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, 2018

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		**98-0424072**
(State or other jurisdiction of incorporation or organization)		**(I.R.S. Employer Identification Number)**
Universal Biosensors, Inc. 1 Corporate Avenue, Rowville, 3178, Victoria Australia **(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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☒

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$28,184,504 (equivalent to US$20,831,167) as of June 30, 2018.

The number of shares outstanding of each of the registrant's classes of common stock as of February 13, 2019:

Title of Class	Number of Shares
Common Stock, par value US$0.0001 per share	176,939,470

Documents incorporated by reference:

Certain information contained in the registrant's definitive Proxy Statement for the 2019 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-46 of our Annual Report to Stockholders for the fiscal year ended December 31, 2018 (our "2018 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 a specialist medical diagnostics company focused on the research, development and manufacture of in vitro diagnostic test devices for consumer and professional point-of-care use.

We were incorporated in the State of Delaware on September 14, 2001 and our shares of common stock in the form of CHESS Depositary Interests ("CDIs") have been quoted on the Australian Securities Exchange ("ASX") since December 13, 2006. Our securities are not currently traded on any other public market. Our wholly owned subsidiary and primary operating vehicle, Universal Biosensors Pty Ltd ("UBS") was incorporated as a proprietary limited company in Australia on September 21, 2001. UBS conducts our 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 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 in diabetes care. We developed a blood glucose product with LifeScan ("OneTouch Verio®") which as of December 31, 2018 was available in countries that represent over 90% of the world self-monitoring blood glucose market. During 2018, LifeScan gave notice and exercised its right to "convert" its obligation to pay quarterly service fees to UBS. Accordingly, we will not receive any further quarterly service fees beyond 2018 and we do not expect to receive any further revenues from LifeScan unless we enter into a new agreement with LifeScan in the future. 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.

We are using our electrochemical cell technology platform to develop point-of-care testing systems for a number of different markets. Our current focus is on the coagulation testing market.

We have, since 2012 worked with Siemens Healthcare Diagnostics Inc. ("Siemens") in relation to a range of products for the point-of-care coagulation testing market, pursuant to a Collaboration Agreement with Siemens ("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 ("Supply Agreement"), UBS is the manufacturer of test strips for this product and further tests still in development for Siemens. In addition, for part of the year, UBS was engaged in point-of-care coagulation product development for the consumer, home testing market which could be distributed globally. In order to reduce expenditures and manage cash flow, management suspended development spending on the company's "in house" coagulation test device and redirected those engineering and science resources to the Siemens program development initiatives.

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 a specialist medical diagnostics company focused primarily on the research, development and manufacture of in vitro diagnostic test devices for consumer and professional point-of-care use. In addition, we own, manage and operate a hemostasis laboratory. Key aspects of our strategy for 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;
- participating in healthcare markets across the globe; and
- identifying and pursuing related opportunities for growth.

Plan of Operations for the Remainder of the Fiscal Year Ending December 2019

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

- seek to enter into collaborative, strategic or distribution arrangements with other life sciences companies or other industry participants with respect to the development and commercialization of specific tests or specific fields, particularly in light of the determination by LifeScan to exercise its right to buy out its obligation to pay us future quarterly service fees and our expectation that we will not continue to collaborate with LifeScan going forward;
- 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 options within the overall strategic initiatives.

Description of our business

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

Industry background

We operate in the high growth, point-of-care segment of the global in vitro diagnostics (IVD) industry. 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.

Point-of-care 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. Assuming neither we nor Siemens terminates the Collaboration Agreement, we intend to continue to work with Siemens to develop other test strip and analyzer products for the point-of-care coagulation market.

Principal Products and Services

UBS is the manufacturer of PT-INR coagulation test strips for Siemens’ Xprecia Stride™ Coagulation Analyzer. We continue to work with Siemens to develop other products for the point-of-care coagulation testing market which UBS expects to manufacture once approved for sale. UBS also conducts research and development to demonstrate the broader application of our technology platform.

On February 8, 2019, we entered into a term sheet agreement with UBS and Siemens (the "Term Sheet Agreement"). The Term Sheet Agreement provides that we have agreed to negotiate with UBS and Siemens in good faith for a specified period (subject to extension if mutually agreed) possible modifications to our commercial relationship, including the Collaboration Agreement and Supply Agreements. Under the term sheet agreement, our obligations, as well as those of UBS and Siemens, to apply commercially reasonable efforts and to apply reasonably necessary resource to certain research and development activities under the Collaboration Agreement have been suspended pending the outcome of the negotiation. Under the Term Sheet Agreement, we and UBS have also agreed to not make any dividend payments or similar distributions, or engage in M&A transactions (subject to an exception which would allow us and UBS to enter into M&A transactions where the directors of either company determine, in good faith, that not proceeding with such a transaction would be inconsistent with their fiduciary duties).

On September 21, 2018 LifeScan exercised its right to convert its obligation to pay quarterly service fees to us. We received the lump sum service fees of US$31,503,880 (equivalent to A$44,635,704) from LifeScan on February 18, 2019, which are restricted as described above pursuant to the Term Sheet Agreement with Siemens. We assessed if any amount of the lump sum service fees were attributable to the remaining obligation under the Master Services and Supply Agreement that states that LifeScan could require us to provide manufacturing services at our Rowville facility to recommence production of glucose strips. We conclude that this obligation has no fair value attributable to it due to (i) high set-up costs to recommence manufacturing, (ii) the required lead time to gain regulatory compliance, and (iii) the fact there is deemed to be no commercial rationale for LifeScan to request us to recommence glucose-strip manufacturing on the basis of current information. As such, the lump sum service fee revenue has been fully recognized this fiscal year and no revenue has been deferred. As LifeScan has exercised its right to convert its obligation to pay quarterly service fees to us, beyond 2018 we will not be receiving any quarterly services fees from LifeScan. After the payment of the one-time lump sum service fee, LifeScan has the ability to terminate the Master Services and Supply Agreement with 12 months' notice.

Facilities

Universal Biosensors Pty Ltd leases approximately 5,000 square meters of office, research and development and manufacturing facilities at 1 Corporate Avenue, Rowville in Melbourne, Australia. We have 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, 2020 with 2 further options to renew each for 5 years. 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

Siemens is responsible for the sales and distribution of its products.

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-care. 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-care 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.

If we are developing a product for a customer or partner, our customers and partners are generally responsible for obtaining and maintaining all applicable regulatory clearances and determining the location and timing for the individual submissions. We may provide a supporting role in this process.

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-care 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-care diagnostic 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. Based on current product sales and our projects, the owned and licensed patents and patent applications that we consider most significant by virtue of their importance to our platform together with the last of the patents to expire within the patent family are set forth in the table below.

Patent	Expiration Year
Apparatus and Method for Electrochemical Protease Sensor (this patent family relates to a sensor to detect cleavage of an electrochemical substrate for use in measuring blood or plasma coagulation in assays such as prothrombin time and thrombin potential)	2028
Electrochemical On-Board Control Detection (this patent family relates to an on-board control system of a sensor, wherein the control system can test/verify the viability of the sensor)	2030
Electrochemical Cell (this patent family relates to a method and an electrochemical biosensor for determining the concentration of an analyte in a carrier)	2022
Electrochemical Method (this patent family provides an improved method and biosensor for determination of the concentration of an analyte in a carrier which provides improved accuracy, reliability and speed over prior techniques)	2024
Electrochemical Method for Measuring Chemical Reaction Rates (this patent family relates to the measurement of the progress of a chemical reaction that generates an electroactive reaction product that is subsequently detected at an electrode amperometrically or coulometrically)	2023

Electrochemical Cell Connector (this patent family relates to a connector to provide electrical connection between an electrochemical cell of a strip type sensor and meter circuitry)	2026
Method and Apparatus for Rapid Electrochemical Analysis (this patent application relates to an improved method and apparatus for electrochemical analysis)	2026
Methods and Apparatus for Analyzing a Sample in the Presence of Interferents (this patent application relates to methods and apparatus for determining analyte concentrations in a rapid and accurate manner)	2026
System and Method for measuring an Analyte in a Sample (this patent relates to a method for measuring a temperature corrected glucose concentration over a temperature range)	2029
Systems and Methods for Discriminating Control Solution from a Physiological Sample (this patent application relates to systems and methods for discriminating between a control solution and blood sample)	2028
Systems and Methods of Discriminating Control Solution from a Physiological Sample (this patent application relates to systems and methods for discriminating between a control solution and a blood sample based on a summation of current values and comparing reference values to threshold values)	2027

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. We also license intellectual property from Siemens and SpeeDx Pty Ltd, who are both primarily responsible for the prosecution and maintenance of the patents and patent applications licensed to us by them.

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-care 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 a future strategy in the consumer, home, point-of-care testing and self-testing coagulation markets. 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 continued to receive 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. During 2018, LifeScan gave notice and exercised its right to "convert" its obligation to pay quarterly service fees to UBS. Accordingly, we will not receive any further quarterly service fees beyond 2018 and we do not expect to receive any further revenues from LifeScan unless we enter into a new agreement with LifeScan in the future.

	Years Ended December 31, 2018	2017
	A$	A$
Home country - Australia	490,962	294,717
Foreign countries		
- U.S.A.	1,428,350	1,131,772
- Germany	1,603,817	3,641,781
- Switzerland	66,084,950	20,057,644
- Canada	238,056	222,229
- Other	101,817	137,854
Total - foreign countries	69,456,990	25,191,280
Total income	69,947,952	25,485,997
% of total income derived from - LifeScan	94%	79%
- Siemens	3%	18%
- Other	2%	3%

In 2018, revenue from services was primarily represented by the lump sum service fees, which are restricted pursuant to the Term Sheet Agreement with Siemens, and the quarterly service fees from LifeScan.

We did not have any significant backlog orders as of December 31, 2018 and 2017.

Competitive conditions of our business

Siemens is responsible for all sales and marketing decisions with respect to the products we develop for them and for any decision to introduce the products to new territories and the timing of those decisions. In December 2014, Siemens received the CE mark for sale of the Xprecia Stride™ Coagulation Analyzer in Europe and initiated a limited release in Europe. On October 4, 2016, Siemens received regulatory clearance from the US FDA to sell the Xprecia Stride™ Coagulation Analyzer in the US and initiated sales activities in the US in May 2017.

The worldwide point-of-care coagulation testing market was estimated at around US$1.0 billion in 2011 and is forecast to grow by around 10% per annum to US$1.8 billion by 2017. 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-care settings. Our belief is that much testing done in the central lab can be more efficiently and profitably performed at the point-of-care. 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-care space, but also the providers of testing who operate in centralized settings. Further our belief is that self-service, home, point-of-care 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 13, 2019, the total number of employees we had was 84 of which 50 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 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 LifeScan having exercised its right to convert its obligation to pay quarterly service fees to us and to deliver one final lump sum payment, we do not expect to receive revenues from LifeScan in the future, and if we do not replace those revenue streams with others pursuant to the development of new products and/or establishing new partnerships, our results of operations will be materially adversely affected.

On September 21, 2018, LifeScan exercised its right to convert its obligation to pay quarterly service fees to us under the Master Services and Supply Agreement. Following receipt of the lump sum service fee on February 18, 2019, which is restricted pursuant to the Term Sheet Agreement with Siemens, the Master Services and Supply Agreement ceased to be a material agreement to us and either LifeScan or us may determine to terminate that agreement without material consequence to us. Effectively, neither party is or will be continuing to perform any services under that Agreement going forward. Accordingly, if we are unable to replace the revenues we previously received from LifeScan with 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. If the sublicense under the Collaboration Agreement was terminated, the ability for Siemens to commercialize the products we have developed with them may be restricted or eliminated which would have a material adverse effect on us. The Collaboration Agreement with Siemens expires on the end of all payment obligations under the Collaboration Agreement and the Supply Agreement. The Collaboration Agreement can be terminated by Siemens as set out in the agreement including for our insolvency, after 60 days' notice for our uncured material breach, upon 30 days' written notice to us for any reason (provided that if it does so prior to the milestones being achieved, it must pay a termination fee), or if a developed product infringes a third party patent and it is not commercially viable to work around or obtain a license for the infringed patent.

The Supply Agreement with Siemens expires after 10 years but Siemens may extend the term of the Supply Agreement for an additional five-years. Siemens may also extend the term of the Supply Agreement under other limited circumstances, but in no event beyond 18 years from the Effective Date. Siemens may terminate the Supply Agreement prior to its expiration upon 42 months' prior written notice to us, or due to uncured material breach and persistent failures by us to supply products.

On February 8, 2019, we entered into the Term Sheet Agreement with UBS and Siemens. The Term Sheet Agreement provides that we have agreed to negotiate with UBS and Siemens in good faith for a specified period (subject to extension if mutually agreed) possible modifications to our commercial relationship, including the Collaboration Agreement and Supply Agreements. Under the Term Sheet Agreement, us and UBS have agreed to not make any dividend payments or similar distributions, or engage in M&A transactions (subject to an exception which would allow us and UBS to enter into M&A transactions where the directors of either company determine, in good faith, that not proceeding with such a transaction would be inconsistent with their fiduciary duties). Under the term sheet agreement, our obligations, as well as those of UBS and Siemens, to apply commercially reasonable efforts and to apply reasonably necessary resource to certain research and development activities under the Collaboration Agreement have been suspended pending the outcome of the negotiation. As is common with these types of agreements, potential outcomes of negotiation may include but are not limited to changes in the business relationship. Our inability to reach an agreement with Siemens could affect future performance by either party under the agreement, could lead to the termination of the various agreements, litigation or could result in other disputes, which may have a material adverse effect on our business, financial condition and results of operations.

Any termination of the Collaboration Agreement or Supply Agreement may severely and adversely affect our financial results, business and business prospects and the future of our research and development activities. Amongst other things we would not receive remaining milestones under the Collaboration Agreement and would be required to reimburse Siemens for certain prepaid milestones. We would also not receive any fees from manufacturing product (except in certain circumstances where Siemens manufactures products or has products manufactured by a third party on its behalf where Siemens is obligated to pay us a fee for each product manufactured and the profit-sharing obligations under the Collaboration Agreement continue to apply).

Siemens controls the registration and commercialization of the point-of-care coagulation tests we have been developing with them.

Subject to the terms of the Collaboration Agreement, Siemens controls the registration and commercialization of the point-of-care coagulation tests we have been developing with them. Decisions made by Siemens with respect to registration and commercialization affect the extent and timing of revenues to us under the Collaboration Agreement and Supply Agreement. Siemens may determine not to continue with the commercialization of the product which may have a material adverse effect on our business and financial position. Similarly, Siemens controls the decision whether or not to continue the development of the remaining tests in development and, if development is successful, the decision to launch those tests and, if launched, the timing of such launch, the jurisdictions in which the product will be launched and the nature of any such launch. As a result of factors related to the product (such as technical and development hurdles, delays and performance), Siemens may choose not to continue the development of one or more of the remaining tests in development. Even if development is successful, it may choose not to launch one or more of such products, it may choose to launch in a limited number of jurisdictions, may delay the launch, or its sales and marketing efforts to commercialize may not be successful, all of which may render prior development efforts unproductive and worthless and would reduce or eliminate our revenues from product sales and/or manufacturing which may have a material adverse effect on our business and financial position.

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. This product represents Siemens' first entry into this point-of-care coagulation testing market and sales of the product are currently comparatively low and accordingly we have a limited track record of market acceptance of the product. Revenues derived from the sale of this product were significantly lower in 2018 than in 2017 and we do not expect sales to increase significantly in 2019. 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.

Although the Xprecia Stride™ Coagulation Analyzer was released in Europe in December 2014 and initial sales activities commenced in the United States in May 2017, since those dates, sales of the product have been comparatively low and accordingly we have a limited track record of market acceptance of the product. If Siemens withdraws the product or does not submit purchase orders for a certain amount of product, our manufacturing capacity may not be fully utilized. If this occurs, we will be faced with surplus capacity in our manufacturing operations and our revenues from this product will decline or be eliminated. Further, Siemens may obtain the right to manufacture product or have a third party manufacture product on its behalf if certain events occur (for example, insolvency, failure to supply). The Supply Agreement with Siemens may also be terminated as a result of either party defaulting on its material obligations. If any of these circumstances arise, we would cease to have the potential to receive manufacturing revenues from the sale of product purchased by Siemens.

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.

Quarterly service fees from LifeScan have historically represented a significant proportion of our revenue.

On September 21, 2018, LifeScan exercised its right to convert its obligation to pay quarterly service fees to us under the Master Services and Supply Agreement. Following receipt of the lump sum service fee, which is restricted pursuant to the Term Sheet Agreement with Siemens, the Master Services and Supply Agreement ceased to be a material agreement to us and either LifeScan or us may determine to terminate that agreement without material consequence to us.

The majority of our products and services revenue has historically been derived from LifeScan. LifeScan has exercised its right to buy out, or "convert," its obligation to pay quarterly service fees, which are no longer payable. We do not currently receive meaningful revenues from other collaborative arrangements or strategic alliances with third parties and there is a substantial risk that we may not be able to replace the LifeScan revenues with other revenues that are sufficient to fund our operating needs.

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 in the form of the lump sum service fee from LifeScan, which is restricted pursuant to the Term Sheet Agreement with Siemens, along with cash flows from operations and existing cash and cash equivalents. Our operating activities have historically provided a proportion of cash to fund our working capital requirements and, together with the lump sum service fee, are expected to be 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, the termination of any of our key commercial contracts with Siemens, 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.

We cannot guarantee that shareholders will in the near term derive immediate value from the lump sum payment we expect to receive from LifeScan.

We have not yet determined whether we will use any or a portion of the cash received from LifeScan to make a dividend payment to our shareholders or re-invest those amounts in research and development. Further, our ability to make any such dividend payment is currently limited by the terms of our Term Sheet Agreement with Siemens. Accordingly, we cannot guarantee that shareholders will derive value in the near term, in the form of an increase in our stock price or a dividend, as a result of our receiving the lump sum payment from LifeScan.

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.

In order to reduce expenditures and manage cash flow, management has suspended development spending on our "in house" coagulation test device and redirected those engineering and science resources to the Siemens program development initiatives. As a result, efforts to enter into collaborative arrangements, licensing agreements, strategic alliances or distribution arrangements for these products have likewise been suspended and any potential revenues from such arrangements have consequentially been delayed.

Even if we recommence development activities, we may not be able to enter into such collaborative arrangements, licensing arrangements, strategic alliances or distribution arrangements in a timely fashion and on acceptable terms, if at all. Our ability to enter into collaborative, strategic or distribution arrangements will suffer if the technologies developed by us are not perceived as being comparable or superior to established laboratory methods or other products.

If we do not recommence development efforts on our own product and/or we are unable 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 in development 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 reserves 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 reserves 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.

Our agreements with our product development and manufacturing customers to date have contained milestone based payments, many of which are payable upon the achievement of technical development milestones. Such milestone payments may not cover the cost of our research and development activities. In the event we are not successful in achieving the relevant development milestone, we will not receive the milestone payments associated with the milestone which would have an adverse effect on our revenue and financial position. The determination of whether a milestone has been achieved may also be the subject of a dispute with our customer. Certain of our milestones under our various agreements have been pre-paid by our customers or partners. In the event we are not successful in achieving the relevant development and regulatory milestone, the milestone payments will need to be repaid based upon the specific circumstances and conditions. Furthermore, if we are unable to develop a product for a customer, it may eliminate an important revenue stream for us which may result in us not being profitable, or trigger dissolution of partnerships or collaborative relationships.

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-care 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-care 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 medical devices and therefore 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.

Risks associated with 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-care 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-care 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-care testing, nor may the health economic benefits sufficiently support point-of-care 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-care 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-care tests.

The market for in vitro diagnostics 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-care tests are likely to experience significant and continuing competition from traditional pathology laboratory based testing as well as other point-of-care 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.

Whilst we have made a small profit for the 2016 financial year, a small loss for the 2017 financial year and a profit in the 2018 year by virtue of the recognition of the lump sum service fee from LifeScan, which is restricted pursuant to the Term Sheet Agreement with Siemens, our operations may not be profitable in the future. To date, we have 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. After 2018 we will no longer have the benefit of quarterly service fees from LifeScan and the revenue from the sale of other products and provision of services will only fund a small portion of our operating expenses. Our revenues from the sale of our Xprecia Stride product by Siemens were significantly lower in 2018 than in 2017 and we do not expect that those revenues will increase significantly or at all in 2019. 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 million. We are however eligible to claim a non-refundable tax offset as part of the current year tax computation. 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. We expect our revenue to be less than A$20 million in 2019.

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. We have recently experienced a number of staff changes and a significant number of employees resigned or sought new opportunities in 2018. 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.

Our primary development 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.

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;
- 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.

For example, from the initial quotation of our shares in the form of CDIs on the Australian Securities Exchange on December 13, 2006 until February 13, 2019, the closing price per share of our shares ranged from a low of A$0.14 during May 2014 to a high of A$2.02 during the first quarter of the 2010 fiscal year and was A$0.24 on February 13, 2019. 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 18% of our shares. For details of our substantial stockholders and the interests of our directors, refer to "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.

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, 2020 with 2 further options to renew each for 5 years. 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.

We have entered into a Term Sheet Agreement with Siemens as described above under Business – Principal Products and Services. Our inability to reach an agreement with Siemens could affect future performance by either party under the Agreement, could lead to the termination of the Agreement, or could result in other disputes or claims for damages which will have a material adverse effect on our business, financial condition and results of operations.

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 have not determined whether we will seek the quotation of our shares of common stock on any United States public trading market. 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.

Our shares of common stock are traded on the ASX in the form of CHESS Depositary Interests, or CDIs, under the ASX trading code "UBI". The Clearing House Electronic Subregister System, or "CHESS", 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. CHESS 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 CHESS. 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 CHESS 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 13, 2019, there were 176,939,470 shares of our common stock issued and outstanding and 15,060,217 employee options that are exercisable for an equivalent number of shares of common stock (7,417,221 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 Ac. 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 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 13, 2019	1,518	11

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."

Recent Sales of Unregistered Securities

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 on the basis that none of the recipient of such shares are "U.S. person" as such term is defined in Regulation S.

Period Ending	Number of Options Exercised and Corresponding Number of Shares Issued	Option Exercise Price	Proceeds Received (A$)
2017			
April	3,332	A$ 0.23	766
August	41,667	A$ 0.00	0
October	66,667	A$ 0.00	0
	111,666		766
2018			
July	251,667	A$ 0.00	0
August	251,667	A$ 0.00	0
November	50,000	A$ 0.00	0
	553,334		0

The funds have been and will be used for working capital requirements including the continued development of our existing pipeline of point-of-care 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:

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

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

	Number of shares	Weighted average issue price (A$)
Balance at December 31, 2017	492,749	0.31
Granted	191,636	0.24
Release of restricted shares	(373,139)	0.31
Balance at December 31, 2018	311,246	0.28

(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

There were no repurchases of equity securities in 2018.

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 2018 Annual Report under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations" on pages F2 to F17.

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

We refer you to the "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 F19 through F46, and "Report of Independent Registered Public Accounting Firm" on page F18 of this 2018 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. Rick Legleiter, Chief Executive Officer, and Salesh Balak, Chief Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Messrs. Legleiter and Balak concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting. During the fiscal quarter ended December 31, 2018, 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 Principal Executive Officer and Principal Financial Officer, assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2018. 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 Principal Executive Officer and Principal Financial Officer, concluded that, as of December 31, 2018, our internal control over financial reporting was effective.

/s/ Rick Legleiter
Rick Legleiter
Principal Executive Officer

/s/ Salesh Balak
Salesh Balak
Principal Financial Officer

February 22, 2019

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 item regarding our directors and executive officers is incorporated by reference to our Definitive Proxy Statement to be filed with the SEC in connection with our Annual Meeting of Stockholders in 2019 (the "2019 Proxy Statement") under the caption "Management of the Company."

The information required by this item regarding "Compliance with Section 16(a) of the Exchange Act" is incorporated by reference to the 2019 Proxy Statement under the caption "Other Matters – Section 16(a) Beneficial Ownership Reporting Compliance."

We have adopted our Code of Ethics for Senior Financial Officers, a code of ethics that applies to our Principal Executive Officer and Principal Financial Officer. This code of ethics may be accessed and reviewed through our website at www.universalbiosensors.com. We intend to satisfy any disclosure requirements regarding an amendment to, or waiver from, a provision of the Code of Ethics for our Principal Executive Officer and Principal Financial Officer, by posting such information on our website at www.universalbiosensors.com. A copy of the Code of Ethics for Senior Financial Officers will be provided without charge upon written request to our Company Secretary at 1 Corporate Avenue, Rowville VIC 3178 Australia.

The information regarding the procedures by which security holders may recommend nominees to our Board of Directors is incorporated by reference to the 2019 Proxy Statement under the caption "Management of the Company – Board Committees – Remuneration and Nomination Committee." There have been no material changes to the procedures by which security holders may recommend nominees to our Board of Directors.

The information required by this item regarding our Audit and Compliance Committee is incorporated by reference to the 2019 Proxy Statement under the caption "Management of the Company – Board Committees – Audit and Compliance Committee."

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this item is incorporated by reference to the 2019 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."

Discussions on the frequency of the shareholder advisory votes on executive compensation are incorporated by reference to the 2019 Proxy Statement under the caption "Executive Compensation".

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

The information regarding the security ownership of certain beneficial owners and management is incorporated by reference to the 2019 Proxy Statement under the caption "Security Ownership of Certain Beneficial Owners and Management."

The information regarding "Securities Authorized for Issuance under Equity Compensation Plans" is incorporated by reference to our 2019 Proxy Statement under the caption "Executive Compensation – Equity Compensation Plan Information."

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

The information required by this item is incorporated by reference to the 2019 Proxy Statement under the caption "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 2019 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-18 through F-46 of our Annual Report to Stockholders for the fiscal year ended December 31, 2018, as provided in Item 8 hereof:

(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	Amended and restated certificate of incorporation dated December 5, 2006.	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	Amended and restated by-laws dated December 5, 2006.	Incorporated by reference to our Amendment No. 5 to Form 10 filed on April 29, 2008 as Exhibit 3.2.
10.1	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.	Incorporated by reference to our Current Report on Form 8-K filed on August 30, 2011 as Exhibit 10.1.
10.2	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.	Incorporated by reference to our Current Report on Form 8-K filed on August 30, 2011 as Exhibit 10.2.
10.3	Form of indemnity agreement entered into with directors of us, our chief financial officer and company secretary	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	Employee Option Plan.	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	Employment agreement between Universal Biosensors Pty Ltd and Mr. Salesh Balak effective November 27, 2006.	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	Collaboration Agreement between Universal Biosensors Pty Ltd and Siemens Healthcare Diagnostics Inc. dated September 9, 2011.	Incorporated by reference to our Quarterly Report on Form 10-Q filed on November 3, 2011 as Exhibit 10.20. 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	Amendment to Collaboration 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 10.1. 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	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.
10.11	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.
10.12	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.
10.13	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.
10.14	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.
10.15	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.
10.16	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.

10.17	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.
10.18	Letter agreement entitled "Conditional Prepayment of Milestones and other amendments" between Universal Biosensors Pty Ltd and Siemens Healthcare Diagnostics Inc. dated March 9, 2016.	Incorporated by reference to our Quarterly Report on Form 10-Q filed on April 21, 2016 as Exhibit 10.2.
10.19	Amendment to Collaboration Agreement between Universal Biosensors Pty Ltd and Siemens Healthcare Diagnostics Inc. dated March 9, 2016.	Incorporated by reference to our Current Report on Form 8-K filed on March, 2016 as Exhibit 99.1.
10.20	Executive Service Agreement between Universal Biosensors Pty Ltd and Rick Legleiter dated 7 August 2017.	Incorporated by reference to our Current Report on Form 8-K filed on August 7, 2017 as Exhibit 10.1.
10.21	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 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 Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act.	Filed herewith.

101 The following materials from the Universal Biosensors, Inc. Annual Report on Form 10-K for the financial year ended December 31, 2018 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 22, 2019

By: /s/ Rick Legleiter
Rick Legleiter
Principal Executive Officer

POWER OF ATTORNEY

Each person whose signature appears below hereby constitutes and appoints Rick Legleiter and 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:

Signature	Title	Date
/s/ Rick Legleiter Rick Legleiter	Chief Executive Officer (Principal Executive Officer)	February 22, 2019
/s/ Salesh Balak Salesh Balak	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 22, 2019
/s/ David Hoey David Hoey	Director	February 22, 2019
/s/ Judith Smith Judith Smith	Director	February 22, 2019
/s/ Marshall Heinberg Marshall Heinberg	Director	February 22, 2019
/s/ Craig Coleman Craig Coleman	Non-Executive Chairman and Director	February 22, 2019

Universal Biosensors, Inc.

2018 Annual Report

Contents

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 a specialist medical diagnostics company focused primarily on the research, development and manufacture of in vitro diagnostic test devices for consumer and professional point-of-care use. In addition, we own, manage and operate a hemostasis laboratory. Key aspects of our strategy for increasing shareholder value include:

- executing on our 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;
- participating in healthcare markets across the globe; and
- identifying and pursuing related opportunities for growth.

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

- seek to enter into collaborative, strategic or distribution arrangements with other life sciences companies or other industry participants with respect to the development and commercialization of specific tests or specific fields, particularly in light of the determination by LifeScan to exercise its right to buy out its obligation to pay us future quarterly service fees and our expectation that we will not continue to collaborate with LifeScan going forward;
- 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 options 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 CHESS Depositary Interests ("CDIs") have been quoted on the Australian Securities Exchange ("ASX") since December 13, 2006. Our securities are not currently traded on any other public market. Our wholly owned subsidiary and primary operating vehicle, 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 in diabetes care. We developed a blood glucose product with LifeScan ("OneTouch Verio®") which as of December 31, 2018 was available in countries that represent over 90% of the world self-monitoring blood glucose market. During 2018, LifeScan gave notice and exercised its right to "convert" its obligation to pay quarterly service fees to UBS. Accordingly, we will not receive any further quarterly service fees beyond 2018 and we do not expect to receive any further revenues from LifeScan unless we enter into a new agreement with LifeScan in the future. 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.

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Universal Biosensors, Inc.

We are using our electrochemical cell technology platform to develop point-of-care testing systems for a number of different markets. Our current focus is on the coagulation testing market.

We have, since 2012 worked with Siemens Healthcare Diagnostics, Inc. ("Siemens") in relation to a range of products for the point-of-care coagulation testing market, pursuant to a Collaboration Agreement with Siemens ("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 ("Supply Agreement"), UBS is the manufacturer of test strips for this product and further tests still in development for Siemens. In addition, for part of the year, UBS was engaged in point-of-care coagulation product development for the consumer home testing market which could be distributed globally. In order to reduce expenditures and manage cash flow, management suspended development spending on the company's "in house" coagulation test device and redirected those engineering and science resources to the Siemens program development initiatives.

Results of Operations

Analysis of Consolidated Revenue

Our total revenue for the current financial year has increased compared to the 2017 financial year primarily as we recognized one-off revenue of A$44,635,704 as a result of the LifeScan lump sum service fees during the 2018 financial year.

In summary:

- decrease in revenue from products due to prior year inventory buildup and lack of market penetration for the product;
- weakening of the AUD against the USD and increase in the number of blood glucose strips sold by LifeScan has resulted in an increase in the quarterly service fees; and
- increase in other services revenue primarily as a result of increase in HRL revenues.

During 2018, LifeScan gave notice and exercised its right to "convert" its obligation to pay quarterly service fees to UBS. Accordingly, we will not receive any further quarterly service fees beyond 2018 and we do not expect to receive any further revenues from LifeScan unless we enter into a new agreement with LifeScan in the future.

On February 8, 2019, we entered into a Term Sheet Agreement with UBS and Siemens pursuant to which we have agreed to negotiate with UBS and Siemens in good faith for a specified period (subject to extension if mutually agreed) possible modifications to our commercial relationship, including the Collaboration Agreement and Supply Agreements. Under the term sheet agreement, our obligations, as well as those of UBS and Siemens, to apply commercially reasonable efforts and to apply reasonably necessary resource to certain research and development activities under the Collaboration Agreement have been suspended pending the outcome of the negotiation. Under the Term Sheet Agreement, we and UBS have also agreed to not make any dividend payments or similar distributions, or engage in M&A transactions (subject to an exception which would allow us and UBS to enter into M&A transactions where the directors of either company determine, in good faith, that not proceeding with such a transaction would be inconsistent with their fiduciary duties).

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:

Management's Discussion and Analysis of Financial Condition and Results of Operations
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	Years Ended December 31,	
	2018	2017
	A$	A$
Revenue from products	1,672,321	4,066,929
Cost of goods sold	(1,607,340)	(3,014,995)
	64,981	1,051,934
Product contribution margin	4%	26%

The movement in revenues is primarily volume driven. Management is of the view that revenues increased in 2017 as a result of the full commercial launch by Siemens of the Xprecia Stride™ Coagulation Analyzer after successful completion of its limited release and inventory buildup for future sales. Due to the latter and as foreshadowed, the revenues during the current period are low. Management believes that the revenues will remain low until the Xprecia Stride™ Coagulation Analyzer gains meaningful market share. The volatile and low production margin from the sale of our PT-INR strips is reflective of lower 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;
- 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,	
	2018	2017
	A$	A$
Revenue from services:		
Lump sum services fees	44,635,704	0
Quarterly service fees	21,378,404	19,992,641
Other services	1,770,485	1,131,710
	67,784,593	21,124,351
Cost of services	(904,139)	(936,213)
Net margin	66,880,454	20,188,138

Lump sum service fees – During the 2018 financial year, LifeScan gave notice and exercised its right to "convert" its obligation to pay quarterly service fees to Universal Biosensors. The lump sum service fees has been calculated by multiplying the total quarterly service fees for the 2018 financial year by two and converting the same into AUD using the period end exchange rate. We assessed if any amount of the lump sum service fees were attributable to the remaining obligation under the Master Services and Supply Agreement that states that LifeScan could require us to provide manufacturing services at our Rowville facility to recommence production of glucose strips. We conclude that this obligation has no fair value attributable to it due to (i) high set-up costs to recommence manufacturing, (ii) the required lead time to gain regulatory compliance, and (iii) the fact there is deemed to be no commercial rationale for LifeScan to request us to recommence glucose-strip manufacturing on the basis of current information. As such, the lump sum service fee revenue has been fully recognized during the third quarter of 2018 and no revenue has been deferred. As LifeScan has exercised its right to convert its obligation to pay quarterly service fees to us, beyond 2018 we will not be receiving any quarterly services fees from LifeScan. After the payment of the one-time lump sum service fee, LifeScan has the ability to terminate the Master Services and Supply Agreement with 12 months' notice.

Management's Discussion and Analysis of Financial Condition and Results of Operations
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Quarterly service fees – The quarterly service fees from LifeScan, as reflected below, increased by 7% in 2018 when compared to 2017 reflecting primarily the weakening of the AUD against the USD and increase in volume.

	Years Ended December 31,	
	2018	2017
	Millions	Millions
No. of strips sold	1,766.93	1,727.29
Quarterly service fees - USD	15.75	15.45
Quarterly service fees - AUD	21.38	19.99

The quarterly service fee for each quarter in a LifeScan financial year is calculated based on the number of OneTouch Verio® blood glucose test strips sold in such LifeScan financial year as follows: US$0.0125 per strip for the first 500 million strips sold in a financial year and US$0.0075 per strip for sales in excess of 500 million strips in such financial year. Quarterly service fees are reported and paid by LifeScan in USD. Accordingly, revenues recognized by us from quarterly services fees paid by LifeScan were impacted by the movement of the AUD against the USD over the periods covered above. Revenue from quarterly service fees were up 5% in 2018 due to weakening of AUD against USD.

Other services - We generated revenues principally from calibration services performed by HRL and from Siemens based on work undertaken for them. The increase in revenue from other services in 2018 is primarily as a result of an increase in consolidated revenue in HRL of 110% in 2018 when compared to 2017.

Contribution from Products & Services

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

	Years Ended December 31,	
	2018	2017
	A$	A$
Lump sum services fees	44,635,704	0
Quarterly service fees	21,378,404	19,992,641
Manufacturing contribution	64,981	1,051,934
Other services	866,346	195,497
Contribution from products & services	66,945,435	21,240,072

The increase in period-to-period total contributions from products and services reflected in the table above is primarily represented by the lump sums service fees and growth in the quarterly service fee both of which have a 100% margin. The manufacturing contribution represents sale of our Xprecia Stride™ strips. The production margin, although positive, remains low and volatile and is highly dependent on volume. Contribution from other services increased during the year and is directly reflective of the increase in HRL revenues.

The Australian consumer price index rose 1.8% over the twelve months to the December quarter 2018 and it did not have a material impact on our net sales, revenue and income.

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

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

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

	Years Ended December 31,	
	2018	2017
	A$	A$
Net income/(loss)	37,564,356	(764,717)
Interest income	(491,038)	(172,376)
Interest expense	2,211,186	2,294,195
Income tax expense	4,352,564	0
Depreciation - cost of goods sold & services	391,572	488,730
Depreciation - other operating costs & expenses	1,721,882	2,100,763
EBITDA	45,750,522	3,946,595

Increase in EBITDA primarily as a result of the recognition of the lump sum service fees during the 2018 financial year.

Product Support

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

Product support for the respective periods is as follows:

	Years Ended December 31,	
	2018	2017
	A$	A$
Product support	227,517	604,984

We expect product support expenditure to decrease over time.

Depreciation

Depreciation of fixed assets is based on a straight line basis over the useful life of property, plant and equipment. Depreciation is allocated to cost of goods sold and research and development based on output. As more units are being produced for commercial production, a larger proportion of depreciation is charged to cost of goods sold as opposed to research and development expenses resulting in a decline in depreciation charged to research and development. Similarly, if more production is research and development oriented, a higher proportion of depreciation expense will be charged to research and development.

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

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	Years Ended December 31,	
	2018	2017
	A$	A$
Research and development depreciation	1,552,597	1,915,058
General and administrative depreciation	168,052	171,157
Product support depreciation	1,233	14,548
	1,721,882	2,100,763

Research and Development Expenses

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

	Years Ended December 31,	
	2018	2017
	A$	A$
Research and development expenses	11,578,246	10,828,879

Research and development expenditure increased by 7% during 2018 compared to 2017. During these two years, our research and development activities were primarily focused around the blood coagulation platform. The increase in research and development expenses is primarily represented by the ramp up of the further tests in development for Siemens as we head towards regulatory clinical trials. This financial year we also temporarily re-commenced work on our home PT-INR self-testing device which has contributed to the increase in expenditure as well. We suspended development spending on the company's "in house" coagulation test device towards the end of 2018 and redirected those engineering and science resources to the Siemens program development initiatives. Research and development expenditure also include separation payments made to certain staff during the second quarter of 2018 as part of management initiative to reduce expenditures. Whilst this represented a cost during this period, the overall research and development expenditure has decreased during the subsequent quarters 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,	
	2018	2017
	A$	A$
Research and development expenses	11,578,246	10,828,879
Research and development tax incentive income	0	(122,341)
	11,578,246	10,706,538

Included in research and development is tax incentive income for the 2017 financial year of an amount of A$122,341 which relates to research and development tax incentive income the Company received from the Australian Government for the year ended December 31, 2016 following a change in the original estimate. For the years ended December 31, 2018 and 2017 we are not eligible for refundable tax offset as our aggregate turnover exceeded A$20 million. We are however eligible to claim a non-refundable tax offset as part of the current year tax computation. 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 what it will cost to complete our individual research and development programs successfully or when or if they will be commercialized. The timing and cost of any program is dependent upon achieving technical objectives, which are inherently uncertain, 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 optimise outcomes.

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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. Research and development activities undertaken on behalf of our customers and partners were A$8,312,131 and A$7,680,795, respectively for 2018 and 2017.

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

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

Our principal research and development activity is in blood coagulation testing.

In September 2011 we entered into a Collaboration Agreement with Siemens which was amended in September 2012 and March 2016, pursuant to which we will develop a range of test strips and reader products for the hospital point-of-care and alternative site coagulation testing markets. 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. In 2012, we entered into a Supply Agreement with Siemens under which we manufacture and supply the test strips for this product and will manufacture and supply the test strips for further tests still in development with Siemens.

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 and maintenance fees incurred for patent applications, audit and accounting services. General and administrative expenses are generally fixed in nature.

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

	Years Ended December 31,	
	2018	2017
	A$	A$
General and administrative expenses	6,995,089	6,689,431

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General and administrative expenses increased by 5% during 2018 compared to 2017. There is an ongoing effort by management to restrict spending on non-core activities noting that the increase in part is based upon separation payments made to certain staff during the second quarter of 2018 as part of management initiative to reduce expenditures. Despite these initiatives, general and administrative expenditure increased in 2018 as a result of costs incurred in engaging expert advice to assist the Company with a view to resetting its contracts with one of its partners.

Interest Income

Interest income increased by 185% during 2018 compared to 2017. The increase in interest income is generally attributable to the higher amount of funds available for investment noting that in addition to Australian currency, from this financial year, our U.S. denominated currency have been placed in term deposit accounts which generate interest income.

	Years Ended December 31,	
	2018	2017
	A$	A$
Interest income	491,038	172,376

Interest Expense

Interest expense predominantly relates to interest being charged on a short-term borrowing initiated by the Company for the 2017 financial year. These short-term loans were taken out to fund our insurance premiums and were repaid during the 2017 financial year. The interest expense reflects the total amount financed and the interest rate charged to us every year. No short-term borrowings were initiated in 2018 and as a result there is no interest expense.

	Years Ended December 31,	
	2018	2017
	A$	A$
Interest expense	0	9,610

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. This term loan was fully repaid in November 2018. The breakdown of the financing costs is as follows:

	Years Ended December 31,	
	2018	2017
	A$	A$
Interest expense	2,211,186	2,284,585
Other debt issuance costs	779,931	509,149
	2,991,117	2,793,734

Interest expense relates to applicable interest of 10.5% levied on the loan. Interest expense has decreased as the term loan was fully repaid in November 2018. 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. Other debt issuance costs increased primarily as a result of the early repayment of the term loan which resulted in the debt issuance costs being amortised over a shorter period.

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Marketing Support Payment

During 2009, LifeScan chose not to proceed with the registration of the then current product but to proceed with an enhanced product, called OneTouch Verio®, and acknowledged that there would be a delay as a result. As a result of this change, LifeScan agreed to pay additional amounts per strip manufactured by us in 2010 and 2011 up to a specified volume limit ("manufacturing initiation payments"). At the same time, we agreed to pay LifeScan a marketing support payment in each of the two years following the first calendar year in which 1 billion strips are sold by LifeScan equal to 40% of the total manufacturing initiation payments made. LifeScan sold just over 900 million strips in the 2015 financial year. Management concluded that this loss contingency be accrued in 2015 as it is both probable and the amount can be reliably estimated. LifeScan has sold over a billion strips during the 2016 financial year. The total amount of marketing support payments to be paid to LifeScan is US$2,048,602 (equivalent to A$2,902,525) and have been recorded as "Other liabilities" in consolidated balance sheets.

Research and development tax incentive income

Research and development tax incentive income for the respective periods are as follows:

	Years Ended December 31,	
	2018	2017
	A$	A$
Research and development tax incentive income	0	122,341

For the years ended December 31, 2018 and 2017, the aggregate turnover of the Company has exceeded A$20 million and it is 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.

As at December 31, 2016, the Company ascertained that the aggregate turnover for the year then ended was less than A$20 million and accordingly recorded research and tax development tax incentive income of $7,400,000. During 2017, upon finalising its tax returns, the Company determined that the research and development tax incentive income for the 2016 financial year was $7,522,341. An amount of A$122,341, being the difference in research and development tax incentive income initially recorded and the subsequent restatement has been recorded as research and development tax incentive income as at December 31, 2017.

Research and development tax incentive income not yet received as at respective year ends is recorded in "Other current assets" in the consolidated balance sheets, noting that all such amounts have been received as at December 31, 2017.

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 million, or

(2) as a 38.5% non-refundable tax offset if aggregate turnover of the entity is more than or equal to A$20 million.

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

Exchange gain/ for the respective periods are as follows:

	Years Ended December 31,	
	2018	2017
	A$	A$
Exchange gain	577,505	731,289

Foreign exchange gains 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 year as its carrying value is 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 this calendar 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 will be 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.

The Internal Revenue Services in the U.S. ("IRS") issued their first set of guidance on GILTI in September 2018 and are 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. Based on the current legislation, our U.S. tax liability is US$3,072,040 (equivalent to A$4,352,564).

Critical Accounting Estimates and Judgments

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

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

(a) Revenue Recognition

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

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

(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.

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.

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(e) Warrants

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

Exercise Price at Valuation Date

The exercise price of the warrants has been determined as stated in the Credit Agreement. For further details, see Notes to Consolidated 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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Financial Condition, Liquidity and Capital Resources

Net Financial Assets

Our net financial assets position is shown below:

	Years Ended December 31,	
	2018	2017
	A$	A$
Financial assets:		
Cash and cash equivalents	11,797,789	26,259,918
Accounts receivables	50,209,561	4,397,268
Total financial assets	62,007,350	30,657,186
Debt:		
Long term secured loan	0	19,029,076
Total debt	0	19,029,076
Net financial assets	62,007,350	11,628,110

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

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

The lump sum service fees of A$44,635,704 has resulted in an improvement to our net financial asset position.

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

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

We regularly review all our financial assets for impairment. There were no impairments recognized for the years ended December 31, 2018 and 2017.

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, 2018 and 2017, we did not have any assets or liabilities that utilize Level 3 inputs. The valuation of our foreign exchange derivatives is based on the market approach using observable market inputs, such as forward rates, and incorporates non-performance risk (the credit standing of the counterparty when the derivative is in a net asset position, and the credit standing of the Company when the derivative is in a net liability position). Our derivative assets are categorized as Level 2.

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We had no derivatives or outstanding contracts in place through the years ended December 31, 2018 and 2017.

Measures of Liquidity and Capital Resources

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

	Years Ended December 31,	
	2018	2017
	A$	A$
Cash and cash equivalents	11,797,789	26,259,918
Working capital (current assets less current liabilities)	50,830,568	24,746,728
Ratio of current assets to current liabilities	4.85 : 1	3.97 : 1
Shareholders' equity per common share	0.29	0.07

The movement in cash and cash equivalents and working capital during the above periods was primarily due to the repayment of loan and the lump sum service fees.

Cash and cash equivalents have declined primarily as a result of the repayment of the term loan in November 2018. There has been a significant improvement to our working capital position as a result of the recording of the lump sum service fees during 2018.

We have not identified any collection issues with respect to receivables. We received the lump sum service fees of US$31,503,880 (equivalent to A$44,635,704) from LifeScan on February 18, 2019.

Summary of Cash Flows

	Years Ended December 31,	
	2018	2017
	A$	A$
Cash provided by/(used in):		
Operating activities	1,764,437	8,705,024
Investing activities	(356,785)	(1,021,051)
Financing activities	(20,946,065)	(368,864)
Net increase/(decrease) in cash, cash equivalents and restricted cash	(19,538,413)	7,315,109

The Company has generated positive operating cash flows in 2018 and 2017.

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, interest on our long term secured loan and general and administrative expenditure. Decline in operating cash flows in 2018 when compared to 2017 as 2017 includes the receipt of the research and development tax incentive income of A$7,522,341 for the 2016 financial year. No such amounts were received during the 2018 financial year as the Company was not eligible the refundable tax offset.

Our net cash used in investing activities for all periods is primarily for the purchase of various plant and equipment and for the various continuous improvement program we are undertaking.

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

Management's Discussion and Analysis of Financial Condition and Results of Operations
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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, 2018 are:

	A$
Less than 1 year	256,644
1 – 3 years	38,657
3 – 5 years	1,129
More than 5 years	0
Total minimum lease payments	296,430

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 view our operations as a single 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 and continue to derive significant revenues from LifeScan. As a result of LifeScan exercising its right in September 2018 to convert its obligation to pay quarterly service fees, we will not receive any further quarterly service fees from LifeScan beyond 2018.

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.

The Company has recorded foreign currency transaction gains of A$577,505 and A$731,289 for the years ended December 31, 2018 and 2017, respectively.

Management's Discussion and Analysis of Financial Condition and Results of Operations
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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, 2018 and 2017, 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 each of the two years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018 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 22, 2019

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

Universal Biosensors, Inc.

Consolidated Balance Sheets

	December 31, 2018 A$	December 31, 2017 A$
ASSETS		
Current assets:		
Cash and cash equivalents	11,797,789	26,259,918
Inventories, net	744,466	662,132
Accounts receivable	50,209,561	4,397,268
Prepayments	158,492	887,303
Restricted cash	15,589	15,309
Other current assets	1,105,291	860,254
Total current assets	64,031,188	33,082,184
Non-current assets:		
Property, plant and equipment	29,101,932	37,224,442
Less accumulated depreciation	(23,475,544)	(27,264,680)
Property, plant and equipment - net	5,626,388	9,959,762
Restricted cash	320,000	3,220,000
Total non-current assets	5,946,388	13,179,762
Total assets	69,977,576	46,261,946
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	695,405	329,586
Income taxes payable	4,352,564	0
Accrued expenses	1,696,644	1,472,692
Other liabilities	2,902,525	2,626,413
Deferred revenue	2,356,583	2,356,583
Employee entitlements liabilities	1,196,899	1,550,182
Total current liabilities	13,200,620	8,335,456
Non-current liabilities:		
Asset retirement obligations	2,600,000	2,600,000
Employee entitlements liabilities	39,468	64,358
Long term secured loan	0	19,029,076
Deferred revenue	3,463,737	3,463,737
Total non-current liabilities	6,103,205	25,157,171
Total liabilities	19,303,825	33,492,627
Commitments and contingencies	0	0
Stockholders' equity:		
Preferred stock, US$0.01 par value. Authorized 1,000,000 shares; issued and outstanding nil in 2018 (2017: nil)		
Common stock, US$0.0001 par value. Authorized 300,000,000 shares; issued and outstanding 177,243,520 shares in 2018 (2017: 176,498,550)	17,724	17,650
Additional paid-in capital	93,815,185	93,450,721
Accumulated deficit	(80,397,343)	(79,632,626)
Current year income/(loss)	37,564,356	(764,717)
Accumulated other comprehensive income	(326,171)	(301,709)
Total stockholders' equity	50,673,751	12,769,319
Total liabilities and stockholders' equity	69,977,576	46,261,946

See accompanying notes to the financial statements.

Universal Biosensors, Inc.

Consolidated Statements of Comprehensive Income/(Loss)

	Years Ended December 31,	
	2018	2017
	A$	A$
Revenue		
Revenue from products	1,672,321	4,066,929
Revenue from services	67,784,593	21,124,351
Total revenue	69,456,914	25,191,280
Operating costs & expenses		
Cost of goods sold	1,607,340	3,014,995
Cost of services	904,139	936,213
Total cost of goods sold & services	2,511,479	3,951,208
Contribution from products & services	66,945,435	21,240,072
Other operating costs & expenses		
Product support	227,517	604,984
Depreciation	1,721,882	2,100,763
Research and development	11,578,246	10,828,879
General and administrative	6,995,089	6,689,431
Total operating costs & expenses	20,522,734	20,224,057
Profit/(loss) from operations	46,422,701	1,016,015
Other income/(expense)		
Interest income	491,038	172,376
Interest expense	0	(9,610)
Financing costs	(2,991,117)	(2,793,734)
Research and development tax incentive income	0	122,341
Exchange gain	577,505	731,289
Impairment of fixed assets	(2,574,709)	0
Loss on disposal of fixed assets	(8,498)	(3,394)
Total other income/(expense)	(4,505,781)	(1,780,732)
Net income/(loss) before tax	41,916,920	(764,717)
Income tax expense	(4,352,564)	0
Net income/(loss)	37,564,356	(764,717)
Earnings per share		
Basic net income/(loss) per share	0.21	(0.00)
Average weighted number of shares - basic	176,732,183	176,417,431
Diluted net income/(loss) per share	0.21	(0.00)
Average weighted number of shares - diluted	177,152,938	176,417,431
Other comprehensive gain/(loss), net of tax:		
Foreign currency translation reserve	(24,462)	(3,506)
Reclassification for (gains)/losses realized in net income	0	0
Other comprehensive gain/(loss)	(24,462)	(3,506)
Comprehensive gain/(loss)	37,539,894	(768,223)

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				
		A$	A$	A$	A$	A$
Balances at January 1, 2017	176,386,884	17,639	93,167,465	(79,632,626)	(298,203)	13,254,275
Net loss	0	0	0	(764,717)	0	(764,717)
Other comprehensive loss	0	0	0	0	(3,506)	(3,506)
Exercise of stock options issued to employees	111,666	11	755	0	0	766
Stock option expense	0	0	282,501	0	0	282,501
Balances at December 31, 2017	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	177,243,520	17,724	93,815,185	(42,832,987)	(326,171)	50,673,751

See accompanying notes to the financial statements.

Universal Biosensors, Inc.

Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2018	2017
	A$	A$
Cash flows from operating activities provided by:		
Net income/(loss)	37,564,356	(764,717)
Adjustments to reconcile net income/(loss) to net cash provided by operating activities:		
Depreciation and amortization	2,113,454	2,589,493
Share based payments expense	318,545	282,501
Impairment of fixed assets	2,574,709	0
Loss on disposal of fixed assets	8,498	3,394
Unrealized foreign exchange gains	(472,934)	(31,112)
Financing costs - amortization of warrants	213,359	212,168
Change in assets and liabilities:		
Inventory	(82,334)	177,118
Accounts receivable	(45,812,293)	450,741
Prepayment and other assets	483,774	7,405,162
Income tax payable	4,352,564	0
Deferred revenue	0	(546,655)
Employee entitlements	(356,643)	(35,416)
Accounts payable and accrued expenses	859,382	(1,037,653)
Net cash provided by operating activities	1,764,437	8,705,024
Cash flows from investing activities:		
Proceeds from sale of property, plant and equipment	2,582	0
Purchases of property, plant and equipment	(448,867)	(1,292,369)
Proceeds from government grants in relation to property, plant & equipment	89,500	271,318
Net cash used in investing activities	(356,785)	(1,021,051)
Cash flows from financing activities:		
Repayment of borrowings	(20,689,655)	(369,630)
Borrowing costs	(256,410)	0
Proceeds from stock options exercised	0	766
Net cash used in financing activities	(20,946,065)	(368,864)
Net increase/(decrease) in cash, cash equivalents and restricted cash	(19,538,413)	7,315,109
Cash, cash equivalents and restricted cash at beginning of period	29,495,227	23,622,322
Effect of exchange rate fluctuations on the balances of cash held in foreign currencies	2,176,564	(1,442,204)
Cash, cash equivalents and restricted cash at end of period	12,133,378	29,495,227

See accompanying notes to the financial statement

Universal Biosensors, Inc.

Notes to Consolidated Financial Statements
(for the years ended December 31, 2018 and 2017)

(1) Basis of Presentation

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

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

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments purchased with an initial maturity of three months or less to be cash equivalents. For cash and cash equivalents, the carrying amount approximates fair value due to the short maturity of those instruments. The Company maintains cash and restricted cash, which includes tenant and credit card security deposits. As at December 31, 2018 and 2017, 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, 2018 and 2017)

Derivative Instruments and Hedging Activities

Derivative financial instruments

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

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

Cash flow hedges

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

Where a derivative financial instrument is designated as a hedge of the variability in cash flows of a recognized asset or liability, or a highly probable forecast transaction, the effective part of any 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, 2018 and 2017, 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.

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- Cost approach – based on the cost to acquire or construct comparable assets less an allowance for functional and/or economic obsolescence.
- Income approach – based on the present value of a future stream of net cash flows.

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

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

Inventory

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

	Years Ended December 31,	
	2018	2017
	A$	A$
Raw materials	302,056	380,540
Work in progress	442,410	253,483
Finished goods	0	28,109
	744,466	662,132

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.

	Years Ended December 31,	
	2018	2017
	A$	A$
Accounts receivable	50,209,561	4,397,268
Allowance for doubtful debts	0	0
	50,209,561	4,397,268

Property, Plant, and Equipment - net

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

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

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

Impairment of Long-Lived Assets

The Company reviews its capital assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. In performing the review, the Company estimates undiscounted cash flows from products under development that are covered by these patents and licenses. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than the carrying amount of the asset. If the evaluation indicates that the carrying value of an asset is not recoverable from its undiscounted cash flows, an impairment loss is measured by comparing the carrying value of the asset to its fair value, based on discounted cash flows. Impairment of long-lived assets as at December 31, 2018 and 2017 were A$2,574,709 and nil, respectively.

Other Liabilities

Other liabilities represent marketing support payment due to LifeScan.

	Years Ended December 31,	
	2018	2017
	A$	A$
Current liabilites		
Marketing support payment	2,902,525	2,626,413
	2,902,525	2,626,413

During 2009, LifeScan chose not to proceed with the registration of the then current product but to proceed with an enhanced product, called OneTouch Verio®, and acknowledged that there would be a delay as a result. As a result of this change, LifeScan agreed to pay additional amounts per strip manufactured by the Company in 2010 and 2011 up to a specified volume limit ("manufacturing initiation payments"). At the same time, the Company agreed to pay LifeScan a marketing support payment in each of the two years following the first calendar year in which 1 billion strips are sold by LifeScan equal to 40% of the total manufacturing initiation payments made. The first calendar year in which 1 billion strips were sold by LifeScan was during the 2016 financial year. These amounts will be paid to LifeScan once supporting documentation has been provided to us. The total amount of marketing support payments to be paid to LifeScan in US$ once all the documentation is received is US$2,048,602 (equivalent to A$2,902,525).

Research and Development

Research and development expenses consist of costs incurred to further the Group's research and product development activities and include salaries and related employee benefits, costs associated with clinical trial and preclinical development, regulatory activities, research-related overhead expenses, costs associated with the manufacture of clinical trial material, costs associated with developing a commercial manufacturing process, costs for consultants and related contract research, facility costs and depreciation. Research and development costs are expensed as incurred.

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

	Years Ended December 31,	
	2018	2017
	A$	A$
Research and development expenses	11,578,246	10,828,879

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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 2017 financial year has been filed in all these jurisdictions.

Asset Retirement Obligations

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

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

ARO for the years ended December 31, 2018, and 2017 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

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

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

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

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. Revenue recognition principles are assessed for each new contractual arrangement and the appropriate accounting is determined for each service.

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On September 21, 2018 LifeScan exercised its right to convert its obligation to pay quarterly service fees to us. The lump sum service fees of US$31,503,880 (equivalent to A$44,635,704) was paid to Universal Biosensors on February 18, 2019. The lump sum service fee has been calculated by multiplying the total quarterly service fees received for the 2018 financial year by two and converting the same into AUD using the period end exchange rate. We assessed if any amount of the lump sum service fees were attributable to the remaining obligation under the Master Services and Supply Agreement that states that LifeScan could require us to provide manufacturing services at our Rowville facility to recommence production of glucose strips. We conclude that this obligation has no fair value attributable to it due to (i) high set-up costs to recommence manufacturing, (ii) the required lead time to gain regulatory compliance, and (iii) the fact there is deemed to be no commercial rationale for LifeScan to request us to recommence glucose-strip manufacturing on the basis of current information. As such, the lump sum service fee revenue has been fully recognized this financial year and no revenue has been deferred.

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

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

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

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

Master Services and Supply Agreement

In October 2007, the Company and LifeScan entered into a Master Services and Supply Agreement, under which the Company would provide certain services to LifeScan in the field of blood glucose monitoring and act as a non-exclusive manufacturer of blood glucose test strips. The Master Services and Supply Agreement was subsequently amended and restated in May 2009. The Company has concluded the Master Services and Supply Agreement should be accounted for as three separate units of accounting: 1) research and development to assist LifeScan in receiving regulatory clearance to sell the blood glucose product (milestone payment), 2) contract manufacturing of the blood glucose test strips (contract manufacturing) which ceased in December 2013, and 3) ongoing services and efforts to enhance the product (product enhancement).

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

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Collaboration Agreement

On September 9, 2011 the Company entered into a Collaboration Agreement with Siemens to develop coagulation related products for hospital point-of-care and ambulatory care coagulation markets. In addition to an up-front, non-refundable payment of A$2,961,245 (equivalent to US$3 million), the Collaboration Agreement (as amended) contains a further seven payments from Siemens upon the achievement of certain defined milestones. These seven milestones to a large extent relate to feasibility, regulatory submissions and the launch of the products to be developed. The Company has concluded that the up-front payment is not a separate unit of accounting and recorded the amount as deferred revenue to be recognized as revenue across other deliverables in the arrangement with Siemens based upon the Company's best estimate of selling price. The deliverables related to each of the seven milestone are considered substantive and are not priced at a significant incremental discount to the other deliverables. As the achievement of the milestones is contingent upon a future event, the revenue for each deliverable will be recognized as the contingencies are met and the consideration becomes fixed and determinable.

Interest income

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

Research and development tax incentive income

Research and development tax incentive income is recognized when there is reasonable assurance that the income will be received, the relevant expenditure has been incurred, and the consideration can be reliably measured. The research and development tax incentive is one of the key elements of the Australian Government's support for Australia's innovation system and is supported by legislative law primarily in the form of the Australian Income Tax Assessment Act 1997 as long as eligibility criteria are met. Generally speaking, 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 million, or
2. as a 38.5% non-refundable tax offset if aggregate turnover of the entity is more than A$20 million.

In accordance with SEC Regulation S-X Article 5-03, the Company's research and development 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.

For the year ended December 31, 2018 and 2017, the aggregate turnover of the Company had exceeded A$20 million and accordingly it was not eligible for a refundable tax offset. The Company was however eligible for the non-refundable tax offset. The eligible R&D activities and expenditures are able to be claimed 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$").

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

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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$577,505 and A$731,289 in each of the years ended December 31, 2018 and 2017, respectively.

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

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

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

Commitments and Contingencies

Liabilities for loss contingencies, arising from claims, assessments, litigation, fines, and penalties and other sources are recorded when it is probable that a liability has been incurred and the amount of the assessment can be reasonably estimated. These were nil as at December 31, 2018 and 2017. Purchase commitments contracted for as at December 31, 2018 and 2017 were A$941,864 and A$2,359,443, respectively.

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, 2018 and 2017 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.

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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.

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. 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$
2018			
Foreign currency translation reserve	(24,462)	0	(24,462)
Reclassification for gains realised in net income	0	0	0
Other comprehensive loss	(24,462)	0	(24,462)
2017			
Foreign currency translation reserve	(3,506)	0	(3,506)
Reclassification for gains realised in net income	0	0	0
Other comprehensive loss	(3,506)	0	(3,506)

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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.

Recent Accounting Pronouncements

(a) Recent issued accounting standards not yet adopted

ASU No.2016-02, "Leases'

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

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

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

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, Revenue from Contracts with Customers (Topic 606), which provides companies with a single revenue recognition model for recognizing revenue from contracts with customers. The core principle of the new standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. There are two permitted transition methods under the new standard, the full retrospective method or the modified retrospective method. The new standard is effective for annual reporting periods beginning after December 15, 2017. The Company has adopted this standard on January 1, 2019.

UBI has selected the modified retrospective method where the effect of applying the standard will be recognized at the date of initial application, without restating previous years. The Company has evaluated the impact of the adoption of ASU 2014-09 and it will not have a material impact on the Company's consolidated financial statements.

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

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

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

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(b) Recently adopted accounting pronouncements

ASU No.2016-18, "Restricted Cash'

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

ASU No.2016-15, "Classification of Certain Cash Receipts and Cash Payments"

On August 26, 2016, the FASB issued ASU 2016-15, which amends the guidance in ASC 230 to eliminate diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The guidance in the ASU is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted for all entities. The Company has adopted this guidance in 2016 and it has not had a material impact on the Company's consolidated financial statements.

ASU No.2016-16, "Income Taxes: Intra-Entity Transfers of Assets Other Than Inventory'

On October 24, 2016, the FASB issued ASU 2016-16, which removes the prohibition in ASC 740 against the immediate recognition of the current and deferred income tax effects of intra-entity transfers of assets other than inventory. This ASU is effective for annual periods beginning after December 15, 2017, and interim periods within those annual periods. Early adoption is permitted for all entities as of the beginning of a fiscal year for which neither the annual or interim financial statements have been issued. Entities should apply the ASU's amendments on a modified retrospective basis, recognizing the effects in retained earnings as of the beginning of the year of adoption. The Company has adopted this guidance in 2017 and it has not had a material impact on the Company's consolidated financial statements.

ASU No.2017-01, "Business Combination: Clarifying the Definition of a Business'

On January 5, 2017, the FASB issued ASU 2017-01 to clarify the definition of a business in ASC 805. The amendments in the ASU are intended to make application of the guidance more consistent and cost-efficient. The ASU is effective for annual periods beginning after December 15, 2017, including interim periods therein. The ASU must be applied prospectively on or after the effective date, and no disclosures for a change in accounting principle are required at transition. Early adoption is permitted for transactions (i.e., acquisitions or dispositions) that occurred before the issuance date or effective date of the standard. The Company has adopted this guidance in 2017 and it has not had a material impact on the Company's consolidated financial statements.

ASU No.2017-09, "Compensation – Stock Compensation: Scope of Modification Accounting'

On May 10, 2017, the FASB issued ASU 2017-09, which amends the scope of modification accounting for share-based payment arrangements. The ASU provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting under ASC 718. This ASU is effective for annual reporting periods, including interim periods within those annual reporting periods, beginning after December 15, 2017. Early adoption is permitted. The Company has adopted this guidance in 2017 and it has not had a material impact on the Company's consolidated financial statements.

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

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

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ASU No. 2018-09, "Codification Improvements"

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

Reclassification

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

(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.

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, 2020 with 2 further options to renew each for 5 years.

Future minimum lease payments under non-cancelable operating leases (with initial or remaining lease terms in excess of one year) as of December 31, 2018 are:

	A$
Less than 1 year	256,644
1 – 3 years	38,657
3 – 5 years	1,129
More than 5 years	0
Total minimum lease payments	296,430

Rent expense was A$750,798 and A$731,394 for the fiscal years ended December 31, 2018 and 2017, 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. The grants are paid upon achievement of pre-agreed milestones. The milestones generally relate to UBS placing purchase orders, commissioning upgrades and validating the equipment. Amongst other reasons, the Commonwealth of Australia may terminate the grant agreement for breach of the agreement by UBS or for failure to undertake the required programme. Under these circumstances, the Commonwealth of Australia may require UBS to repay some or the entire grant. The Company continues to undertake the project funded by the Commonwealth of Australia.

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

(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.

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

	Years ended December 31,			
	2018		2017	
	A$	%	A$	%
Profit/(loss) before income taxes	41,916,920		(764,717)	
Computed by applying income tax rate of home jurisidction	12,575,076	30	(229,415)	30
Effect of tax rates in foreign jurisdictions	13,316	0	30,589	(4)
Research and development	4,253,289	10	3,986,640	(521)
Temporary timing differences:				
Share based payment	95,564	0	84,750	(11)
Other	(61,115)	(0)	135,846	(18)
Utilisation of carried forward losses	(3,298,121)	(8)	0	0
Utilisation of tax credits	(13,046,757)	(31)	0	0
Change in valuation allowance	(531,252)	(1)	(4,008,410)	524
Global intangible low-taxed income (GILTI) tax	4,352,564	10	0	0
Income tax expense/(benefit)	4,352,564	10	0	0

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

	As of December 31,	
	2018	2017
	A$	A$
Foreign	(44,386)	(596,189)
Domestic (Australia)	41,961,306	(168,528)
	41,916,920	(764,717)

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

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	As of December 31,	
	2018	2017
	A$	A$
Deferred tax assets:		
Operating loss carry forwards	0	3,491,300
Depreciation and amortization	1,578,478	1,454,394
Asset retirement obligations	780,000	780,000
Employee entitlements	366,039	477,783
Accruals	1,325,955	1,292,788
Decline in value of patents	1,195,965	1,184,629
Unrealised exchange loss	(583,029)	(660,410)
Other	241,152	(88,877)
Total deferred tax assets	4,904,560	7,931,607
Valuation allowance for deferred tax assets	(4,904,560)	(7,931,607)
Net deferred tax asset	0	0

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, 2018 the Company has nil (A$11,637,669 at December 31, 2017) of accumulated tax losses available for carry forward against future earnings, which under Australian tax laws do not expire but may not be available under certain circumstances. The Company also has A$3,459,966 (A$10,963,961 at December 31, 2017) of non-refundable R&D tax offset as at December 31, 2018. The R&D Tax offset is a non-refundable tax offset, which assists to reduce a company's tax liability. Once the liability has been reduced to zero, any excess offset may be carried forward into future income years. UBI has US tax losses available for carry forward against future earnings of nil as of December 31, 2018 (US$1,011,321 as of December 31, 2017). 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$709,191 and CAD$676,899 as at December 31, 2018 and 2017, respectively.

(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.

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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 2017 and 2018 were 10,229,500 and nil, respectively.

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

	Oct-17	Oct-17	Oct-17	Feb-17
Exercise Price (A$)	0.50	0.60	0.80	0.50
Share Price at Grant Date (A$)	0.38	0.38	0.38	0.39
Volatility	68%	68%	68%	69%
Expected Life (years)	5	5	5	6
Risk Free Interest Rate	2.36%	2.36%	2.36%	2.47%
Fair Value of Option (A$)	0.15	0.13	0.11	0.13

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 A$
Balance at December 31, 2017	22,003,215	0.63
Granted	0	0.00
Exercised	(553,334)	0.00
Lapsed	(6,295,997)	0.70
Balance at December 31, 2018	15,153,884	0.63

At December 31, 2018, the number of options exercisable was 7,510,888 (2017: 11,880,702). At December 31, 2018, total stock compensation expense/(income) recognized in the consolidated condensed statements of comprehensive income was A$318,545 (2017: A$282,501).

The following table represents information relating to stock options outstanding under the plans as of December 31, 2018:

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Exercise Price A$	Options Outstanding Shares	Options Outstanding Weighted average remaining life in years	Options Exercisable Shares
$0.50	8,000	0	8,000
$0.00	178,334	0	178,334
$0.94	354,667	0	354,667
$1.72	560,000	1	560,000
$0.75	20,000	0	20,000
$0.73	12,000	1	12,000
$1.09	155,000	1	155,000
$0.00	50,000	1	50,000
$0.79	24,000	1	24,000
$0.71	30,000	2	30,000
$0.49	152,500	2	152,500
$0.00	80,000	2	80,000
$0.17	50,000	3	50,000
$0.23	185,000	3	185,000
$0.00	80,000	3	80,000
$0.45	224,166	4	224,166
$0.50	4,605,000	4	4,605,000
$0.33	140,667	5	97,671
$0.50	644,550	5	644,550
$0.50	1,600,000	4	0
$0.60	2,700,000	4	0
$0.80	3,300,000	4	0
	15,153,884		7,510,888

The table below sets forth the number of employee stock options exercised and the number of shares issued in the period from December 31, 2016. 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$)
2017	111,666	A$ 0.01	766
2018	553,334	A$ 0.00	0

As of December 31, 2018, there was A$579,682 of unrecognized compensation expense related to unvested share-based compensation arrangements under the Employee Option Plan. This expense is expected to be recognized as follows:

Fiscal Year	A$
2019	320,926
2020	258,756
	579,682

The aggregate intrinsic value for all options outstanding as at December 31, 2018 was zero.

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(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 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, 2017:

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

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

	Number of shares	Weighted average issue price (A$)
Balance at December 31, 2017	492,749	0.31
Granted	191,636	0.24
Release of restricted shares	(373,139)	0.31
Balance at December 31, 2018	311,246	0.28

(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. With effect from October 1, 2017, Mr. Denver continues to provide services to the Company in an advisory capacity between October 1, 2017 and June 30, 2018.

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 18% 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 this period Viburnum Funds Pty Ltd continue to pay all the salary entitlements of the seconded person. Universal Biosensors is solely responsible for the reimbursement of certain expenditure 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, 2018 was A$21,716.

There were no other related party transactions during 2018 and 2017 other than as disclosed above.

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(7) Financial Instruments

	Years Ended December 31,	
	2018	2017
	A$	A$
Financial assets:		
Cash and cash equivalents	11,797,789	26,259,918
Accounts receivables	50,209,561	4,397,268
Total financial assets	62,007,350	30,657,186
Debt:		
Long term secured loan	0	19,029,076
Total debt	0	19,029,076
Net financial assets	62,007,350	11,628,110

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 2018 and 2017.

Derivative Instruments and Hedging Activities

We had no derivatives or outstanding contracts in place through the years ended December 31, 2018 and 2017

(8) Property, Plant and Equipment, net

	As of December, 31	
	2018	2017
	A$	A$
Plant and equipment	18,028,590	26,176,290
Leasehold improvements	9,130,310	9,105,120
Capital work in process	1,943,032	1,943,032
	29,101,932	37,224,442
Accumulated depreciation	(23,475,544)	(27,264,680)
Property, plant & equipment, net	5,626,388	9,959,762

Capital work in process relates to assets under construction and comprises primarily specialized manufacturing 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, 2018 and 2017 was A$8,993,225 and A$8,453,505, respectively.

From 2017 to 2019, the Company is 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. Plant and equipment is presented net of the government grant of A$360,818 for the year ended December 31, 2018 (2017: A$271,318). 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$2,113,454 and A$2,589,493 for the fiscal years ended December 31, 2018 and 2017, respectively.

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(9) Accrued Expenses

Accrued expenses consist of the following:

	As of December, 31	
	2018	2017
	A$	A$
Legal, tax and accounting fees	716,937	683,091
Salary and related costs	306,162	104,515
Research and development materials	554,496	587,126
Other	119,049	97,960
	1,696,644	1,472,692

(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 CHESS Depositary Interests ("CDIs"). Each CDI represents beneficial ownership in one underlying share. Legal title to the shares underlying CDIs is held by CHESS Depositary 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.

	Years Ended December 31,	
	2018	2017
Weighted average shares used as denominator in calculating:		
Basic net income/(loss) per share	176,732,183	176,417,431
Diluted net income/(loss) per share	177,152,938	176,417,431

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 420,755 and nil for the years ended December 31, 2018 and 2017, 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.

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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.

No liability has arisen under these indemnities as of December 31, 2018 and 2017.

(13) Segments

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

The Company operates predominantly in one geographical area, being Australia and continues to derive significant revenues from LifeScan. Beyond 2018 we will not be receiving any quarterly services fees from LifeScan as it has exercised its right to convert its obligation to pay quarterly service fees to us.

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,	
	2018	2017
	A$	A$
Home country - Australia	490,962	294,717
Foreign countries		
- U.S.A.	1,428,350	1,131,772
- Germany	1,603,817	3,641,781
- Switzerland	66,084,950	20,057,644
- Canada	238,056	222,229
- Other	101,817	137,854
Total - foreign countries	69,456,990	25,191,280
Total income	69,947,952	25,485,997
% of total income derived from - LifeScan	94%	79%
- Siemens	3%	18%
- Other	2%	3%

(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.

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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.

	December 31, 2018		December 31, 2017	
	US$	A$	US$	A$
2018	0		1,956,563	
2019	0		15,875,875	
2020	0		0	
Thereafter	0		0	
Total minimum payments	0		17,832,438	
Less amount representing interest and other fees	0		(2,832,438)	
Gross balance of long term debt	0		15,000,000	
Less fair value of warrants recorded within loan (a)	(815,655)		(815,655)	
Plus interest accretion	815,655		658,334	
Total carrying value	0	0	14,842,679	19,029,076
Less current portion	0	0	0	0
Total carrying value, non-current portion	0	0	14,842,679	19,029,076

For 2017, the carrying value of the borrowings approximated its fair value. The fair value was estimated by discounting future cash flows at the currently offered rates for borrowings of similar remaining maturities.

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

Athyrium Credit Agreement

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

The credit agreement was amended again on December 29, 2017 ("Amendment"). Subject to the terms of the Amendment, the Amendment modifies 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 $2,000,000 within 12 months after the date Lenders provide any such consent. In connection with the Amendment, UBI has 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.

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

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

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

Other

In December 2016, UBS entered into an arrangement with Elantis Premium Funding Ltd to fund the Group's 2017 insurance premium. The total amount financed was A$369,630 at inception and the short-term borrowing was fully repaid in September 2017. Interest was charged at a fixed rate of 2.60% per annum. The short-term borrowing was secured by the insurance premium refund. The Company's 2018 and 2017 insurance program was funded from its operating cash flows.

(16) Warrants

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

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

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

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

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

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

(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.

Universal Biosensors, Inc.

Notes to Consolidated Financial Statements
(for the years ended December 31, 2018 and 2017)

	Years Ended December 31,	
	2018	2017
	A$	A$
Cash and cash equivalents	11,797,789	26,259,918
Restricted cash - current assets	15,589	15,309
Restricted cash - non-current assets	320,000	3,220,000
	12,133,378	29,495,227

	Years Ended December 31,	
	2018	2017
	A$	A$
Collateral for facilities (a) - current assets	15,589	15,309
Collateral for facilities (b) - non-current assets	320,000	320,000
Financial covenant pursuant to the credit agreement (c) - current assets	0	2,900,000
	335,589	3,235,309

(a) Represents bank guarantee of CDN$15,000 as security deposit on HRL's credit card
(b) Represents bank guarantee of A$250,000 for commercial lease of UBS' premises and security deposit on Company's credit cards of A$70,000
(c) Represents amounts pledged as collateral for financing arrangements as contractually required by the Lenders. This restriction lapsed upon the repayment of the term loan

Interest earned on the restricted cash as at December 31, 2018 and 2017 were A$62,037 and A$73,615, respectively.

(18) Subsequent Events

On February 8, 2019, we entered into a Term Sheet Agreement with UBS and Siemens pursuant to which we have agreed to negotiate with UBS and Siemens in good faith for a specified period (subject to extension if mutually agreed) possible modifications to our commercial relationship, including the Collaboration Agreement and Supply Agreements. Under the term sheet agreement, our obligations, as well as those of UBS and Siemens, to apply commercially reasonable efforts and to apply reasonably necessary resource to certain research and development activities under the Collaboration Agreement have been suspended pending the outcome of the negotiation. Under the Term Sheet Agreement, we and UBS have also agreed to not make any dividend payments or similar distributions, or engage in M&A transactions (subject to an exception which would allow us and UBS to enter into M&A transactions where the directors of either company determine, in good faith, that not proceeding with such a transaction would be inconsistent with their fiduciary duties).

Universal Biosensors, Inc.

Schedule ii – Valuation and Qualifying Accounts
(for the years ended December 31, 2018 and 2017)

	Balance at Beginning of Period	Additions: Charged to Costs and Expenses	Additions: Charged to Other Accounts	Deductions	Balance at end of Period
	A$	A$	A$	A$	A$
Year ended December 31, 2017					
Deferred income tax valuation allowance	12,106,409	(4,008,410)	(166,392)	0	7,931,607
Year ended December 31, 2018					
Deferred income tax valuation allowance	7,931,607	(16,876,129)	13,849,082	0	4,904,560

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, Rick Legleiter, 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 22, 2019

/s/ Rick Legleiter
Rick Legleiter
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 22, 2019

/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, 2018, 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 22, 2019.

/s/ Rick Legleiter
Rick Legleiter
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.