. Any claim for damages by our customers or other claim against us could be substantial.

There are many elements to manufacturing products that can cause variability beyond acceptable limits. We may be required to discard defective products after we have incurred significant material and labor costs, resulting in manufacturing delays and delayed shipment to customers. Further, if our suppliers are unable to provide materials in conformance with specifications, we may be required to discard materials, which may also cause delays in the manufacture and shipment of products.

Reduced margins would have a material adverse effect on our business and financial position.

Our revenues may decline and/or our costs may increase, either of which could result in reduced margins, which would have a material adverse effect on our business and financial position. The primary factors that pose this risk include selling prices, increased manufacturing costs and currency fluctuations.

Increases in our costs to manufacturing products or conducting development work may decrease our margins or cause us to suffer a loss on the manufactured products. Additionally, we may suffer decreased margins due to the global reach of our business exposing us to market risk from changes in foreign currency exchange rates. The majority of our cash receipts are in US dollars and expenses are in Australian dollars, and we are exposed to foreign exchange exposure particularly when we have to convert our US dollar cash receipts into Australian dollars to fund our operations. Additionally, we use, from time to time, financial instruments, primarily foreign currency forward contracts to hedge certain forecasted foreign currency commitments arising from trade accounts receivables, trade accounts payable and fixed purchase obligations. These hedging activities are largely dependent upon the accuracy of our forecasts and as such, our foreign currency forward contracts may not cover our full exposure to exchange rate fluctuations. Although we believe our foreign exchange policies are reasonable and prudent under the circumstances, we may experience losses from un-hedged currency fluctuations, which could be significant. If our costs increase or our margins decrease, it would have an adverse effect on our business and financial position.



New product design and development and clinical testing is costly, labor intensive and the outcomes uncertain.

The design and development of different tests on our platform takes a number of years to complete, is costly and the outcomes are uncertain. Although development risk generally reduces the further a test is developed, the tests we develop have a significant degree of technical risk, and irrespective of the stage of development, design and development work and product validation, the development of the test may be unsuccessful or not warrant product commercialization. If development activities are unsuccessful, we may need to delay, reduce the scope of or eliminate some or all of our development programs and significant monies and management time invested may be rendered unproductive and worthless.

Diagnostic devices must be tested for safety and performance in laboratory and clinical trials before regulatory clearance for marketing is achieved. Such studies are costly, time consuming and unpredictable. Clinical trials may not be successful and marketing authorization may not be granted which may result in us not being profitable, or trigger dissolution of partnerships or collaborative relationships. The outcome of early clinical trials may not be predictive of the success of later clinical trials. Failed clinical trials may result in considerable investments of time and money being rendered unproductive and worthless.

Additionally, unanticipated trial costs or delays could cause substantial additional expenditure that is not reimbursed by a partner, cause us to miss milestones which trigger a financial payment or cause us or a partner to delay or modify our plans significantly. This would harm our business, time to market, financial condition and results of operations.

If we cannot maintain our intellectual property rights, our ability to make or develop point of use tests would be restricted or eliminated, and the value of our technology and diagnostic tests may be adversely affected.

Our ability to obtain proprietary rights, maintain trade secret protection and operate without infringing the proprietary rights of third parties is an integral part of our business.

A number of companies, universities and research institutions have or may be granted patents that cover technologies that we need to complete development of a particular product. We may choose or be required to seek licenses under third party patents which would be costly, may not be available on commercially acceptable terms, or at all. Further, we may be unaware of other third party patents or proprietary rights that are infringed by our point of use tests.

Much of our platform intellectual property rights are licensed to us from LifeScan. If we were to breach the License Agreement and LifeScan were to validly terminate the agreement in response, it would seriously restrict or eliminate our ability to develop and commercialize our existing and future tests which would have a material adverse effect on us as it would restrict or eliminate our existing commercialization opportunities. We also license other intellectual property from third parties as part of our other development efforts.

LifeScan and our other licensors have a considerable degree of control over the manner that the intellectual property licensed to us is maintained and protected and, as a result, we have reduced control with respect to the maintenance and protection of our licensed patent portfolio. LifeScan is responsible for the prosecution and maintenance of the intellectual property it licenses to us and we are largely dependent on them to defend proceedings or prosecute infringers. The same applies to our other licensors. Our business would be harmed if the licensed patents were infringed or misappropriated. Prosecuting third parties and defending ourselves against third-party claims would be costly, time consuming and divert management's attention from our business, potentially leading to delays in our development or commercialization efforts. Additionally, if third parties made successful claims, we may be liable for substantial damages or license fees, be required to stop marketing the infringing product or take other actions that are adverse to our business.

Risks associated with regulatory clearance and changes to regulation.

The products we are involved in developing are subject to extensive regulation in all major markets. The process of obtaining regulatory clearance is costly and time consuming and there can be no assurance that the required regulatory clearances will be obtained. Products cannot be commercially sold without regulatory clearance. We and our customers and partners may be unable to obtain the necessary clearances to sell or if the clearances are delayed, revoked or subject to unacceptable conditions, the product may not be able to be commercialized which would have a material adverse effect on us.



If we were required and able to change suppliers and third party contract manufacturers, applicable regulatory bodies may require new testing and compliance inspections and require that we demonstrate structural and functional comparability between the same products manufactured by different organizations, resulting in additional costs and potential delays in time to market which could be detrimental to our business.

Furthermore, regulation is ongoing and manufacturers and marketers of products are subject to continuous review and periodic inspections. Potentially costly responses may be required to be given by us and our customers including product modification, or post-marketing clinical trials as a condition of approval to further substantiate safety and efficacy or investigate issues of interest. If we or our customers fail to comply with applicable regulatory requirements it may result in fines, delays, suspensions of clearances, seizures, recalls of products, operating restrictions or criminal prosecutions and could have a material adverse effect on our operations. Additionally, changes in existing regulations or the adoption of new regulations could make regulatory compliance by us more difficult in future and could hamper our ability to produce our products when we require.

We are dependent on our suppliers.

Similar to most major manufacturers in our industry, we are dependent upon our suppliers for certain raw materials and components. We have preferred suppliers, making us vulnerable to supply disruption, which could harm our business and delay manufacturing operations. We seek to enter into long term contractual arrangements with certain of our suppliers, however we may not always be able to do so on acceptable terms. If our manufacturing requirements change, such long term contractual arrangements may cause us to have excess or obsolete inventory. We may not be able to guarantee the supply of certain of our materials which may in turn affect our ability to supply product to our customers. We may have difficulty locating alternative suppliers in a timely manner or on commercially acceptable terms, and switching components may require product redesign and further regulatory clearance which could significantly delay production. Likewise, our customers and partners are subject to supply risks which may delay their ability to supply customers with product which would impact our revenue and have a consequential adverse effect on our business and results of operations. Supply disruption may also impact on our research and development programs.

To the extent we agree to be responsible for manufacturing meters for any of our customers and partners, we anticipate that we will outsource the manufacture of these meters. There is no guarantee that we will be able to enter into any such arrangement on acceptable terms, if at all, and as a result there is a risk of lengthy and costly delays of bringing our products to market. Further, if our contract manufacturers fail to achieve and maintain required production yields or manufacturing standards, it could result in product withdrawals, delays, recalls, product liability claims and other problems that could seriously harm our business. Any meter shortages or manufacturing delays could result in delays or reduction in our revenues, with consequential adverse effect on our business and results of operations.

We face risks manufacturing product or providing services.

There are technical challenges to establishing and maintaining commercial manufacturing for products, including maintaining the consistency of our incoming raw materials, equipment design and automation, material procurement, production yields and quality control and assurance. We may fail to achieve and maintain required production yields or manufacturing standards which could result in financial loss, patient injury or death, product recalls or withdrawals, product shortages, delays or failures in product testing or delivery, breach of our agreements with any partner and other problems that could seriously harm our business.

The success of our business is heavily dependent upon market factors such as growth of the point of use testing market and our ability to compete effectively within the highly competitive in vitro diagnostics market.

Our business success relies on the growth of both the existing and emerging point of use testing market. We cannot be sure that this market will grow as we anticipate. Such growth will require continued support and demand from payers, patients and healthcare professionals and the endorsement by professional bodies that influence the practice of medicine. Research and clinical data may not sufficiently support point of use testing, nor may the economic benefits sufficiently support point of use testing as an alternative to current practice. Even if the data is compelling, significant resources may be required to educate users and change in practice may be slower and more costly than we anticipate. If point of use testing fails to be adopted at the rate we expect, the sector may remain unattractive to the size of partner we seek to attract and as a consequence, we may need to change our business model. This may require us to incur more cost and/or our anticipated growth will be adversely affected and our results will suffer.



We may face intense competition in development, marketing and selling point of use tests.

The market for in vitro diagnostics and point of use testing in food and drink and agriculture is intensely competitive, price sensitive and subject to rapid change. We and our customers and partners may be unable to accurately anticipate changes in the markets and the direction of technological innovation and the demands of end users, competitors may develop improved technologies and the market place may conclude that our products are obsolete. Our larger competitors enjoy several competitive advantages including significantly greater financial resources, greater brand recognition, greater expertise in conducting clinical trials, obtaining regulatory clearances and managing manufacturing operations, and greater experience in product sales and marketing. Early-stage companies may also prove to be significant competitors.

Competition will be faced from existing products as well as products in development. Point of use tests are likely to experience significant and continuing competition from traditional pathology laboratory based testing as well as other point of use tests. Our and our customers' and partners' commercial opportunity will be reduced or eliminated if competitors develop and commercialize safer, more effective, more convenient, or cheaper products, or reach the market sooner than we do. Any such developments adversely affecting the market for products developed by us may force us and our partners to reduce production or discontinue manufacturing which would cause our operating results to suffer. There can be no assurances given with respect to our or any partner's ability to compete effectively in the competitive markets in which we operate.

Adverse economic conditions may harm our business.

Market and economic conditions have been volatile. Market and economic concerns include fluctuations in foreign exchange rates, inflation, interest rates, rate of economic growth, taxation laws, consumer spending, unemployment rates, government fiscal, monetary and regulatory policies and consumer and business sentiment. Any of these factors have the potential to cause costs to increase or revenues to decline. Turbulence in international markets and economies may adversely affect our ability to enter into collaborative arrangements, the behavior and financial condition of our current and any future customers and partners and the spending patterns of users of the products we are developing. This may adversely impact demand for our services and for products developed by us. In addition, economic conditions could also impact our suppliers, which may impact on their ability to provide us with materials and components which in turn may negatively impact our business.

Our operations may not be profitable, particularly in the near term.

Prior to 2019, we have largely funded our operations and capital expenditures from revenue from quarterly service fees from LifeScan and the sale of other products and provision of services and with proceeds from the sale of our securities, debt financing, government grants and rebates including the research and development tax incentive income and interest on investments. As of 2019 we no longer have had the benefit of quarterly service fees from LifeScan and the revenue from the sale of other products and provision of services only funded a small portion of our operating expenses. Though the revenues from the sale of our Xprecia Stride™ product by Siemens in 2019 have improved on prior years, we do not expect that those revenues will increase significantly in 2020. We may also require additional capital to fund our business operations, which may not be available on acceptable commercial terms, or at all.

We may not be able to raise capital or secure credit if and when required.

We may not be able to raise capital or secure further credit if and when required. If we are unable to raise capital or secure further credit when required, we may have to delay, reduce the scope of or eliminate some or all of our development programs or commercialization efforts or liquidate some or all of our assets.

We benefit from government grants and rebates.

Our principal sources of liquidity are cash flows from operations (revenue from services and product sales). We have also financed our business operations through government grants and rebates, including the refundable tax offset ("tax incentive income"). The refundable tax offset is one of the key elements of the Australian Government's support for Australia's innovation system and if eligible, provides the recipient with cash based upon our eligible research and development activities and expenditures. For the years ended December 31, 2017 and 2018 we were not eligible for refundable tax offset as our aggregate turnover exceeded A\$20,000,000. We are however eligible to make this claim for the year-ended 2019 as our revenues are less than A\$20,000,000. Despite these, there can be no assurance that we will qualify and be eligible for such incentives or that the Australian Government will continue to provide incentives, offsets, grants and rebates on similar terms or at all.



The loss of a key employee or the inability to recruit and retain high caliber staff to manage future anticipated growth could have a material adverse effect on our business.

As with most growth companies, our future success is substantially dependent on our key personnel. Certain key personnel would be difficult to replace and the loss of any such key personnel may adversely impact the achievement of our objectives. Our ability to operate successfully and manage the business depends significantly on attracting and retaining additional highly qualified personnel. The loss of any key personnel may be disruptive or have a material adverse effect on the future of our business. Effective succession planning is important for our long-term success and failure to ensure effective transfers of knowledge and smooth transitions involving key employees could hinder our strategic planning and execution. The competition for qualified employees in scientific research and medical diagnostic and laboratory industries is particularly intense and there are a limited number of persons with the necessary skills and experience.

We have completed a scaled-down restructure in 2019 to align cost management with the current business strategy. While management expects the current organization structure to be adequate in achieving its business objectives, there is no guarantee that key personnel will not resign to seek new opportunities in 2020 and beyond.

Our primary development, testing and manufacturing operations are conducted at a single location. Any disruption at our facility could adversely affect our operations and increase our expenses.

Our primary operations are conducted at our Corporate Avenue facility in Melbourne, Australia. HRL also provides us with calibration services from its facilities in Hamilton, Canada. We take precautions to safeguard our facilities, including security, health and safety protocols and maintain applicable insurance. However, we may be impacted by cybersecurity risks, industrial action or operating equipment and facilities may not operate as intended or be unavailable as a result of unanticipated failures or other events outside of our control such as a natural disaster, fire, flood or earthquake or catastrophic breakdowns or deliberate acts of destruction. The occurrence of any of these events may restrict our ability to supply product or our ability to provide coagulation testing and calibration services, could cause substantial delays in our operations, damage or destroy our manufacturing and laboratory equipment or inventory, and cause us to incur additional expenses. The insurance we maintain against fires, floods, earthquakes and other natural disasters may not be adequate to cover our losses in any particular case.

Additionally, the HRL lease currently expires on January 31, 2021 with no further options to extend the current lease. We are currently in discussions with the landlord to either extend the current lease for a longer term or provide us with another space within the existing facility. In the event our landlord rejects our proposal, our operations will be significantly affected as we won't be able to conduct testing services for our customers and partners. In addition we would not be in a position to continue manufacturing Xprecia Stride™ strips as the mandatory calibration process as required by the regulations is also performed by HRL. In the event we are not able to supply the Xprecia Stride™ strips to Siemens, we will be in breach of the 2019 Siemens Agreements and Siemens may call upon the US\$5 million bank guarantee we have provided. Relocation of these services are achievable but would take considerable time and cost to implement.

Investors may be subject to Australian and/or US taxation.

The receipt of dividends by Australian tax resident security holders and any subsequent disposal of our securities by any such Australian tax resident may have both United States and Australian tax consequences depending upon their individual circumstances. This may result in a security holder being subject to tax in both jurisdictions and a tax credit may or may not be available in one jurisdiction to offset the tax paid in the other jurisdiction depending upon the security holder's individual circumstances.

We may be subject to increased U.S. taxation.

Pursuant to the new U.S. tax reform rules, we are subject to regulations addressing Global Intangible Low-Taxed Income ("GILTI") effective from 2018. The GILTI rules are 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 Internal Revenue Services in the U.S. ("IRS") issued their first set of guidance on GILTI in September 2018 and is expected to provide further guidance on the treatment of GILTI. We continue to review the anticipated impacts of the GILTI rules and other legislation passed under the U.S. Tax Cuts and Jobs Act.



The price of our shares is highly volatile and could decline significantly.

Our shares of common stock in the form of CDIs were quoted on the ASX and began trading on December 13, 2006. The price of our shares is highly volatile and could decline significantly. The market price of our shares historically has been, and we expect will continue to be, subject to significant fluctuations over short periods of time. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the entry into, or termination of, key agreements, including collaboration and supply agreements and licensing agreements with key strategic partners;
- any inability to obtain additional financing on favorable terms to fund our operations and pursue our business plan if additional financing becomes necessary;
- future sales of our common stock or debt or convertible debt securities or other capital-raising activities, and the terms of those issuances of securities;
- time to market and future revenue streams from product sales, if any, by our collaborative partners, and the extent of demand for, and sales of, our products;
- the initiation of material developments in, or conclusion of disputes or litigation with our customers or partners or to enforce or defend any of our intellectual property rights or otherwise;
- our results of operations and financial condition, including our cash reserves, cash burn and cost level;
- general and industry-specific economic and regulatory conditions that may affect our ability to successfully develop and commercialize products;
- the loss of key employees;
- the introduction of technological innovations or other products by our competitors;
- sales of a substantial number of CDIs by our large stockholders;
- changes in estimates or recommendations by securities analysts, if any, who cover our common stock;
- issuance of shares by us, and sales in the public market of the shares issued, upon exercise of our outstanding warrants; and
- period-to-period fluctuations in our financial results.

We may experience a material decline in the market price of our CDIs, regardless of our operating performance and therefore, a holder of our shares may not be able to sell those shares at or above the price paid by such holder for such shares. Sales by our larger shareholders may create volatility, price pressure or impact how the value of our shares is perceived.

Class action litigation has been brought in the past against companies which have experienced volatility in the market price of their securities. We may become involved in this type of litigation in the future. Litigation of this type is often extremely expensive and diverts management's attention and our resources.

Our securities are not currently traded on any United States public markets and there are currently restrictions on the ability of United States persons to acquire our securities on the ASX.

There is no public market for our shares in the United States or in any other jurisdiction other than Australia. We have not determined whether we will seek the quotation of our shares on any United States public trading market. Even if our shares are in the future listed on a United States public market, the liquidity of our shares may not improve, and the United States market price may not accurately reflect the price or prices at which purchasers or sellers would be willing to purchase or sell our common stock.

In addition, our securities are "restricted securities" as that term is defined in Rule 144 under the United States Securities Act of 1933, as amended ("Securities Act"). Restricted securities may be resold to U.S. persons as defined in Regulation S only if registered for resale or pursuant to an exemption from registration under the Securities Act. We have not agreed to register any of our common stock for resale by security holders.

We may be involved in litigation.

There has been substantial litigation and other proceedings in the medical diagnostic industries. Defending against litigation and other third party claims would be costly and time consuming and would divert management's attention from our business, which could lead to delays in our development or commercialization efforts. If third parties are successful in their claims, we might have to pay substantial damages or take other actions that are adverse to our business.



Changes in laws may adversely affect our business.

Our business and the business of our customers and partners are subject to the laws and regulations in a number of jurisdictions. Unforeseen changes in laws and government policy both in Australia, the EU, the US and elsewhere, could materially impact our operations, assets, contracts and profitability.

We are exposed to risks relating to evaluations of controls required by Section 404 of the Sarbanes-Oxley Act.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002 (“Sarbanes-Oxley Act”) and related regulations implemented by the SEC, have substantially increased legal and financial compliance costs. We expect that our ongoing compliance with applicable laws and regulations, including the Exchange Act and the Sarbanes-Oxley Act, will involve significant and potentially increasing costs. In particular, we must annually evaluate our internal controls systems to allow management to report on our internal controls. We must perform the system and process evaluation and testing (and any necessary remediation) required to comply with the management certification and, when applicable, auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. If we are not able to continue to satisfy the requirements of Section 404 adequately, we may be subject to sanctions or investigation by regulatory authorities, including the SEC. Any action of this type could adversely affect our financial results, investors’ confidence in our company and our ability to access capital markets, and could cause our stock price to decline.

A significant amount of our shares are controlled by individuals or voting blocks, and the interests of such individuals or voting blocks could conflict with those of the other stockholders.

Single stockholders with significant holdings or relatively small groups of stockholders have the power to influence matters requiring the approval of stockholders. Viburnum Funds Pty Ltd, as investment manager for its associated funds and entities holds a beneficial interest and voting power over approximately 21% of our shares. For details of our substantial stockholders and the interests of our directors, refer to “Part III, Item 12 — Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters”.

Our success is reliant on the accuracy, reliability and proper use of sophisticated information processing systems and management information technology and the interruption in these systems could have a material adverse effect on our business, financial condition and results of operations.

Our success is reliant on the accuracy, reliability and proper use of sophisticated information processing systems and management information technology. Our information technology systems are designed and selected in order to facilitate the entering of order entry, customer billing, to maintain customer records, to provide product traceability, to accurately track purchases, to manage accounting, finance, administration and manufacturing, generate reports and provide customer service and technical support. Any interruption in these systems could have a material adverse effect on our business, financial condition and results of operations.

The failure of our information systems to function as intended or their penetration by outside parties with the intent to corrupt them or our failure to comply with privacy laws and regulations could result in business disruption, litigation and regulatory action, and loss of revenue, assets or personal or other confidential data.

We use information systems to help manage business processes, collect and interpret data and communicate internally and externally with employees, suppliers, consumers, customers and others. Some of these information systems are managed by third-party service providers. We have backup systems and business continuity plans in place, and we take care to protect our systems and data from unauthorized access. Nevertheless, failure of our systems to function as intended, or penetration of our systems by outside parties intent on extracting or corrupting information or otherwise disrupting business processes, could place us at a competitive disadvantage, result in a loss of revenue, assets or personal or other sensitive data, litigation and regulatory action, cause damage to our reputation and that of our brands and result in significant remediation and other costs. Failure to protect personal data, respect the rights of data subjects, and adhere to strict cybersecurity protocols could subject us to substantial fines and other legal challenges under regulations such as the EU General Data Protection Regulation. As we are increasingly relying on digital platforms in our business, the magnitude of these risks is likely to increase.



Our operations may be impaired as a result of disasters, business interruptions or similar events.

We could have an interruption in our business, loss of inventory or data, or be rendered unable to accept and fulfill customer orders as a result of a natural disaster, catastrophic event, epidemic or computer system failure. Natural disasters could include an earthquake, fire, flood, tornado or severe storm. A catastrophic event could include a terrorist attack. An epidemic could affect our operations, major facilities or employees' and consumers' health. Production of certain of our products is concentrated in a single manufacturing site.

We cannot provide assurance that our disaster recovery plan will address all of the issues we may encounter in the event of a disaster or other unanticipated issue, and our business interruption insurance may not adequately compensate us for losses that may occur from any of the foregoing. In the event that a natural disaster, terrorist attack or other catastrophic event were to destroy any part of our facilities or interrupt our operations for any extended period of time, or if harsh weather or health conditions prevent us from delivering products in a timely manner, our business, financial condition or operating results could be adversely affected.

Provisions in our charter documents and under Delaware law could make the possibility of our acquisition, which may be beneficial for our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove current management.

Provisions in our certificate of incorporation and our bylaws may delay or prevent an acquisition of us or a change in our management, and frustrate or prevent attempts by our stockholders to replace or remove our current management by making it more difficult to remove our current directors. Such provisions include:

- the division of our Board into classes whose terms expire at staggered intervals over a three year period and advance notice requirements for nominations to our Board and proposing matters that can be acted upon at shareholder meetings;
- our stockholders do not have the power to call special meetings of our stockholders; and
- the requirement that actions by our stockholders by written consent be unanimous.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation Law that, subject to exceptions, would prohibit us from engaging in any business combinations with any interested stockholder, as defined in that section, for a period of three years following the date on which that stockholder became an interested stockholder.

Limitation on Independent Registered Public Accounting Firm's Liability.

The liability of PricewaterhouseCoopers (an Australian partnership which we refer to as PwC Australia), with respect to claims arising out of its audit report included in this Annual Report, is subject to the limitations set forth in the Professional Standards Act 1994 of New South Wales, Australia, as amended (the Professional Standards Act) and Chartered Accountants Australia and New Zealand (NSW) scheme adopted by Chartered Accountants Australia and New Zealand on 8 October 2014 and approved by the New South Wales Professional Standards Council pursuant to the Professional Standards Act (the NSW Accountants Scheme). For matters occurring on or prior to 7 October 2014, the liability of PwC Australia may be subject to the limitations set forth in predecessor schemes. The current NSW Accountants Scheme expires on 7 October 2019 unless further extended or replaced.

The Professional Standards Act and the NSW Accountants Scheme may limit the liability of PwC Australia for damages with respect to certain civil claims arising in, or governed by the laws of, New South Wales directly or vicariously from anything done or omitted to be done in the performance of its professional services for us, including, without limitation, its audits of our financial statements. The extent of the limitation depends on the timing of the relevant matter and is:

- in relation to matters occurring on or after 8 October 2013, a maximum liability for audit work of A\$75 million; or
- in relation to matters occurring on or prior to 7 October 2013, the lesser of (in the case of audit services) ten times the reasonable charge for the service provided and a maximum liability for audit work of A\$75 million.

The limitations do not apply to claims for breach of trust, fraud or dishonesty.



In addition, there is equivalent professional standards legislation in place in other states and territories in Australia and amendments have been made to a number of Australian federal statutes to limit liability under those statutes to the same extent as liability is limited under state and territory laws by professional standards legislation. Accordingly, liability for acts or omissions by PwC Australia in Australian states or territories other than New South Wales may be limited in a manner similar to that in New South Wales. These limitations of liability may limit recovery upon the enforcement in Australian courts of any judgment under US or other foreign laws rendered against PwC Australia based on or related to its audit report on our financial statements. Substantially all of PwC Australia's assets are located in Australia. However, the Professional Standards Act and the NSW Accountants Scheme have not been subject to judicial consideration and therefore how the limitation might be applied by the courts and the effect of the limitation on the enforcement of foreign judgments are untested.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.



ITEM 2. PROPERTIES.

UBS leases approximately 5,000 square meters of office, research and development and manufacturing facilities at 1 Corporate Avenue, Rowville in Melbourne, Australia. The lease for the premises at 1 Corporate Avenue Rowville expires on March 31, 2022 with an option to renew the lease for two further terms of three years each.

We manufacture our test strips using custom manufacturing equipment.

Depending on the number of strips required to be manufactured, it may become necessary in the future for us to acquire additional large scale equipment to satisfy manufacturing demand. If our existing facilities and equipment are fully utilized for the manufacture of test strips for one of our customers or our own products, we will need to secure additional or alternative facilities and establish additional large scale equipment sufficient to meet future manufacturing requirements.

If the volume of strips to be manufactured continues to be low, we may need to consider a more appropriate sized facility.

HRL leases approximately 482 square meters of office and laboratory facilities at 15(H) Wing, Second Floor, 711 Concession Street, Hamilton, Ontario. The lease for 711 Concession Street expires on January 31, 2021. Either HRL or its landlord can terminate the lease early by giving 6 months' notice.



ITEM 3. LEGAL PROCEEDINGS.

There are no material legal proceedings pending against us.



ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.



PART II

ITEM 5. MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market information

Our shares of common stock are not currently traded on any established United States public trading market. We do not currently intend to seek the quotation of our shares of common stock on any United States public trading market. We cannot assure you that we will never seek to be quoted on any United States public trading market or that we would meet any applicable listing requirements.

Our shares of common stock are traded on the ASX in the form of CHES Depositary Interests, or CDIs, under the ASX trading code “UBI”. The Clearing House Electronic Subregister System, or “CHES”, is an electronic system which manages the settlement of transactions executed on the ASX and facilitates the paperless transfer of legal title to ASX quoted securities. CHES cannot be used directly for the transfer of securities of U.S. domiciled companies. CDIs are used as a method of holding and transferring the legal title of these securities on the ASX which are not able to be electronically traded in CHES. CDIs are exchangeable, at the option of the holder, into shares of our common stock at a ratio of 1:1. The main difference between holding CDIs and holding the underlying securities (in this case our shares) is that a holder of CDIs has beneficial ownership of the equivalent number of our shares instead of legal title. Legal title is held by CHES Depositary Nominees Pty Ltd, or “CDN”, and the shares are registered in the name of CDN and held by CDN on behalf of and for the benefit of the holders of CDIs. CDN is a wholly owned subsidiary of ASX.

Holders of CDIs who do not wish to have their trades settled in CDIs on the ASX may request that their CDIs be converted into shares, in which case legal title to the shares of common stock are transferred to the holder of the CDIs. Likewise, stockholders who wish to be able to trade on the ASX can do so by requesting that their shares be converted into CDIs and by lodging their applicable share certificate with our share registrar and signing a share transfer form with respect to the relevant shares. Our share registrar will then transfer the shares from the stockholder to CDN and establish a CDI holding in the name of the stockholder (now a CDI holder).

Security details

As of February 20, 2020, there were 177,571,854 shares of our common stock issued and outstanding and 1,911,450 employee options that are exercisable for an equivalent number of shares of common stock (1,911,450 of which were exercisable or exercisable within 60 days thereafter). All of our issued and outstanding shares of common stock are fully paid.

Under applicable U.S. securities laws all of the shares of our common stock are “restricted securities” as that term is defined in Rule 144 under the Securities Act. Restricted securities may be resold to U.S. persons as defined in Regulation S only if registered or pursuant to an exemption from registration under the Securities Act. We have not agreed to register any of our common stock for resale by security holders.

Holders

Currently, CDN holds the majority of our shares on behalf of and for the benefit of the holders of CDIs. The balance of the shares are held by certain of our employees generally as part of our restricted employee share scheme. Set out below is the approximate aggregate number of our registered holders of CDIs and shares at the specific date below:

Date	Total Number of Registered Holders	Number of Holders that are United States Residents
At February 20, 2020	1,460	10

Dividends

To date, we have not declared or paid any cash dividends on our shares or CDIs. Our ability to pay dividends is currently restricted by the terms of our pending Term Sheet Agreement with Siemens described above under “Business—Principal Products and Services.”



Exercise of Employee Stock Options

The table below sets forth the number of employee stock options exercised and the number of shares of common stock issued within the past three financial years. We issued these shares in reliance upon exemptions from registration under Regulation S under the Securities Act of 1933, as amended, on the basis that none of the recipient of such shares are “U.S. person” as such term is defined in Regulation S.

<u>Period Ending</u>	<u>Number of Options Exercised and Corresponding Number of Shares Issued</u>	<u>Option Exercise Price</u>	<u>Proceeds Received (A\$)</u>
2018			
July	251,667	A\$0.00	0
August	251,667	A\$0.00	0
November	50,000	A\$0.00	0
	<u>553,334</u>		<u>0</u>
2019			
February	210,000	A\$0.00	0
April	20,000	A\$0.17	3,400
May	73,334	A\$0.00	0
November	25,000	A\$0.00	0
	<u>328,334</u>		<u>3,400</u>

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

Restricted Employee Shares Issued to Employees

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. 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 permanent full-time 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. We issue these shares in reliance upon exemptions from registration under Regulation S under the Securities Act on the basis that none of the recipient of such shares are “U.S. person” as such term is defined in Regulation S.

The table below sets forth the restricted shares issued by the Company within the past two financial years:

	<u>Number of Restricted Shares Issued</u>	<u>Market Value of Restricted Shares Issued (A\$)</u>
December, 2018	191,636	45,993

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

	<u>Number of shares</u>	<u>Weighted average issue price (A\$)</u>
Balance at December 31, 2018	311,246	0.28
Granted	0	0.00
Release of restricted shares	(190,432)	0.30
Balance at December 31, 2019	<u>120,814</u>	<u>0.24</u>



- (1) The number of securities 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 amended and restated certificate of incorporation. The Listing Rules of ASX generally prohibits companies whose securities are quoted on ASX from issuing securities exceeding 15% of issued share capital in any 12 month period, without stockholder approval.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

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.

To date the Company has not entered into any buyback transactions.



ITEM 6. SELECTED FINANCIAL DATA.

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



ITEM 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The information required by this item is incorporated by reference to our 2019 Annual Report under the caption “Management’s Discussion and Analysis of Financial Condition and Results of Operations” on pages F2 to F15.



ITEM 7A. 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 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item is incorporated by reference to our 2019 Annual Report under the captions “Consolidated Balance Sheets”, “Consolidated Statements of Comprehensive Income/(Loss)”, “Consolidated Statements of Changes in Stockholders’ Equity and Comprehensive Income/(Loss)”, “Consolidated Statements of Cash Flows”, and “Notes to Consolidated Financial Statements”, on pages F17 through F43, and “Report of Independent Registered Public Accounting Firm” on page F16 of this 2019 Annual Report.



ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.



ITEM 9A. 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 December 31, 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 9A that have materially affected, or are reasonably likely to materially affect, the Company’s internal control over financial reporting.



MANAGEMENT’S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) and 15d – 15(f) under the Exchange Act). Our internal control over financial reporting is a process designed 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 and includes those policies and procedures that:

- Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and the dispositions of the assets of the Company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and the board of directors of the Company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluations of effectiveness to future periods are subject to risk that controls may become inadequate because of changes in conditions or because of declines in the degree of compliance with the policies or procedures.

Our management, with the participation of the Interim Principal Executive Officer and Principal Financial Officer, assessed the effectiveness of the Company’s internal control over financial reporting as of December 31, 2019. In making this assessment, the Company’s management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) in Internal Control-Integrated Framework (2013).

Based on this evaluation, our management, with the participation of the Interim Principal Executive Officer and Principal Financial Officer, concluded that, as of December 31, 2019, our internal control over financial reporting was effective.

/s/ Salesh Balak
Salesh Balak
Interim Principal Executive Officer

/s/ Salesh Balak
Salesh Balak
Principal Financial Officer

February 26, 2020



REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Being a smaller reporting company and emerging growth company, the Independent Registered Public Accounting Firm is not required to test or report on the effectiveness of internal control over financial reporting.



ITEM 9B. OTHER INFORMATION

None.



PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by this is incorporated by reference to our Definitive Proxy Statement to be filed with the SEC in connection with our Annual Meeting of Stockholders in 2020 (the "2020 Proxy Statement") under the captions "Management of the Company" and "Delinquent Section 16 (a) Reports."



ITEM 11. EXECUTIVE COMPENSATION.

The information required by this item is incorporated by reference to the 2020 Proxy Statement under the captions “Management of the Company – Compensation of Directors”, “Executive Compensation” and “Management of the Company – Board Committees – Compensation Committee Interlocks and Insider Participation.”



ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information required by this item is incorporated by reference to the 2020 Proxy Statement under the captions “Security Ownership of Certain Beneficial Owners and Management,” and “Executive Compensation – Equity Compensation Plan Information.”



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ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required by this item is incorporated by reference to the 2020 Proxy Statement under the captions “Certain Relationships and Related Transactions,” and “Management of the Company.”



ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required by this item is incorporated by reference to the 2020 Proxy Statement under the caption "Independent Public Accountants – Audit Fees."

**PART IV****ITEM 15. EXHIBITS, FINANCIAL STATEMENTS AND SCHEDULES.****(a)(1) Financial Statements**

The following financial statements are incorporated by reference from pages F-16 through F-43 of our Annual Report to Stockholders for the fiscal year ended December 31, 2019, as provided in Item 8 hereof:

<u>Report of Independent Registered Public Accounting Firm</u>	F-16
<u>Consolidated Balance Sheets</u>	F-17
<u>Consolidated Statements of Comprehensive Income/((Loss)</u>	F-18
<u>Consolidated Statements of Changes in Stockholders' Equity and Comprehensive Income/((Loss)</u>	F-19
<u>Consolidated Statements of Cash Flows</u>	F-20
<u>Notes to Consolidated Financial Statements</u>	F-21

(a)(2) Financial Statement Schedules – Schedule II—Valuation and Qualifying Accounts. All other schedules are omitted because of the absence of the conditions under which they are required or because the required information is included elsewhere in the financial statements.

(a)(3) and (b) Exhibits – Refer below.

Exhibit Number	Description	Location
3.1	<u>Amended and restated certificate of incorporation dated December 5, 2006.</u>	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 3.1.
3.2	<u>Amended and restated by-laws dated December 5, 2006.</u>	Incorporated by reference to our Amendment No. 5 to Form 10 filed on April 29, 2008 as Exhibit 3.2.
4.3	<u>Description of Securities</u>	Filed herewith.
10.1	<u>Amended and Restated License Agreement between LifeScan, Inc. and Universal Biosensors Pty Ltd dated on August 29, 2011 and effective as of August 19, 2011.</u>	Incorporated by reference to our Current Report on Form 8-K filed on August 30, 2011 as Exhibit 10.1.
10.2	<u>Amended and Restated Development and Research Agreement between Cilag GmbH International and Universal Biosensors Pty Ltd dated on August 29, 2011 and effective as of August 19, 2011.</u>	Incorporated by reference to our Current Report on Form 8-K filed on August 30, 2011 as Exhibit 10.2.
10.3	<u>Form of indemnity agreement entered into with directors of us, our chief financial officer and company secretary</u>	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.3.
10.4	<u>Employee Option Plan.</u>	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.7.
10.5	<u>Employment agreement between Universal Biosensors Pty Ltd and Mr. Satesh Balak effective November 27, 2006.</u>	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.8.



- 10.6 [Amended and Restated Master Services and Supply Agreement \(which amends and restates the Master Services and Supply Agreement by and between Universal Biosensors Pty. Ltd., Universal Biosensors, Inc., and LifeScan, Inc. dated October 29, 2007 filed on November 14, 2007 as Exhibit 10.1 to our Quarterly Report on Form 10-Q and the First Amendment to the Master Services and Supply Agreement filed on March 30, 2009 as Exhibit 10.14 to our Annual Report on Form 10-K\).](#) Incorporated by reference to our Quarterly Report on Form 10-Q filed on August 7, 2009 as Exhibit 10.3. Confidentiality treatment has been granted for portions of this exhibit. These confidential portions have been omitted and were filed separately with the SEC.
- 10.7 [Manufacturing Initiation Payment Addendum to Master Services and Supply Agreement \(which is an addendum to the Amended and Restated Master Services and Supply Agreement filed on August 7, 2009 as Exhibit 10.3 to our Quarterly Report on Form 10-Q\).](#) Incorporated by reference to our Quarterly Report on Form 10-Q filed on August 7, 2009 as Exhibit 10.4. Confidentiality treatment has been granted for portions of this exhibit. These confidential portions have been omitted and were filed separately with the SEC.
- 10.8 [Supply Agreement between Universal Biosensors Pty Ltd and Siemens Healthcare Diagnostics, Inc. dated September 20, 2012.](#) Incorporated by reference to our Quarterly Report on Form 10-Q/A filed on February 4, 2013 as Exhibit 10.2. Confidentiality treatment has been granted for portions of this exhibit. These confidential portions have been omitted and were filed separately with the SEC.
- 10.9 [Supplemental Agreement – Reader Product Support Obligations and Responsibilities between Universal Biosensors Pty Ltd and Siemens Healthcare Diagnostics, Inc. dated September 20, 2012.](#) Incorporated by reference to our Quarterly Report on Form 10-Q/A filed on February 4, 2013 as Exhibit 10.3. Confidentiality treatment has been granted for portions of this exhibit. These confidential portions have been omitted and were filed separately with the SEC.
- 10.10 [Credit Agreement dated December 19, 2013 by and among Athyrium Opportunities Fund \(A\) LP as Administrative Agent and a Lender, Universal Biosensors Pty Ltd as borrower, Universal Biosensors, Inc. as a Guarantor, and the other Lenders and Guarantors as party thereto from time to time.](#) Incorporated by reference to our Current Report on Form 8-K filed on December 20, 2013 as Exhibit 10.1.
- 10.11 [Third Amendment to Amended and Restated Master Services and Supply Agreement by and among Universal Biosensors, Inc., Universal Biosensors Pty Ltd, and Cilag GmbH International.](#) Incorporated by reference to our Current Report on Form 8-K filed on December 20, 2013 as Exhibit 10.2.
- 10.12 [Common Stock Purchase Warrant by and among Athyrium Opportunities Fund \(A\) LP and Universal Biosensors, Inc.](#) Incorporated by reference to our Current Report on Form 8-K filed on December 20, 2013 as Exhibit 10.3.
- 10.13 [Common Stock Purchase Warrant by and among Athyrium Opportunities Fund \(B\) LP and Universal Biosensors, Inc.](#) Incorporated by reference to our Current Report on Form 8-K filed on December 20, 2013 as Exhibit 10.4.
- 10.14 [Deed of Extension of Lease between Universal Biosensors Pty Ltd and Bowmayne Pty Ltd dated March 24, 2014.](#) Incorporated by reference to our Quarterly Report on Form 10-Q filed on April 25, 2014 as Exhibit 10.34.
- 10.15 [Amendment to Credit Agreement by and among Athyrium Opportunities Fund \(A\) LP as Administrative Agent and a Lender, Universal Biosensors Pty Ltd as borrower, Universal Biosensors, Inc. as a Guarantor, and the other Lenders and Guarantors as party thereto from time to time dated January 30, 2015.](#) Incorporated by reference to our Current Report on Form 8-K filed on February 2, 2015 as Exhibit 10.1.



- 10.16 [Amendment Number 2 and Consent to Credit Agreement by and among Athyrium Opportunities Fund \(A\) LP as Administrative Agent and a Lender, Universal Biosensors Pty Ltd as borrower, Universal Biosensors, Inc. as a Guarantor, and the other Lenders and Guarantors as party thereto from time to time dated December 29, 2017.](#) Incorporated by reference to our Current Report on Form 8-K filed on January 3, 2018 as Exhibit 10.1.
- 13.0 [Annual Report.](#) Filed herewith.
- 14.0 [Code of Ethics.](#) Incorporated by reference to our Annual Report on Form 10-K filed on March 28, 2008 as Exhibit 14.0.
- 21.0 [List of Subsidiaries.](#) Filed herewith.
- 24.0 [Power of Attorney.](#) Included on signature page.
- 31.1 [Certification of Interim Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act.](#) Filed herewith.
- 31.2 [Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act.](#) Filed herewith.
- 32.0 [Certification of Interim Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act.](#) As provided in Rule 406T of Regulation S-T, this information is furnished herewith and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934.
- 101 The following materials from the Universal Biosensors, Inc. Annual Report on Form 10-K for the financial year ended December 31, 2019 formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Comprehensive Income/(Loss), (iii) the Consolidated Statements of Changes in Stockholder's Equity and Comprehensive Income/(Loss), (iv) the Consolidated Statements of Cash Flows and (v) the Notes to Consolidated Financial Statements. As provided in Rule 406T of Regulation S-T, this information is furnished herewith and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934.



ITEM 16. Form 10-K SUMMARY

None.



SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Universal Biosensors, Inc.
(Registrant)

Date: February 26, 2020

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

POWER OF ATTORNEY

Each person whose signature appears below hereby constitutes and appoints Salesh Balak and each of them, his or her attorneys-in-fact, each with the power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this report on Form 10-K, and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them full power and authority to do and perform each and every act and all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that such attorneys in-fact and agents or any of them or his or their substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following on behalf of the registrant and in the capacities and on the dates indicated:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Salesh Balak</u> Salesh Balak	Interim Chief Executive Officer (Interim Principal Executive Officer)	February 26, 2020
<u>/s/ Salesh Balak</u> Salesh Balak	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 26, 2020
<u>/s/ Craig Coleman</u> Craig Coleman	Non-Executive Chairman and Director	February 26, 2020
<u>/s/ Marshall Heinberg</u> Marshall Heinberg	Director	February 26, 2020
<u>/s/ Judith Smith</u> Judith Smith	Director	February 26, 2020
<u>/s/ David Hoey</u> David Hoey	Director	February 26, 2020



Universal Biosensors, Inc.
2019 Annual Report

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Unless otherwise noted, references on this Annual Report 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”).



Management's Discussion and Analysis of Financial Condition and Results of Operations

Universal Biosensors, Inc.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes that appear elsewhere in this Annual Report. In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates and beliefs and other forward-looking information, including the types of forward looking statements described in our Form 10-K. Our (and our customer's, partners' and industry's) actual results, levels of activity, performance or achievements may differ materially from those discussed in the forward-looking statements below and elsewhere in our Form 10-K. Factors that could cause or contribute to these differences include those discussed below and elsewhere in our Form 10-K, particularly in "Risk Factors."

Our Business

We are specialists in the design and development of electrochemical cells (strips) used in conjunction with point of use devices that are used in various industries such as healthcare (point of care), food and drink and agriculture. 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; and
- identifying and pursuing related opportunities for growth.

Our plan of operations over the remainder of the fiscal year ending December 2020 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 were incorporated in the State of Delaware on September 14, 2001 and our shares of common stock in the form of CHESSE Depository Interests ("CDIs") have been quoted on the Australian Securities Exchange ("ASX") since December 13, 2006. Our securities are not currently traded on any other public market. Our wholly owned subsidiary and primary operating vehicle, UBS was incorporated as a proprietary limited company in Australia on September 21, 2001. UBS conducts our primary research, development and manufacturing activities in Melbourne, Australia. A subsidiary of UBS, Hemostasis Reference Laboratory Inc. ("HRL") was incorporated in British Columbia, Canada on November 30, 2016. HRL conducts coagulation testing and calibration services for products we manufacture as well as for other customers in Hamilton, Canada.

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.



Management's Discussion and Analysis of Financial Condition and Results of Operations

Universal Biosensors, Inc.

We are using our electrochemical cell technology platform to develop point of use devices for a number of different markets.

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.

Results of Operations

Analysis of Consolidated Revenue

As discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations – Our Business", during 2018, LifeScan effected the LifeScan Conversion and UBI recognized a one-off revenue of A\$44,635,704. Accordingly, we have not and will continue not to 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 90% during our 2019 financial year as compared to our 2018 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 favourable 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 may 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 (at UBI's discretion and 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.



Management’s Discussion and Analysis of Financial Condition and Results of Operations

Universal Biosensors, Inc.

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:

	Years Ended December 31,	
	2019	2018
	AS	AS
Revenue from products	4,863,347	1,672,321
Cost of goods sold	(2,866,081)	(1,607,340)
	<u>1,997,266</u>	<u>64,981</u>
Product contribution margin	41%	4%

The movement in revenues is primarily volume driven. Revenues increased by 191% in the 2019 financial year when compared to the 2018 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 has not and 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:

	Years Ended December 31,	
	2019	2018
	AS	AS
Revenue from services:		
Lump sum services fees	0	44,635,704
Quarterly service fees	164,577	21,378,404
Other services	1,869,275	1,770,485
	<u>2,033,852</u>	<u>67,784,593</u>
Cost of services	(705,612)	(904,139)
Net margin	<u>1,328,240</u>	<u>66,880,454</u>

Lump sum service fees – This was paid to the Company by LifeScan after the LifeScan Conversion.

Quarterly service fees – Whilst we no longer receive the quarterly service fees due to the LifeScan Conversion, the Company notes there was an underpayment of quarterly services fees of AS\$164,577 relating to prior years, the sum of which has been recorded and receipted by the Company during the 2019 financial year.



Management’s Discussion and Analysis of Financial Condition and Results of Operations

Universal Biosensors, Inc.

Other services – Other services is comprised of as follows:

	Years Ended December 31,	
	2019	2018
	A\$	A\$
Other services:		
Coagulation testing services	1,094,669	1,193,948
Contract research and development	703,239	505,695
Other	71,367	70,842
	<u>1,869,275</u>	<u>1,770,485</u>

Coagulation testing services performed by HRL for the 2019 financial year decreased by 8% when compared to the 2018 financial year. The decline was as a result of the completion of a major project during the first half of the year which was not replaced during the second half of the year. The overall revenue for HRL after including testing services conducted for UBI however increased by 2% to A\$1,765,455 during the same period. Contract research and development services revenue primarily represents the delivery of a milestone during the current financial year under the Siemens Collaboration Agreement wherein we recognized revenue of US\$500,000 (equivalent to A\$658,675). Other services represent ad-hoc services provided to our customers and partners at their request.

Contribution from Products & Services

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

	Years Ended December 31,	
	2019	2018
	A\$	A\$
Lump sum services fees	0	44,635,704
Quarterly service fees	164,577	21,378,404
Manufacturing contribution	1,997,266	64,981
Other services	1,163,663	866,346
Contribution from products & services	<u>3,325,506</u>	<u>66,945,435</u>

The decrease in period to period total contributions from products and services reflected in the table above is primarily as a result of the Company not receiving any further 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 has been recorded and received by the Company in the current financial year.

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.

Contribution from other services increased over the year primarily as a result of achievement of a milestone pursuant to the Collaboration Agreement.

The Australian consumer price index rose 1.8% over the twelve months ending December 31, 2019 and did not have a material impact on our net sales, revenue and income.

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.



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

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

	Years Ended December 31,	
	2019	2018
	A\$	A\$
Net income/(loss)	(4,846,285)	37,564,356
Interest income	(825,944)	(491,038)
Interest expense	0	2,211,186
Income tax expense/(benefit)	(1,317,479)	4,352,564
Depreciation - cost of goods sold & services	350,517	391,572
Depreciation and amortization - other operating costs & expenses	1,159,654	1,721,882
EBITDA	(5,479,537)	45,750,522

The decrease in EBITDA for all periods are primarily the result of the Company not receiving any further revenue 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.

We expect product support expenditure to decrease over time.

Depreciation and Amortization Expenses

	Years Ended December 31,	
	2019	2018
	A\$	A\$
Depreciation	715,835	1,721,882
Amortization	443,819	0
	<u>1,159,654</u>	<u>1,721,882</u>

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 at December 31, 2018 as its carrying value was no longer supported by future revenues streams.

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

	Years Ended December 31,	
	2019	2018
	A\$	A\$
Research and development	574,338	1,552,597
General and administrative	585,012	168,052
Product support	304	1,233
	<u>1,159,654</u>	<u>1,721,882</u>

Amortization expense represents intangible assets amortized over their estimated useful lives. These intangible assets were acquired in September 2019 pursuant to the Siemens Acquisition.



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Research and Development Expenses

Research and development expenditure principally reflects the effort required in product development of the tests we are developing. Our primary focus was the research and development activities in the blood coagulation testing. Research and development expenditure decreased by 52% in the 2019 financial year compared to the 2018 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 one-off cost during the period, the overall research and development expenditure for the financial year ended December 31, 2019 decreased as a result of the decline in headcount.

Research and development expenses, net of the research and development tax incentive income (refundable tax offset) for the respective periods are as follows:

	Years Ended December 31,	
	2019	2018
	A\$	A\$
Research and development expenses	5,535,212	11,578,246
Research and development tax incentive income	(2,802,697)	0
	<u>2,732,515</u>	<u>11,578,246</u>

The Company qualifies for the research and tax development tax incentive income for the 2019 financial year as its aggregate turnover is less than A\$20,000,000.

For the financial year ended December 31, 2018, the Company was not eligible for refundable tax offset as its aggregate turnover exceeded A\$20,000,000. We are however eligible to claim a non-refundable tax offset for the year ended December 31, 2018. We can carry forward a non-refundable tax offset to a later year once satisfying the standard tax offset carry-forward rules and utilise it to reduce the Company’s tax liability.

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.



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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 decreased by less than 1% during the 2019 financial year compared to the 2018 financial year.

Although there was an increase in our legal and consultant fees incurred as part of contract negotiations supporting customer relationship management and partner development, our overall general and administrative expenses declined as a result of cost saving measures undertaken by the Company including reduction in Board fees, savings in salaries and wages after the departure of certain staff during the year including our Chief Executive Officer and transitioning of work in-house such as company secretarial work now undertaken internally.

Interest Income

Interest income increased by 68% during the 2019 financial year compared to the 2018 financial year. The increase in interest income is generally attributable to the higher amount of funds available for investment.

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:

	Years Ended December 31,	
	2019	2018
	AS	AS
Interest expense	0	2,211,186
Other debt issuance costs	0	779,931
	<u>0</u>	<u>2,991,117</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.



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Research and development tax incentive income

The Company is eligible and has recorded research and development tax incentive income of A\$2,802,697 for the 2019 financial year. For the 2018 financial year, the aggregate turnover of the Company exceeded A\$20,000,000 and it was not eligible for a refundable tax offset ("research and development tax incentive income"). The eligible R&D activities and expenditures are however able to be claimed as a non-refundable tax offset as part of the current year income tax computation and any amounts included as a tax asset will be subject to recognition rules under ASC 740 "Income Taxes".

Research and development tax incentive income is generally in line with the level of research and development expenses.

Research and development tax incentive income for the 2019 financial year has not yet been received and as such is recorded in "Other current assets" in the consolidated balance sheets.

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, entities which are 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 or equal to A\$20,000,000.

Exchange gain

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 year-end exchange rates of monetary assets and liabilities denominated in foreign currencies.

Impairment of fixed assets

Certain fixed assets were written off during the 2018 financial year as its carrying value was no longer supported by future revenues streams.

Income tax expense

Pursuant to the new U.S. tax reform rules, Universal Biosensors, Inc. (parent entity of the Universal Biosensors Group domiciled in U.S.) is subject to regulations addressing Global Intangible Low-Taxed Income ("GILTI") effective from the 2018 financial year. 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 function 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. At a very broad level, the U.S. domiciled entity was subject to GILTI taxes in 2018 for the expected earnings and subject to certain other criteria of its non-U.S. domiciled subsidiaries (CFCs) due to the new tax reform regulations.

Our U.S. tax liability as at December 31, 2018 was US\$3,072,040 (equivalent to A\$4,352,564). This amount was revised to US\$3,065,267 (equivalent to A\$4,342,586) when the Company finalized and lodged its U.S. tax returns. The difference is reflected as income tax benefit.



Management's Discussion and Analysis of Financial Condition and Results of Operations

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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 the 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 Zero Exercise Price Employee Options ("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.



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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\$15,000,000 loan facility, we issued to the Lenders (Athyrium Opportunities Fund (A) LP and Athyrium Opportunities Fund (B) LP) warrants entitling the holder to purchase up to an aggregate total of 4,500,000 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 Financial Statements – *Note 16, 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.



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(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:

	Years Ended December 31,	
	2019	2018
	AS	AS
Financial assets:		
Cash and cash equivalents	30,229,530	11,797,789
Accounts receivables	116,626	50,209,561
Total financial assets	<u>30,346,156</u>	<u>62,007,350</u>
Debt:		
Long term secured loan	0	0
Total debt	<u>0</u>	<u>0</u>
Net financial assets	<u>30,346,156</u>	<u>62,007,350</u>

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 a term loan.

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 fees 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 from the date of issuance. 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.

**Management's Discussion and Analysis of Financial Condition and Results of Operations**

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

We regularly review all our financial assets for impairment. There were no impairments recognized for the years ended December 31, 2019 and 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. For the years ended December 31, 2019 and 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).

We had no derivatives or outstanding contracts in place through the years ended December 31, 2019 and 2018.

Measures of Liquidity and Capital Resources

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

	Years Ended December 31,	
	2019	2018
	AS	AS
Cash and cash equivalents	30,229,530	11,797,789
Working capital (current assets less current liabilities)	26,912,358	50,830,568
Ratio of current assets to current liabilities	3.65 : 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, prepayment of US\$4,000,000 towards future strip sales by Siemens on November 1, 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

	Years Ended December 31,	
	2019	2018
	AS	AS
Cash provided by/(used in):		
Operating activities	33,239,631	1,764,437
Investing activities	(10,281,242)	(356,785)
Financing activities	3,400	(20,946,065)
Net increase/(decrease) in cash, cash equivalents and restricted cash	<u>22,961,789</u>	<u>(19,538,413)</u>

The Company has generated positive operating cash flows in 2019 and 2018.

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 in 2019 when compared to 2018 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, prepayment of US\$4,000,000 towards future strip sales by Siemens on November 1, 2019, offset by working capital maintenance generally.



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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.

Our net cash used in financing activities in 2018 principally represents repayment of the term loan facility.

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 December 31, 2019 are:

	A\$
Less than 1 year	735,928
1 – 3 years	839,576
3 – 5 years	0
More than 5 years	0
Total minimum lease payments	<u>1,575,504</u>

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.

Recent Accounting Pronouncements

See Notes to Consolidated Financial Statements – *Note 2, Summary of Significant Accounting Policies.*

Financial Risk Management

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

Foreign Currency Market Risk

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

The Company is currently using natural hedging to limit currency exposure.



Management's Discussion and Analysis of Financial Condition and Results of Operations

Universal Biosensors, Inc.

The Company has recorded foreign currency transaction gains of A\$550,251 and A\$577,505 for the years ended December 31, 2019 and 2018, respectively.

Interest Rate Risk

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

Inflation

Our business is subject to the general risks of inflation. Our results of operations depend on our ability to anticipate and react to changes in the price of raw materials and other related costs over which we may have little control. Our inability to anticipate and respond effectively to an adverse change in the price could have a significant adverse effect on our results of operations. In the face of increasing costs, the Company strives to maintain its profit margins through cost reduction programs, productivity improvements and periodic price increases. For the two most recent fiscal years, the impact of inflation and changing prices on our net sales and revenues and on income from continuing operations has not been material.



Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Universal Biosensors, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Universal Biosensors, Inc. and its subsidiaries (the “Company”) as of December 31, 2019 and 2018, and the related consolidated statements of comprehensive income/(loss), consolidated statements of changes in stockholders’ equity and comprehensive income/(loss), and the consolidated statements of cash flows for the years then ended, including the related notes to consolidated financial statements and financial statement schedule listed in the index appearing under Item 15(a)(2) (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers
PricewaterhouseCoopers
Newcastle, Australia
February 26, 2020

We have served as the Company’s auditor since 2006.

PricewaterhouseCoopers, ABN 52 780 433 757
Level 3, 45 Watt Street, PO Box 798, NEWCASTLE NSW 2300
T: +612 4925 1100, F: +612 4925 1199, www.pwc.com.au



Universal Biosensors, Inc.
Consolidated Balance Sheets

	<u>December 31,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
	<u>AS</u>	<u>AS</u>
ASSETS		
Current assets:		
Cash and cash equivalents	30,229,530	11,797,789
Inventories, net	1,078,064	744,466
Accounts receivable	116,626	50,209,561
Prepayments	135,764	158,492
Restricted cash	2,055,473	15,589
Other current assets	3,457,438	1,105,291
Total current assets	<u>37,072,895</u>	<u>64,031,188</u>
Non-current assets:		
Property, plant and equipment	29,021,868	29,101,932
Less accumulated depreciation	(24,271,802)	(23,475,544)
Property, plant and equipment - net	4,750,066	5,626,388
Intangible assets	16,371,996	0
Less amortization of intangible assets	(443,819)	0
Intangible assets - net	15,928,177	0
Restricted cash	4,907,904	320,000
Total non-current assets	<u>25,586,147</u>	<u>5,946,388</u>
Total assets	<u><u>62,659,042</u></u>	<u><u>69,977,576</u></u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	615,377	695,405
Income taxes payable	0	4,352,564
Accrued expenses	1,015,251	1,696,644
Contingent consideration	2,141,022	0
Other liabilities	2,924,069	2,902,525
Deferred revenue	2,682,404	2,356,583
Employee entitlements liabilities	782,414	1,196,899
Total current liabilities	<u>10,160,537</u>	<u>13,200,620</u>
Non-current liabilities:		
Asset retirement obligations	2,600,000	2,600,000
Employee entitlements liabilities	32,443	39,468
Deferred income tax liability	3,050,837	0
Deferred revenue	1,421,680	3,463,737
Total non-current liabilities	<u>7,104,960</u>	<u>6,103,205</u>
Total liabilities	<u><u>17,265,497</u></u>	<u><u>19,303,825</u></u>
Commitments and contingencies	<u>0</u>	<u>0</u>
Stockholders' equity:		
Preferred stock, US\$0.01 par value. Authorized 1,000,000 shares; issued and outstanding nil in 2019 (2018: nil)		
Common stock, US\$0.0001 par value. Authorized 300,000,000 shares; issued and outstanding 177,571,854 shares in 2019 (2018: 177,243,520)	17,757	17,724
Additional paid-in capital	93,396,802	93,815,185
Accumulated deficit	(42,832,987)	(80,397,343)
Current year income/(loss)	(4,846,285)	37,564,356
Accumulated other comprehensive loss	(341,742)	(326,171)
Total stockholders' equity	<u>45,393,545</u>	<u>50,673,751</u>
Total liabilities and stockholders' equity	<u><u>62,659,042</u></u>	<u><u>69,977,576</u></u>

See accompanying notes to the financial statements



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Universal Biosensors, Inc.

Consolidated Statements of Comprehensive Income/(Loss)

	Years Ended December 31,	
	2019	2018
	AS	AS
Revenue		
Revenue from products	4,863,347	1,672,321
Revenue from services	2,033,852	67,784,593
Total revenue	6,897,199	69,456,914
Operating costs & expenses		
Cost of goods sold	2,866,081	1,607,340
Cost of services	705,612	904,139
Total cost of goods sold & services	3,571,693	2,511,479
Contribution from products & services	3,325,506	66,945,435
Other operating costs & expenses		
Product support	47,857	227,517
Depreciation and amortization expenses	1,159,654	1,721,882
Research and development	5,535,212	11,578,246
General and administrative	6,982,606	6,995,089
Total operating costs & expenses	13,725,329	20,522,734
Profit/(loss) from operations	(10,399,823)	46,422,701
Other income/(expense)		
Interest income	825,944	491,038
Financing costs	0	(2,991,117)
Research and development tax incentive income	2,802,697	0
Exchange gain	550,251	577,505
Impairment of fixed assets	0	(2,574,709)
Other	57,167	(8,498)
Total other income/(expense)	4,236,059	(4,505,781)
Net income/(loss) before tax	(6,163,764)	41,916,920
Income tax benefit/(expense)	1,317,479	(4,352,564)
Net income/(loss)	<u>(4,846,285)</u>	<u>37,564,356</u>
Earnings per share		
Basic net income/(loss) per share	(0.03)	0.21
Average weighted number of shares - basic	177,481,639	176,732,183
Diluted net income/(loss) per share	(0.03)	0.21
Average weighted number of shares - diluted	177,481,639	177,152,938
Other comprehensive gain/(loss), net of tax:		
Foreign currency translation reserve	(15,571)	(24,462)
Reclassification for (gains)/losses realized in net income	0	0
Other comprehensive gain/(loss)	(15,571)	(24,462)
Comprehensive gain/(loss)	<u>(4,861,856)</u>	<u>37,539,894</u>

See accompanying notes to the financial statements.



Universal Biosensors, Inc.

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

	Ordinary shares		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
	AS	AS	AS	AS	AS	AS
Balances at January 1, 2018	176,498,550	17,650	93,450,721	(80,397,343)	(301,709)	12,769,319
Net income	0	0	0	37,564,356	0	37,564,356
Other comprehensive loss	0	0	0	0	(24,462)	(24,462)
Exercise of stock options issued to employees	553,334	55	(55)	0	0	0
Shares issued to employees	191,636	19	45,974	0	0	45,993
Stock option expense	0	0	318,545	0	0	318,545
Balances at December 31, 2018	<u>177,243,520</u>	<u>17,724</u>	<u>93,815,185</u>	<u>(42,832,987)</u>	<u>(326,171)</u>	<u>50,673,751</u>
Net loss	0	0	0	(4,846,285)	0	(4,846,285)
Other comprehensive loss	0	0	0	0	(15,571)	(15,571)
Exercise of stock options issued to employees	328,334	33	3,367	0	0	3,400
Stock option expense	0	0	(421,750)	0	0	(421,750)
Balances at December 31, 2019	<u>177,571,854</u>	<u>17,757</u>	<u>93,396,802</u>	<u>(47,679,272)</u>	<u>(341,742)</u>	<u>45,393,545</u>

See accompanying notes to the financial statements.



Universal Biosensors, Inc.

Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2019	2018
	AS	AS
Cash flows from operating activities provided by:		
Net income/(loss)	(4,846,285)	37,564,356
Adjustments to reconcile net income/(loss) to net cash provided by operating activities:		
Depreciation and amortization	1,510,171	2,113,454
Share based payments expense	(421,750)	318,545
Impairment of fixed assets	0	2,574,709
Loss on disposal of fixed assets	5,440	8,498
Unrealized foreign exchange gains	(2,185,332)	(472,934)
Financing costs - amortization of warrants	0	213,359
Change in assets and liabilities:		
Inventory	35,243	(82,334)
Accounts receivable	50,092,936	(45,812,293)
Prepayment and other assets	(2,329,419)	483,774
Income tax payable	(4,352,564)	4,352,564
Deferred revenue	(1,716,236)	0
Employee entitlements	(421,510)	(356,643)
Accounts payable and accrued expenses	(2,131,063)	859,382
Net cash provided by operating activities	<u>33,239,631</u>	<u>1,764,437</u>
Cash flows from investing activities:		
Proceeds from sale of property, plant and equipment	22,505	2,582
Purchases of property, plant and equipment	(137,667)	(448,867)
Proceeds from government grants in relation to property, plant & equipment	3,376	89,500
Acquisition of assets	(10,169,456)	0
Net cash used in investing activities	<u>(10,281,242)</u>	<u>(356,785)</u>
Cash flows from financing activities:		
Repayment of borrowings	0	(20,689,655)
Borrowing costs	0	(256,410)
Proceeds from stock options exercised	3,400	0
Net cash provided by/(used in) financing activities	<u>3,400</u>	<u>(20,946,065)</u>
Net increase/(decrease) in cash, cash equivalents and restricted cash	22,961,789	(19,538,413)
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	2,097,740	2,176,564
Cash, cash equivalents and restricted cash at end of period	<u><u>37,192,907</u></u>	<u><u>12,133,378</u></u>

See accompanying notes to the financial statement



Universal Biosensors, Inc.

**Notes to Consolidated Financial Statements
(for the years ended December 31, 2019 and 2018)**

(1) Basis of Presentation

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

Unless otherwise noted, references 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 its wholly owned Canadian operating subsidiary, Hemostasis Reference Laboratory Inc. (“HRL”).

The Company’s consolidated financial statements have been prepared assuming the Company will continue as a going concern. We rely largely on our existing cash and cash equivalents balance and 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 from the date of issuance. 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.

(2) 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 lives, carrying amount of property, plant and equipment, income tax expense, deferred income taxes, asset retirement obligations, liabilities related to employee benefits and research and development tax incentive income. Actual results could differ from those estimates.

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 performance guarantee issued in favor of a customer, tenant security deposits and credit card security deposits. As at December 31, 2019 and 2018, 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 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 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.



Universal Biosensors, Inc.

**Notes to Consolidated Financial Statements
(for the years ended December 31, 2019 and 2018)**

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.

For cash flow hedges, other than those covered by the preceding statement, the associated cumulative gain or loss is removed from equity and recognized in the consolidated statements of comprehensive income in the same period or periods during which the hedged forecast transaction affects the consolidated 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 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 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 years ended December 31, 2019 and 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 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.



Universal Biosensors, Inc.

**Notes to Consolidated Financial Statements
(for the years ended December 31, 2019 and 2018)**

- 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. Costs of purchased inventory are determined after deducting rebates and discounts.

	<u>Years Ended December 31,</u>	
	<u>2019</u>	<u>2018</u>
	<u>AS</u>	<u>AS</u>
Raw materials	411,233	302,056
Work in progress	213,080	442,410
Finished goods	453,751	0
	<u>1,078,064</u>	<u>744,466</u>

Receivables

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

	<u>Years Ended December 31,</u>	
	<u>2019</u>	<u>2018</u>
	<u>AS</u>	<u>AS</u>
Accounts receivable	116,626	50,209,561
Allowance for doubtful debts	0	0
	<u>116,626</u>	<u>50,209,561</u>

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 that do not extend the life of the asset are charged to operations as incurred, include normal services, and do not include items of a capital nature.



Universal Biosensors, Inc.

**Notes to Consolidated Financial Statements
(for the years ended December 31, 2019 and 2018)**

The Company received 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 is 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 December 31, 2019 and 2018 were A\$2,574,709.

Other Liabilities

Other liabilities represent a 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.

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. A reconciliation of the valuation and qualifying accounts is attached as Schedule ii.

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.

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



Universal Biosensors, Inc.

**Notes to Consolidated Financial Statements
(for the years ended December 31, 2019 and 2018)**

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 years ended December 31, 2019, and 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 balance sheets.

Revenue Recognition

Revenue from products and services

A. Significant accounting policy

Year ended December 31, 2018

For the 2018 financial year, we recognized revenue from all sources based on the provisions of the U.S. SEC’s Staff Accounting Bulletin No. 104 and ASC 605 Revenue Recognition.

The Company’s revenue represents revenue from sales of products, provision of services and collaborative research and development agreements. We recognize revenue from sales of products at the time title of goods passes to the buyer and the buyer assumes the risks and rewards of ownership, assuming all other revenue recognition criteria have been met. Generally, this is at the time products are shipped to the customer. Revenue from services is recognized when a persuasive evidence of an arrangement exists, services have been rendered, the price is fixed or determinable.

Year ended December 31, 2019

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.

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 recorded and received in the 2019 financial year.

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.



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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.

<i>Products and services</i>	<i>Nature, timing of satisfaction of performance obligations, and significant payment terms</i>
Point-of-care coagulation test devices	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 generally 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 has no longer and 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 and received during the current 2019 financial year.

C. Disaggregation of revenue

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

	Year Ended December 31,	
	2019 A\$	2018 A\$
Major product/service lines		
Xprecia Stride™ strips	4,863,347	1,672,321
Lump sum service fees	0	44,635,704
Quarterly service fees	164,577	21,378,404
Coagulation testing services	1,094,669	1,193,948
Other services	774,606	576,537
	<u>6,897,199</u>	<u>69,456,914</u>
Timing of revenue recognition		
Products and services transferred at a point in time	6,897,199	69,456,914
Services transferred over time	0	0
	<u>6,897,199</u>	<u>69,456,914</u>



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D. Contract balances

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

	Year Ended December 31,	
	2019	2018
	AS	AS
Receivables	116,626	50,209,561
Contract assets	0	0
Contract liabilities:		
- Current	2,682,404	2,356,583
- Non-current	1,421,680	3,463,737

Timing of revenue recognition may differ from the timing of invoicing to customers. Accounts receivable represents amounts invoiced and revenue recognized prior to invoicing when we have satisfied our performance obligation and have the unconditional right to payment. A contract asset is an entity's right to payment for goods and services already transferred to a customer but that right to payment is conditional on something other than the passage of time. The contract assets are transferred to the receivables when the rights become unconditional. The contract liabilities primarily relates to the following:

- 2019 financial year – the Company's obligation to transfer Xprecia Stride™ strips to Siemens for which the Company has received consideration from Siemens but the transfer has not yet been completed.
- 2018 financial year - 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:

	Contract Asset	Contract Liability (Current)	Contract Liability (Long-Term)
	AS	AS	AS
Opening balance (January 1, 2019)	0	2,356,583	3,463,737
Closing balance (December 31, 2019)	0	2,686,404	1,421,680
Increase/(decrease)	0	329,821	(2,042,057)
Opening balance (January 1, 2018)	0	2,356,583	3,463,737
Closing balance (December 31, 2018)	0	2,356,583	3,463,737
Increase/(decrease)	0	0	0

The movement in contract liabilities is explained as follows:

- Of the current portion of the total contract liabilities balance as at December 31, 2018, a sum of A\$658,675 was recognized as revenue in January 2019 as the Company met one of its milestones pursuant to the Siemens Collaboration Agreement. The remainder of the milestones consideration previously received but deferred was repaid in September 2019 when the Siemens Collaboration Agreement was terminated.
- There was a prepayment of US\$4,000,000 towards future strip sales by Siemens on November 1, 2019. The balance of the Siemens prepayment account as at December 31, 2019 is US\$2,833,870 (A\$4,104,084), reducing by US\$1,166,130 during Q4 2019 as the Company supplied strips to Siemens.

E. Transaction price allocated to the remaining performance obligations

There was a prepayment of US\$4,000,000 towards future strip sales by Siemens on November 1, 2019. US\$1,166,130 has been recognized as revenue during Q4 2019 as the Company supplied strips to Siemens. The balance of the Siemens prepayment account as at December 31, 2019 is US\$2,833,870 (A\$4,104,084).

Interest income

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



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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.

The Company has recorded research and development tax incentive income of A\$2,802,697 for the 2019 financial year. For the 2018 financial year, the aggregate turnover of the Company exceeded A\$20,000,000 and it was not eligible for a refundable tax offset ("research and development tax incentive income"). The eligible R&D activities and expenditures are however able to be claimed as a non-refundable tax offset as part of the current year income tax computation and any amounts included as a tax asset will be subject to recognition rules under ASC 740 "Income Taxes".

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 Canadian dollars ("CAD\$") for all years presented.

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

Transactions and balances

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

The Company has recorded foreign currency transaction gains of A\$550,251 and A\$577,505 in each of the years ended December 31, 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;



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- 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. These were nil as at December 31, 2019 and 2018. Purchase commitments contracted for as at December 31, 2019 and 2018 were A\$220,569 and A\$2,941,864, respectively. Contingent consideration as at December 31, 2019 was A\$2,141,022 (equivalent to US\$1,500,000) and nil as at December 31, 2018. Pursuant to the Siemens Acquisition, the Company has agreed to pay US\$1,500,000 to Siemens within five days of Siemens achieving a pre-defined milestone. The Company has the discretion of advising Siemens when the milestone is to be achieved but from the date notification is sent by the Company, Siemens has 90 days to fulfill this milestone. Once the milestone is achieved, it will enable UBI to use Siemens proprietary reagent which will allow UBI to access markets in certain jurisdictions.

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 years ended December 31, 2019 and 2018 are considered operating leases. The costs of operating leases are charged to the consolidated statements of comprehensive income on a straight-line basis over the lease term.

Stock-based Compensation

We measure stock-based compensation at grant date, based on the estimated fair value of the award, and recognize the cost as an expense on a straight-line basis over the vesting period of the award. We estimate the fair value of stock options using the Trinomial Lattice model. We also grant our employees Restricted Stock Units ("RSUs") and zero exercise price 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. See note 5 for further details.

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.



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Employee Benefit Costs

The Company contributes 9.50% 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 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.

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 income/(loss) is as follows:

	Before-Tax Amount A\$	Tax (Expense)/ Benefit A\$	Net-of-Tax Amount A\$
2019			
Foreign currency translation reserve	(15,571)	0	(15,571)
Reclassification for gains realised in net income	0	0	0
Other comprehensive loss	<u>(15,571)</u>	<u>0</u>	<u>(15,571)</u>
2018			
Foreign currency translation reserve	(24,462)	0	(24,462)
Reclassification for gains realised in net income	0	0	0
Other comprehensive loss	<u>(24,462)</u>	<u>0</u>	<u>(24,462)</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 recognised 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.



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

On January 1, 2020 the Company adopted the new accounting pronouncement ASU 2016-02. This impacted the Company as it relates to its leases which requires a lessee to recognize all long-term leases on its balance sheet as a liability for its lease obligation, measured at the present value of lease payments not yet paid, and a corresponding asset representing its right to use the underlying asset over the lease term and expands disclosure of key information about leasing arrangements. 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.

(b) Recently adopted accounting pronouncements

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. As an emerging growth company, the Company has adopted this guidance effective 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.

(3) Commitments and Contingent Liabilities

For details on our contingent liabilities, see Notes to Consolidated Financial Statements – *Note 2, Summary of Significant Accounting Policies*.

Operating Leases

The lease for 1 Corporate Avenue, Rowville Victoria expires on March 31, 2022, with two options to renew the lease each for successive three-year periods. The Company's primary bank has issued a bank guarantee of A\$250,000 in relation to a rental bond to secure the payments under the lease. This bank guarantee, which is restricted cash, is secured by a security deposit held at the bank and has been recorded as "Restricted cash" in consolidated balance sheets.

In accordance with the terms of the lease, the lessee has to restore part of the building upon vacating the premises.



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HRL leases approximately 482 square meters of office and laboratory facilities at 15(H) Wing, Second Floor, 711 Concession Street, Hamilton, Ontario. The lease for 711 Concession Street expires on January 31, 2021.

The future minimum lease payments under non-cancelable operating leases (with initial or remaining lease terms in excess of one year) as of December 31, 2019 are:

	A\$
Less than 1 year	735,928
1 – 3 years	839,576
3 – 5 years	0
More than 5 years	0
Total minimum lease payments	<u>1,575,504</u>

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.

Rent expense was A\$755,419 and A\$750,798 for the fiscal years ended December 31, 2019 and 2018, respectively.

Guarantees

There are cross guarantees given by Universal Biosensors, Inc., Universal Biosensors Pty Ltd and Hemostasis Reference Laboratory Inc. as described in note 15. No deficiencies of assets exist in any of these companies. No liability was recognized by the parent entity or the consolidated entity in relation to this guarantee, as the fair value of the guarantees is immaterial.

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. This grant was terminated upon mutual consent on December 19, 2019. The grants were paid upon achievement of pre-agreed milestones. The milestones generally related to UBS placing purchase orders, commissioning upgrades and validating the equipment.

An amount of A\$89,500 and A\$271,318 were received under this grant in June 2018 and November 2017, respectively.

(4) Income Taxes

The Company is subject to income tax in Australia and is required to pay taxes on its Australian profits. As provided under the Australian income tax laws, UBI and its wholly owned resident subsidiary UBS have formed a tax-consolidated group. UBI is required to lodge U.S. federal income tax returns and HRL is required to lodge tax returns in Canada. UBI and HRL are currently in a tax loss situation.



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A reconciliation of the (benefit)/provision for income taxes is as follows:

	Years ended December 31,			
	2019		2018	
	AS	%	AS	%
Profit/(loss) before income taxes	(6,163,764)		41,916,920	
Computed by applying income tax rate of home jurisdiction	(1,849,129)	30	12,575,076	30
Effect of tax rates in foreign jurisdictions	(12,572)	1	13,316	0
Research & development incentive	1,092,085	(18)	4,253,289	10
Disallowed expenses/(income):				
Acquisition of assets	(3,050,837)	49		
Share based payment	(126,525)	2	95,564	0
Other	(676,733)	11	(61,115)	0
Utilization of carry forward losses	0	0	(3,298,121)	(8)
Utilization of tax credits	0	0	(13,046,757)	(31)
Change in valuation allowance	3,316,210	(54)	(531,252)	(1)
Global intangible low-taxed income (GILTI) tax	(9,978)	0	4,352,564	10
Income tax expense/(benefit)	<u>(1,317,479)</u>	<u>21</u>	<u>4,352,564</u>	<u>10</u>

The components of our net income/(loss) before income taxes as either domestic or foreign is as follows:

	As of December 31,	
	2019	2018
	AS	AS
Foreign	359,237	(44,386)
Domestic (Australia)	(6,523,001)	41,961,306
	<u>(6,163,764)</u>	<u>41,916,920</u>

Significant component of the Company's deferred tax assets and liabilities are shown below:

	As of December 31,	
	2019	2018
	AS	AS
Deferred tax assets:		
Operating loss carry forwards	4,506,287	0
Depreciation and amortization	1,709,678	1,578,478
Asset retirement obligations	780,000	780,000
Employee entitlements	239,899	366,039
Accruals	1,133,073	1,325,955
Decline in value of patents	1,170,092	1,195,965
Unrealized exchange loss	10,020	(583,029)
Other	(20,778)	241,152
Total deferred tax assets	9,528,271	4,904,560
Valuation allowance for deferred tax assets	(8,220,770)	(4,904,560)
Net deferred tax asset	<u>1,307,501</u>	<u>0</u>
Deferred tax liabilities:		
Intangible assets	4,358,338	0
Total deferred tax liabilities	4,358,338	0
Net deferred tax liabilities	<u>3,050,837</u>	<u>0</u>

Significant components of deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting and tax purposes. A valuation allowance has been established, as realization of such assets is not more likely than not.

At December 31, 2019 the Company has \$15,020,955 (nil as at December 31, 2018) 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\$3,374,776 at December 31, 2018) of non-refundable R&D tax offset as at December 31, 2019. 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 US tax losses available for carry forward against future earnings of nil as of December 31, 2018 (nil as of December 31, 2018). Pursuant to the US 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\$401,743 and CAD\$738,848 as at December 31, 2019 and 2018, respectively.



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(5) Employee Incentive Schemes

(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. Options granted in 2019 and 2018 were nil.

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.

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 value of all other options granted has been determined either using the closing price of our common stock trading in the form of CDIs on ASX at the time of grant of the options or based on an expected return. ZEPOs exercise price are 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.

Stock option activity during the current period is as follows:

	Number of shares	Weighted average issue price AS
Balance at December 31, 2018	15,153,884	0.63
Granted	0	0.00
Exercised	(328,334)	0.01
Lapsed	(12,914,100)	0.67
Balance at December 31, 2019	<u>1,911,450</u>	<u>0.46</u>



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At December 31, 2019, the number of options vested and exercisable was 1,911,450 (2018: 7,510,888). At December 31, 2019, total stock compensation expense/(income) recognized in the consolidated condensed statements of comprehensive income was (A\$421,750) (2017: A\$318,545).

The following table represents information relating to stock options outstanding under the plans as of December 31, 2019:

Exercise Price A\$	Options Outstanding		Options Exercisable Shares
	Shares	Weighted average remaining life in years	
\$ 0.79	12,000	0	12,000
\$ 0.49	55,000	1	55,000
\$ 0.00	40,000	1	40,000
\$ 0.23	75,000	2	75,000
\$ 0.00	40,000	2	40,000
\$ 0.45	100,000	3	100,000
\$ 0.50	1,165,500	3	1,165,500
\$ 0.33	96,500	4	96,500
\$ 0.50	327,450	4	327,450
	<u>1,911,450</u>		<u>1,911,450</u>

The table below sets forth the number of employee stock options exercised and the number of shares issued in the period from January 1, 2018. We issued these shares in reliance upon exemptions from registration under Regulation S under the Securities Act of 1933, as amended.

Period Ending	Number of Options Exercised and Corresponding Number of Shares Issued	Weighted Average Exercise Price	Proceeds Received (A\$)
2018	553,334	A\$ 0.00	0
2019	328,334	A\$ 0.01	3,400

As of December 31, 2019, there was nil unrecognized compensation expense as all the employee stock options have vested.

The aggregate intrinsic value for all options outstanding as at December 31, 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.

The table below sets forth the restricted shares issued by the Company since January 1, 2018:

	Number of Restricted Shares Issued	Market Value of Restricted Shares Issued (A\$)
December, 2018	191,636	45,993



Universal Biosensors, Inc.

**Notes to Consolidated Financial Statements
(for the years ended December 31, 2019 and 2018)**

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

	<u>Number of shares</u>	<u>Weighted average issue price (A\$)</u>
Balance at December 31, 2018	311,246	0.28
Granted	0	0.00
Release of restricted shares	<u>(190,432)</u>	<u>0.30</u>
Balance at December 31, 2019	<u>120,814</u>	<u>0.24</u>

(6) 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 21% 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 December 31, 2019 and 2018 was A\$14,548 and A\$21,716, respectively.

There were no other related party transactions during 2019 and 2018 other than as disclosed above.

(7) Financial Instruments

	<u>Years Ended December 31,</u>	
	<u>2019</u>	<u>2018</u>
	<u>A\$</u>	<u>A\$</u>
Financial assets:		
Cash and cash equivalents	30,229,530	11,797,789
Accounts receivables	<u>116,626</u>	<u>50,209,561</u>
Total financial assets	<u>30,346,156</u>	<u>62,007,350</u>
Debt:		
Long term secured loan	0	0
Total debt	<u>0</u>	<u>0</u>
Net financial assets	<u>30,346,156</u>	<u>62,007,350</u>



Universal Biosensors, Inc.

**Notes to Consolidated Financial Statements
(for the years ended December 31, 2019 and 2018)**

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

We regularly review all our financial assets for impairment. There were no impairments recognized in 2019 and 2018.

Derivative Instruments and Hedging Activities

We had no derivatives or outstanding contracts in place through the years ended December 31, 2019 and 2018.

(8) Property, Plant and Equipment, net

	As of December, 31	
	2019	2018
	A\$	A\$
Plant and equipment	19,853,389	18,028,590
Leasehold improvements	9,130,310	9,130,310
Capital work in process	38,169	1,943,032
	29,021,868	29,101,932
Accumulated depreciation	(24,271,802)	(23,475,544)
Property, plant & equipment, net	4,750,066	5,626,388

Capital work in process relates to assets under construction and comprises primarily specialized manufacturing and testing equipment. Legal right to the assets under construction rests with the Company. The amounts capitalized for capital work in process represent the percentage of expenditure that has been completed, and once the assets are placed into service, the Company begins depreciating the respective assets. The accumulated amortisation of capitalised leasehold improvements for the fiscal years ended December 31, 2019 and 2018 was A\$9,130,310 and A\$8,993,225, respectively.

From 2017 to 2019, the Company was entitled to receive Commonwealth of Australia grant monies under grant agreements to support its development activities, including in connection with the purchase of plant and equipment. This grant was terminated by mutual consent on December 19, 2019. Plant and equipment is presented net of the government grant of A\$360,818 for the year ended December 31, 2019 (2018: A\$360,818). The grants are recognized against the acquisition costs of the related plant and equipment as and when the related assets are purchased. Grants received in advance of the relevant expenditure are treated as deferred income and included in Current Liabilities on the balance sheet as the Company does not control the monies until the relevant expenditure has been incurred. Grants due to the Company under research agreements are recorded as Currents Assets on the balance sheet.

Depreciation expense was A\$1,066,352 and A\$2,113,454 for the fiscal years ended December 31, 2019 and 2018, respectively.

(9) Accrued Expenses

Accrued expenses consist of the following:

	As of December, 31	
	2019	2018
	A\$	A\$
Legal, tax and accounting fees	689,637	716,937
Salary and related costs	175,241	306,162
Research and development materials	21,037	554,496
Other	129,336	119,049
	1,015,251	1,696,644



Universal Biosensors, Inc.

**Notes to Consolidated Financial Statements
(for the years ended December 31, 2019 and 2018)**

(10) Stockholders' Equity - Common Stock

Holders of common stock are generally entitled to one vote per share held on all matters submitted to a vote of the holders of common stock. At any meeting of the shareholders, the presence, in person or by proxy, of the majority of the outstanding stock entitled to vote shall constitute a quorum. Except where a greater percentage is required by the Company's amended and restated certificate of incorporation or by-laws, the affirmative vote of the holders of a majority of the shares of common stock then represented at the meeting and entitled to vote at the meeting shall be sufficient to pass a resolution. Holders of common stock are not entitled to cumulative voting rights with respect to the election of directors, and the common stock does not have pre-emptive rights.

Trading in our shares of common stock on ASX is undertaken using CHESSE Depository Interests ("CDIs"). Each CDI represents beneficial ownership in one underlying share. Legal title to the shares underlying CDIs is held by CHESSE Depository Nominees Pty Ltd ("CDN"), a wholly owned subsidiary of ASX.

Holders of CDIs have the same economic benefits of holding the shares, such as dividends (if any), bonus issues or rights issues as though they were holders of the legal title. Holders of CDIs are not permitted to vote but are entitled to direct CDN how to vote. Subject to Delaware General Corporation Law, dividends may be declared by the Board and holders of common stock may be entitled to participate in such dividends from time to time.

(11) Net Income/(Loss) per Share

Basic net income/(loss) per ordinary share was computed by dividing the net income/(loss) applicable to common stock by the weighted-average number of common stock outstanding during the period. Warrants issued to the Lenders and options granted to employees under the Universal Biosensors Employee Option Plan are considered to be potential ordinary shares for the purpose of calculating diluted net income/(loss) per share.

	<u>Years Ended December 31,</u>	
	<u>2019</u>	<u>2018</u>
Weighted average shares used as denominator in calculating:		
Basic net income/(loss) per share	<u>177,481,639</u>	<u>176,732,183</u>
Diluted net income/(loss) per share	<u>177,481,639</u>	<u>177,152,938</u>

The number of shares not included in the calculation of basic net income/(loss) per ordinary share because the impact would be anti-dilutive were 80,000 and 420,755 for the years ended December 31, 2019 and 2018, respectively.

(12) Guarantees and Indemnifications

The amended and restated certificate of incorporation and amended and restated bylaws of the Company provide that the Company will indemnify officers and directors and former officers and directors in certain circumstances, including for expenses, judgments, fines and settlement amounts incurred by them in connection with their services as an officer or director of the Company or its subsidiaries, provided that such person acted in good faith and in a manner such person reasonably believed to be in the best interests of the Company, and, with respect to any criminal action or proceeding, the Company had reasonable cause to believe that such person's conduct was not unlawful.

In addition to the indemnities provided in the amended and restated certificate of incorporation and amended and restated bylaws, the Company has entered into indemnification agreements with certain of its officers and each of its directors. Subject to the relevant limitations imposed by applicable law, the indemnification agreements, among other things:

- indemnify the relevant officers and directors for certain expenses, judgments, fines and settlement amounts incurred by them in connection with their services as an officer or director of the Company or its subsidiaries; and
- require the Company to make a good faith determination whether or not it is practicable to maintain liability insurance for officers and directors or to ensure the Company's performance of its indemnification obligations under the agreements.

The Company maintains directors' and officers' liability insurance providing for the indemnification of our directors and certain of our officers against certain liabilities incurred as a director or officer, including costs and expenses associated in defending legal proceedings. In accordance with the terms of the insurance policy and commercial practice, the amount of the premium is not disclosed.



Universal Biosensors, Inc.

**Notes to Consolidated Financial Statements
(for the years ended December 31, 2019 and 2018)**

No liability has arisen under these indemnities as of December 31, 2019 and 2018.

(13) 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.

Our total revenue as disclosed below is attributed to countries based on location of customer. Location has been determined generally based on contractual arrangements.

	Years Ended December 31,	
	2019	2018
	AS	AS
Home country - Australia	3,677,486	490,962
Foreign countries		
- U.S.A.	1,437,998	1,428,350
- Germany	4,785,384	1,603,817
- Switzerland	235,945	66,084,950
- Canada	296,183	238,056
- Other	155,451	101,817
Total - foreign countries	6,910,961	69,456,990
Total income	10,588,447	69,947,952
% of total income derived from - LifeScan	2%	94%
- Siemens	53%	3%
- Other	45%	2%

The chief operating decision maker of the Company is the management committee comprising the senior executives of the Company.

(14) Deed of Cross Guarantee

Universal Biosensors, Inc. and its wholly owned subsidiary, Universal Biosensors Pty Ltd, are parties to a deed of cross guarantee under which each company guarantees the debts of the other. By entering into the deed, the wholly-owned entity has been relieved from the requirements to prepare a financial report and directors' report under Class Order 98/1418 (as amended) issued by the Australian Securities and Investments Commission.

The above companies represent a "Closed Group" for the purposes of the Class Order, and as there are no other parties to the Deed of Cross Guarantee that are controlled by Universal Biosensors, Inc., they also represent the "Extended Closed Group".

The consolidated financial statements presented within this report comprise that of Universal Biosensors, Inc. and its wholly owned subsidiary, Universal Biosensors Pty Ltd. These two entities also represent the "Closed Group" and the "Extended Closed Group".

(15) Borrowings

The Company repaid its borrowings in November 2018.



Universal Biosensors, Inc.

**Notes to Consolidated Financial Statements
(for the years ended December 31, 2019 and 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\$25,000,000, which was amended on January 30, 2015 (“Credit Agreement”). Of this amount, US\$15,000,000 had been drawn at December 31, 2013, with a further US\$10,000,000 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.

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 4,500,000 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.

(16) Warrants

Pursuant to the Credit Agreement, UBI issued to the Lenders warrants entitling the holder to purchase up to an aggregate total of 4,500,000 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.



Universal Biosensors, Inc.

**Notes to Consolidated Financial Statements
(for the years ended December 31, 2019 and 2018)**

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.

(17) Restricted Cash

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

	Years Ended December 31,	
	2019	2018
	AS	AS
Cash and cash equivalents	30,229,530	11,797,789
Restricted cash - current assets	2,055,473	15,589
Restricted cash - non-current assets	4,907,904	320,000
	<u>37,192,907</u>	<u>12,133,378</u>

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

	Years Ended December 31,	
	2019	2018
	AS	AS
Collateral for facilities (a) - current assets	16,404	15,589
Performance guarantee (b) - current assets	2,039,069	0
Collateral for facilities (c) - non-current assets	320,000	320,000
Performance guarantee (b) - non-current assets	4,587,904	0
	<u>6,963,377</u>	<u>335,589</u>

- (a) Represents bank guarantee of CDN\$15,000 as security deposit on HRL's credit card
- (b) Performance guarantee represents letter of credit issued in favour of Siemens pursuant to the 2019 Siemens Agreements. The performance guarantee was initially issued for US\$5,000,000 and the same reduces in equal quarterly amounts over the 42 months with effect from September 18, 2019.
- (c) 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 as at December 31, 2019 and 2018 were A\$25,113 and A\$62,037, respectively.

(18) Acquisition of Assets from Siemens

As discussed in more detail in "Management's Discussion and Analysis of Financial Condition and Results of Operations – Our Business", 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.



Universal Biosensors, Inc.

**Notes to Consolidated Financial Statements
(for the years ended December 31, 2019 and 2018)**

(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.

(b) Contingent consideration

Pursuant to the Siemens Acquisition, the Company has agreed to pay US\$1,500,000 to Siemens within five days of Siemens achieving a pre-defined milestone. The Company has the discretion of advising Siemens when the milestone is to be achieved but from the date notification is sent by the Company, Siemens has 90 days to fulfil this milestone. Once the milestone is achieved, it will enable UBI to use Siemens proprietary reagent which will allow UBI to access 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 at the acquisition date are as follows:

	A\$
Intangible assets - distribution rights ¹	12,013,658
Inventory	368,840
Total identifiable assets acquired	12,382,498
Deferred income tax liability on intangible assets ¹	4,358,338
	<u>16,740,836</u>
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 the balance sheet A\$16,371,996 including the effect of the deferred tax.

(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\$443,819 for the year ended December 31, 2019.

	Years Ended December 31,	
	2019	2018
	A\$	A\$
Intangible assets - gross	16,371,996	0
Less accumulated amortization	(443,819)	0
Total intangible assets - net	<u>15,928,177</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.



Universal Biosensors, Inc.

Schedule ii – Valuation and Qualifying Accounts
(for the years ended December 31, 2019 and 2018)

	Balance at Beginning of Period	Additions		Deductions	Balance at end of Period
		Charged to Costs and Expenses	Charged to Other Accounts		
	AS	AS	AS	AS	AS
<i>Year ended December 31, 2018</i>					
Deferred income tax valuation allowance	7,931,607	(16,876,129)	13,849,082	0	4,904,560
<i>Year ended December 31, 2019</i>					
Deferred income tax valuation allowance	4,904,560	4,623,711	0	(1,307,501)	8,220,770



Exhibit 4.3

**DESCRIPTION OF REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF
THE SECURITIES EXCHANGE ACT OF 1934**

The following is a brief description of the securities of Universal Biosensors, Inc. ("UBI", "our company", the "company", "we", "us", or "our") registered pursuant to Section 12 of the Securities Exchange Act, as amended (the "Exchange Act"). We refer in this description of securities to our amended and restated certificate of incorporation as our certificate of incorporation, and we refer to our amended and restated by-laws as our by-laws. The following description of a capital stock does not purport to be complete and is subject to, and qualified in its entirety by, our charter and our by-laws and the applicable provisions of the Delaware General Corporation Law. For a complete description of our capital stock, you should read our certificate of incorporation and by-laws, which are incorporated by reference as exhibits, to this Annual Report on Form 10-K.

General

Our shares of common stock are not currently traded on any established United States public trading market. We have not sought the quotation of our shares of common stock on any United States public trading market, and we cannot assure you that we will seek to be quoted on any United States public trading market or that we would meet any applicable listing requirements. Since December 13, 2006 our shares of common stock are traded on the Australian Securities Exchange ("ASX") in the form of CHESS Depository Interests, or CDIs, under the ASX trading code "UBI".

Our authorized capital stock consists of 300,000,000 shares of common stock, par value of U.S.\$0.0001 per share, and 1,000,000 shares of undesignated preferred stock, par value of U.S.\$0.01 per share.

Common Stock

The rights attaching to our shares of common stock are derived through a combination of our certificate of incorporation, by-laws and the Delaware General Corporation Law and other applicable laws. Holders of our shares of common stock are entitled to notice of and to be present at and to vote at stockholder meetings. One third of the issued shares of common stock outstanding and entitled to vote at a meeting, present in person or represented by proxy, constitute a quorum at all meetings of stockholders. Special meetings of stockholders may be called only by our board of directors, our chairman or certain of our executive officers. There is no ability for stockholders to call a special meeting. Holders of our shares of common stock are entitled to one vote for each share held of record for the election of directors and on all matters submitted to a vote of stockholders. Holders of our shares of common stock are entitled to receive dividends ratably, if any, as may be declared by our board of directors out of legally available funds, subject to any preferential dividend rights of any preferred stock then outstanding and Delaware General Corporation Law. Upon our dissolution, liquidation or winding up, holders of our common stock are entitled to share ratably in our net assets legally available after the payment of all our debts and other liabilities, subject to the preferential rights of any preferred stock then outstanding. Holders of our common stock are not entitled to cumulative voting rights with respect to the election of directors, and our shares of common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

In order to allow trading of our common stock on the Australian Securities Exchange, or ASX, CHESS Depository Interests, or CDIs, are issued to stockholders in uncertificated form, and our certificate of incorporation and by-laws contain provisions designed to incorporate the requirements of the listing rules of the ASX into such documents for as long as we are listed on the ASX. CDIs represent beneficial ownership of the underlying share of our common stock, the legal ownership of which is held by CHESS Depository Nominees Pty Ltd, or CDN, which is controlled by ASX. CDIs are structured so that each of the CDIs represents one of our shares of common stock. A CDI holder may choose to either leave their holdings in the form of CDIs (so that legal title remains in the name of CDN) or convert the CDIs into shares of common stock and hold legal title in their own right. Our shares are quoted on the ASX, but trades are settled by the delivery of CDIs. Legal title to all shares remains with CDN, unless and until a CDI holder requests in writing a transfer of beneficially owned shares from CDN to the holder, in which case a paper transfer will be effected in accordance with our certificate of incorporation and by-laws. We maintain a register of individual CDI holders through Registries Limited in Sydney, Australia.



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UNIVERSAL BIOSENSORS

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CDI holders have the right to direct CDN on how CDN should vote. ASX rules require us to send a notice of stockholder meetings to each CDI holder at the address recorded in the register of CDI holders. The notice must: (a) inform the holder of the holder's rights to direct CDN on how it should vote with respect to the resolutions in the notice; (b) provide a mechanism for the holder to direct CDN on how to vote; and (c) provide the date and time by which the holder must provide such direction to CDN. CDI holders are to receive all direct economic benefits of the shares of common stock underlying their CDIs. Any dividend declared in respect of our shares of common stock underlying CDIs will be distributed to the CDI holders. In the event of our liquidation, dissolution or winding up, CDI holders will be entitled to the same economic benefits on their CDIs as stockholders.

Preferred Stock

Pursuant to our certificate of incorporation, without further action by the stockholders, the board of directors has the authority to issue up to 1,000,000 shares of preferred stock, par value \$0.01 per share, in one or more series (although ASX rules generally require stockholder approval for certain issuances that exceed 15% of our then outstanding capital stock in any 12 month period without the approval of stockholders). The board of directors also has the right to fix the designations, voting powers, preferences, and relative participating, optional or other rights, any or all of which may be greater than the rights of our shares of common stock, and any qualifications, limitations or restrictions thereof. Shares of preferred stock could thus be issued with terms that could have the effect of delaying, deferring or preventing a change of control, and such issuance could modify the rights of the holders of our common stock otherwise than by a vote of the majority of such holders. We do not currently have any preferred stock outstanding and have no current plans to issue any preferred stock.

Certain Provisions of our Certificate of Incorporation and By-Laws and Delaware Law

Board Election, Composition and Vacancies. In accordance with our certificate of incorporation, our board of directors is divided into three classes serving staggered three-year terms, with one class being elected each year. Directors are elected by a plurality of the votes of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors. Our certificate of incorporation provides that our board of directors may change the size of the board; provided, that, our board shall consist of not less than three or more than nine members. Our certificate of incorporation also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of 70% or more of the shares then entitled to vote at an election of directors. Pursuant to our certificate of incorporation, any vacancy on the board of directors that results from an increase in the number of directors may be filled by a majority of the board of directors then in office, provided that a quorum is present, and any other vacancy occurring on the board of directors may be filled by a majority of the board of directors then in office, even if less than a quorum, or by a sole remaining director.

No Written Consent of Stockholders. Our certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting.

Meetings of Stockholders. Our by-laws provide that only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our stockholders do not have the power to call special meetings. Our by-laws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements. Our by-laws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or business to be brought before annual meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our company secretary prior to the meeting at which the action is to be taken. To be timely, a stockholder's notice must be delivered to or mailed and received at our principal executive offices: (a) in the case of an annual meeting, not less than 90 days and not more than 120 days prior to the anniversary date of the immediately preceding annual meeting, provided, however, that in the event that the annual meeting is called for a date that is not within 30 days before or after such anniversary date, notice by the stockholder in order to be timely must be so received not later than the close of business on the tenth day following the day on which such notice of the date of the annual meeting; and (b) in the case of a special meeting of stockholders called for the purpose of electing directors, not later than the close of business on the tenth day following the day on which notice of the date of the special meeting was mailed or public disclosure of the special meeting was made, whichever occurs first.



Amendment to Certificate of Incorporation or By-Laws. As required by the Delaware General Corporation Law, any amendment of our certificate of incorporation must first be approved by a majority of our board of directors and, if required by law or our certificate of incorporation, thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment, and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to prohibiting stockholder action by written consent, calling special stockholder meetings, our staggered board, removal of directors, the vote required to amend our by-laws, ASX matters, and the vote required to amend our certificate of incorporation, must be approved by our shareholders holding not less than 70% of the outstanding shares entitled to vote on the amendment. Our by-laws may be amended by the affirmative vote of a majority of the directors then in office and may also be amended by the affirmative vote of our shareholders holding at least 70% of the outstanding shares entitled to vote at an election of directors.

Section 203 of the Delaware General Corporation Law. The Company is subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A “business combination” includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An “interested stockholder” is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of our voting stock. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or
- at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

These provisions described above could have an effect of delaying, deferring or preventing a change in control of UBI and could operate with respect to an extraordinary corporate transaction.



Exhibit 21

LIST OF SUBSIDIARIES

Universal Biosensors Pty Ltd.
Hemostasis Reference Laboratory Inc.



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-K 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: February 26, 2020

/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-K 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: February 26, 2020

/s/ Salesh Balak
Salesh Balak
Principal Financial Officer
Universal Biosensors, Inc.



Exhibit 32.0

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

In connection with the annual report of Universal Biosensors, Inc. (the "Company") on Form 10-K for the period ended December 31, 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 February 26, 2020.

/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.