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, 2021

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission file number: 000-52607

Universal Biosensors, Inc.

(Exact name of registrant as specified in its charter)

Delaware *(State or other jurisdiction of incorporation or organization)*	**98-0424072** *(I.R.S. Employer Identification No.)*
Universal Biosensors, Inc. **1 Corporate Avenue,** **Rowville, 3178, Victoria** **Australia** *(Address of principal executive offices)*	**Not Applicable** *(Zip Code)*

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

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

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

Shares of Common Stock, par value US$0.0001 per share

(Title of each class)

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

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

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

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

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

Large accelerated filer ☐	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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐
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$91,148,185 (equivalent to US$68,525,205) as of June 30, 2021.

There were 177,838,504 shares of the registrant's common stock, par value US$0.0001 per share, outstanding as of February 18, 2022.

Documents incorporated by reference:
Certain information contained in the registrant's definitive Proxy Statement for the 2022 annual meeting 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-35 of our Annual Report to Stockholders for the fiscal year ended December 31, 2021 (our "2021 Annual Report") is incorporated by reference in our response to Items 7, 7A, 8 and 9A of Part II.

UNIVERSAL BIOSENSORS, INC.

TABLE OF CONTENTS

Unless otherwise noted, references in this Annual Report on Form 10-K (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"), its wholly owned US operating subsidiary, Universal Biosensors LLC ("UBS LLC") and UBS' wholly owned Canadian operating subsidiary, Hemostasis Reference Laboratory Inc. ("HRL") and wholly owned Dutch operating subsidiary, Universal Biosensors B.V. ("UBS BV"). 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$", "CAD$" and "€" are references to United States dollars, Canadian dollars and Euros, respectively.

Cautionary Note Regarding 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 (the "Securities Act"), 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:

- the impact of global economic and political developments on our business, including economic slowdowns or recessions that may result from the outbreak of COVID-19, which could harm our commercialization efforts for our products as well as the value of our common stock and our ability to access capital markets, if required;
- natural and manmade disasters, including pandemics such as COVID-19, and other force majeures, which could impact our operations, and those of our partners and other participants which operates within our industry;
- 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 statements in this Form 10-K containing the words "anticipates," "assumes," "believes," "can," "could," "estimates," "expects," "future," "illustration," "intends," "may," "plans," "predicts," "will," "would," and similar expressions constitute forward-looking statements, although not all forward-looking statements contain such 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 biosensors company focused on commercializing a range of biosensors in oenology (wine industry), human health including oncology, coagulation, COVID-19, women's health and fertility, non-human and environmental testing using our patented platform technology and hand-held point of use devices. UBI was incorporated as a Delaware corporation on September 14, 2001.

Key recent updates to our Company include:

- Revenue increased 80% (year on year);
- Receipts from customers increased 412%;
- Entering into a technology licensing deal that extends UBI's platform technology measuring range by 1 million times (+) on our hand-held platform device;
- Entering into a technology licensing deal for a cancer biomarker, Tn Antigen;
- Entering into a technology licensing deal using aptamer sensing for an Instant COVID-19 Test;
- The successful development and use of aptamer sensing technology on our hand-held platform device;
- The global launch and sale of Sentia's wine testing platform;
- The global launch of Sentia's Free Sulphur Dioxide product;
- The hiring of a Sentia direct sales force in the USA;
- Entering into 14 separate distribution agreements for the sale of Sentia's wine testing platform device in Australia, France, USA, Italy, Germany, Spain, Portugal, Switzerland, New Zealand, South Africa, Canada, Mexico, Chile, Austria and Greece;
- The completion of Sentia's new Malic Acid wine testing product;
- The further development of additional Sentia wine testing products including Total Sugars, Acetic Acid and Total Acid tests;
- The finalization of the development of UBI's next generation PT-INR Coagulation platform (Xprecia Prime);
- The commencement of clinical studies and the recruitment of "first patient" across 4 sites in the USA for Xprecia Prime;
- The submission to European regulatory authorities to have Xprecia Prime approved for sale in Europe;
- The entering into 16 new distribution agreements for the sale of Xprecia products around the world;
- Entering into various agreements for the development of our cancer Tn Antigen cancer biomarker with Peter MacCallum Cancer Centre, the Victorian Cancer Biobank and the internationally recognized Centre for Cooperative Research in Bioscience, CIC bioGUNE – BRTA (together with its clinical partner Basurto University Hospital, Spain);
- The commencement of an Investigational Clinical Study (300 patient/+) for our Tn Antigen biosensor used for the detection, staging and monitoring of cancer;
- The continued development of our diabetes detection and monitoring biosensor product in animals;
- 245% sales growth and record sales from our HRL laboratory business in Canada;
- Strong sales growth for Xprecia Stride products; and
- The establishment of operating subsidiary companies in the USA and Europe to support the global expansion of the Company's coagulation and wine testing product sales.

Description of our business

Industry background

We operate in the high growth, point-of-care segment of the global in vitro diagnostics (IVD) industry and oenology (wine industry) and other industries where point-of-use devices are or can be used. A large proportion of testing in the IVD industry, has historically been performed either by using expensive equipment or by trained personnel at dedicated or centralized testing sites including hospital laboratories and commercial laboratories. Similarly, a large proportion of testing in the wine industry, has historically been performed either by using expensive equipment or by trained personnel at dedicated or centralized testing sites including commercial laboratories. Significant interest has developed in techniques and technologies that allow testing to be performed "on-the-spot" in real time. While not all tests are suited to being performed at the point-of-use, we believe our electrochemical cell technology and other technologies could be a suitable platform for adapting a number of tests to a point-of-use format as it offers speed, ease of use, reliability, accuracy at a low cost in alternative industries.

Point-of-use tests in development and partnering strategy

We are continuing to demonstrate the broader application of our technology platform for markets with significant commercial potential. To date, we have developed a blood glucose test for detection and monitoring of diabetes in humans 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. The PT-INR tests are also marketed and sold by UBI as well. During 2021, we commenced the direct distribution of Xprecia Stride™ ("Stride") in global markets and continue to invest in the development of a new point-of-care coagulation device. Building upon the success of these globally launched products, the Company continues to focus on the point-of-use market and in March 2021 the Company launched its new product, the Sentia™ ("Sentia") hand-held wine analyzer. Sentia measures free SO_2 levels in post-fermentation wine. The Company continues to further develop other tests to be used in the wine industry. We expect to launch the Sentia "Total Sugar's" Test into the global wine market in Q1 2022. Further analytical tests, Acetic and Total Acid are expected to launch during H2 2022.

Amongst other development work, we have commenced development of biosensor strip and meter to be used for the detection and monitoring of diabetes in non-humans, a next generation PT-INR Coagulation platform, development of Tn Antigen biosensor used for the detection, staging and monitoring of cancer and a platform to be used for SARS-CoV-2 N-Protein (which is the virus that causes COVID-19) ('COVID-19 test').

Principal products and services

We are the manufacturer and distributor of PT-INR coagulation test strips and the distributor of the Siemens' Xprecia Stride™ Coagulation Analyzer, a test used to monitor the effect of the anticoagulant therapy warfarin.

We are the manufacturer and distributor of Sentia SO_2 test strips and the distributor of the Sentia Analyzer, used to measure free SO_2 levels in post-fermentation wine.

HRL provides non-diagnostic laboratory services and performs coagulation testing services.

UBS continues to conduct research and development to demonstrate the broader application of its technology platform.

Facilities

UBS leases approximately 5,000 square meters of office, research and development and manufacturing facilities at 1 Corporate Avenue, Rowville in Melbourne, Australia. UBS has had ISO 13485 certification continuously at that site since May 2007. The lease for 1 Corporate Avenue was terminated and a new lease entered into simultaneously in January 2021. The lease now expires on December 31, 2025 with an option to renew the lease for two further terms of five years each.

HRL leased approximately 482 square meters of office and laboratory facilities at 15(H) Wing, Second Floor, 711 Concession Street, Hamilton, Ontario, Canada. 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 expired on January 31, 2022.

On June 28, 2021, HRL entered a premises lease to occupy approximately 418 square meters of office and laboratory facilities at 44 Frid Street, Hamilton, Ontario, Canada. The lease commenced in February 2022, with a ten-year contractual period. HRL relocated to the new premises in February 2022. The lease does not include an option to renew the lease for a further term.

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. The use of sole sourced materials may be due to sourcing of proprietary and/or patented technology and processes that are intended to provide a unique market differentiation to our product. UBI continuously assesses its sole sourced raw materials and maintains business continuity plans with its suppliers. UBI's continuity plans may include securing secondary supply with alternate suppliers, qualification of alternate manufacturing facilities, maintaining contingency stock and securing a long lead time for the supply of raw materials once notice of termination is given by the supplier. While UBI works closely with its suppliers, there may nonetheless be events that cause supply interruption, reduction or termination that adversely impacts UBI's ability to manufacture and sell certain products.

Distribution

Order back log is not material to our business in as much as orders for our products generally are received and filled on a current basis. Our worldwide revenue for Siemens' Xprecia Stride™ Coagulation Analyzer and for the provision of non-diagnostic laboratory and coagulation testing services are not generally seasonal. Our worldwide revenue for certain of our Sentia products is seasonal based on the respective grape harvest seasons in each territory.

Regulatory clearances

UBI's medical device products and operations are subject to regulation by the U.S. Food and Drug Administration ("FDA") and various other federal and state agencies, as well as by foreign governmental agencies. These agencies enforce laws and regulations that govern the development, testing, manufacturing, labelling, advertising, marketing and distribution, and market surveillance of UBI's medical devices products. These products are also developed, manufactured and sold under an international quality system standard known as ISO 13485.

UBI's Sentia device (non-medical) products are subject to regulation by product safety regulations by many government agencies in multiple jurisdictions. These agencies enforce laws and regulations that govern the safety aspects for development, testing, manufacturing, labelling, advertising, marketing and distribution, and market surveillance of UBI's products. These products are also developed, manufactured and sold under an international quality system standard known as ISO 9001.

UBI actively maintains FDA/ISO Quality Systems that establish standards for its product design, manufacturing, and distribution processes. Prior to marketing or selling most of its medical products, UBI must secure approval from the FDA and counterpart non-U.S. regulatory agencies. Following the introduction of a product, these agencies may engage in periodic reviews of UBI's quality systems, as well as product performance and advertising and promotional materials. These regulatory controls, as well as any changes in FDA policies, can affect the time and cost associated with the development, introduction and continued availability of new products. Where possible, UBI anticipates these factors in its product development and planning processes. These agencies possess the authority to take various administrative and legal actions against UBI, such as product recalls, product seizures and other civil and criminal sanctions.

UBI also is subject to various federal and state laws, and laws outside the United States, concerning healthcare fraud and abuse (including false claims laws and anti-kickback laws), global anti-corruption, transportation, safety and health, and customs and exports. Many of the agencies enforcing these laws have increased their enforcement activities with respect to medical device manufacturers in recent years.

UBI believes it is in compliance in all material respects with applicable law and the regulations promulgated by the applicable agencies (including, without limitation, environmental laws and regulations), and that such compliance has not had, and will not have, a material adverse effect on our operations or results.

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

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

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

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

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

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

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

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

Trademarks

We own the "SENTIA" trademark which we use to market our wine testing products.

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 generally does not provide extended payment terms to its customers.

Dependence on single customer

Our total income as disclosed below is attributed to countries based on location of customer. Location has been determined generally based on contractual arrangements. Total income includes revenue from products and services, interest income, research and development tax incentive income and other income as disclosed in the Consolidated Statements of Comprehensive Income/(Loss).

	Year Ended December 31,	
	2021	2020
	A$	A$
Australia (home country)	4,580,741	5,003,332
Americas	1,419,436	681,806
Europe	3,905,621	2,760,382
Other	250,155	0
Total income	10,155,953	8,445,520

% of total revenue from products and services derived from major customers:

	Year Ended December 31,	
	2021	2020
	A$	A$
Siemens	30%	77%
Bayer	16%	2%
Other	54%	21%

We did not have any significant backlog orders as of December 31, 2021 and 2020.

Competitive conditions of our business

UBI operates in the increasingly challenging medical devices and non-medical devices technology marketplace. Technological advances and scientific discoveries have accelerated the pace of change in technology. The regulatory environment of medical devices products is becoming more complex and vigorous, and economic conditions have resulted in a challenging market. Companies of varying sizes compete in the global technology field. Some are more specialized than UBI with respect to particular markets, and some have greater financial resources than UBI. New companies have entered the field and established companies have diversified their business activities into the technology area. Acquisitions and collaborations by and among companies seeking a competitive advantage also affect the competitive environment.

UBI competes in this evolving marketplace on the basis of many factors, including price, quality, innovation, service, reputation, distribution and promotion. In order to remain competitive in the industries in which UBI operates, it continues to make investments in research and development, quality management, quality improvement, product innovation and productivity improvement.

Human capital management

Through our long operating history and experience with technological innovation, we appreciate the importance of retention, growth and development of our employees. The Company has a talented, motivated, and dedicated team, and is committed to supporting the development of all of its team members and to continuously building on its strong culture. As of February 18, 2022, the Company had approximately 81 employees located in Australia, Canada, the USA and Europe. Females represent 48% of our workforce, including 20% of senior management. 84% of our workforce are permanently employed to ensure throughput of growth and development. None of our employees are subject to a collective bargaining agreement.

Workplace Practices and Policies
The Company is committed to providing a workplace free of harassment or discrimination based on race, color, religion, sex, sexual orientation, gender identity, national origin, disability, veteran status, caste or other legally protected characteristic. The Company is an equal opportunity employer committed to inclusion and diversity.

Compensation and Benefits
The Company recognizes its people are most likely to thrive when they have the resources to meet their needs and the time and support to succeed in their professional and personal lives. In support of this, we believe the Company offers compensation in each of our locations around the globe that is competitive (including salary, incentive bonus, and equity), equitable and enables employees to share in the Company's success.

Growth and Development
The Company invests in tools and resources that support employees' individual growth and development. The Company offers professional development opportunities including leadership training and have development programs and on-demand opportunities to cultivate talent throughout the Company.

Inclusion and Diversity
The Company is committed to hiring inclusively, providing training and development opportunities, fostering an inclusive culture, and ensuring equitable pay for employees, and is continuing to focus on increasing diverse representation at every level of the Company.

Engagement
The Company believes that open and honest communication among team members, managers and leadership fosters an open, collaborative work environment where everyone can participate, develop and thrive. Team members are encouraged to come to their managers with questions, feedback or concerns, and the Company regularly conducts surveys that gauge employee sentiment in areas like career development and overall workplace satisfaction.

Health and Safety
The Company is committed to protecting its employees everywhere it operates. The Company identifies potential risks associated with workplace activities in order to develop measures to mitigate possible hazards. The Company supports employees with general safety training and puts specific programs in place for those working in potentially high-hazard environments, including chemical management, equipment and machinery safety, hazardous materials management and electrical safety. The Company's Safety Committee generally meet monthly to review any incidents, implement additional or update existing safety procedures across the whole operation. The Company has taken additional measures during the COVID-19 pandemic, including providing information resources, face masks and case support.

Available Information

We are required to file a Form 10-K as a result of UBI being registered under the Exchange Act.

We file annual and quarterly reports, proxy statements and other information with the United Stated Securities and Exchange Commission (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 https://www.universalbiosensors.com/investor-centre/corporate-governance.

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.

Key Business Risks

The recent and ongoing COVID-19 pandemic could materially affect our operations, employee availability, financial condition, liquidity and cash flow and the length of such impacts are uncertain.

COVID-19 has spread to Australia and to other countries, including in each of the areas in which our company and our suppliers and customers operate. The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by COVID-19, and the duration of such impact, may be difficult to assess or predict, the widespread pandemic has resulted in significant disruption of global financial markets, which could reduce our ability to access capital in the event it is required and negatively affect our future liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 and related government orders and restrictions could materially affect our business and the value of our common stock. The COVID-19 pandemic continues to evolve rapidly.

The spread of COVID-19 impacts several of our partners and may result in disruption of the supply chain of products and delays in shipments, product development and product launches. In addition, demand for products that include our technologies may be negatively impacted due to economic uncertainty from COVID-19 and a decline in spending by our customers.

The spread of COVID-19 caused us to modify our business practices (including restricting employee travel, enabling and encouraging remote work, and cancellation of physical participation in meetings, events and conferences), and we may take further actions as may be required by government authorities or that we determine are in the best interests of our employees, partners, and community. These actions may adversely impact our productivity and cause delays on new and existing projects. Such delays may negatively impact our revenues. Further, there is no certainty that the measures we have taken or will take will be sufficient to mitigate the risks posed by the virus to the well-being and productivity of our workforce.

We are monitoring the global outbreak and spread of COVID-19 and taking steps in an effort to identify and mitigate the adverse impacts on, and risks to, our business (including but not limited to our employees, suppliers, customers and other business partners) posed by its spread and the governmental and community reactions thereto. We continue to assess and update our business continuity plans in the context of this pandemic, including taking steps in an effort to help keep our workforces healthy and safe.

We may enter into collaborations, licensing arrangements, strategic alliances or partnerships with third parties that may not result in the development of commercially viable products or the generation of significant future revenues or our business would be severely harmed if our key contracts are terminated, or if counterparties to our key contracts do not meet their performance obligations under those contracts.

In the ordinary course of our business, we may enter into collaborations, licensing arrangements, strategic alliances or partnerships to develop proposed products or technologies, pursue new markets, or protect our intellectual property assets. We may also elect to amend or modify similar agreements that we already have in place. Proposing, negotiating and implementing collaborations, licensing arrangements, strategic alliances or partnerships may be a lengthy and complex process, and may subject us to business risks. For example, other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities, or may be the counterparty in any such arrangements. We may not be able to identify or complete any such collaboration in a timely manner, on a cost-effective basis, on acceptable terms or at all. In addition, we may not realize the anticipated benefits of any such collaborations that we do identify and complete. In particular, these collaborations may not result in the development of products or technologies that achieve commercial success or result in positive financial results, or may otherwise fail to have the intended impact on our business.

Additionally, we may not be in a position to exercise sole decision-making authority regarding a collaboration, licensing or other similar arrangement, which could create the potential risk of creating impasses on decisions. Further, our collaborators and business partners may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators and other business partners, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations, termination rights or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with our current or future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we have limited control over the amount and timing of resources that our current collaborators or any future collaborators devote to our arrangement with them or our future products. Disputes between us and our current, future or potential collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium.

For example, we entered into a license agreement with LifeScan Global Corporation, which provide us exclusive license to develop a test strip and meter to be used for the detection and monitoring of diabetes in non-humans. Under certain circumstances, the agreement may be terminated by LifeScan Global Corporation including if we don't launch the product within a specified period of time, if the product is not launched in certain key territories within a specified period of time and if rolling twelve months sales falls below a certain level after a specified period of time. The termination of our existing license agreement with LifeScan Global Corporation would disrupt our ability to commercialize the product which could have a material adverse impact on our financial condition and results of operations, negatively impact our ability to compete and cause our stock price to decline.

Furthermore, 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 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.

We may face challenges in marketing and selling our products, and training new customers on the use of our products which could impact our revenues.

In March 2021 the Company launched its new product, the Sentia™ ("Sentia") hand-held wine analyzer. Sentia measures free SO_2 levels in post-fermentation wine. An additional analytical test, Malic Acid, was launched to the global wine market in January 2022.

We have limited experience marketing and selling Sentia products as well as training new customers on their use, particularly in international markets. Our financial condition and operating results are and will continue to be highly dependent on our ability to adequately promote, market and sell our products, and our ability to train new customers on the use of our products. If our sales and marketing representatives fail to achieve their objectives, our sales could decrease or may not increase at levels that are in line with our forecasts.

Additionally, Siemens' existing customers may choose not to purchase Xprecia Stride™ strips and instrument from UBI following the expiration of their current contracts with Siemens. Without the continuation of supply to existing Xprecia Stride™ customers, the manufacturing of Xprecia Stride™ strips may result in an operating loss to the extent that there are fixed overhead costs that do not vary with production volume.

Our sales and marketing efforts are dependent on independent distributors who are free to market products that compete with our products. If we are unable to maintain or expand our network of independent distributors, our sales may be negatively affected.

We believe a majority of our sales will be to independent distributors for the foreseeable future who may also sell the products of our competitors. If we are unable to maintain or expand our network of independent distributors, our revenues may be negatively impacted.

If any of our key independent distributors were to cease to distribute our products or reduce their promotion of our products as compared to the products of our competitors, our sales could be adversely affected. In that case, we may need to seek alternative independent distributors or increase our reliance on our other independent distributors or we may engage direct sales representatives, which may not prevent our revenues from being adversely affected. Additionally, to the extent we enter into additional arrangements with independent distributors to perform sales, marketing or distribution services, the terms of the arrangements could result in our product margins being lower than if we directly marketed and sold our products.

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 the industry experts, 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 opportunities 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.

There can be no guarantee that Xprecia Stride™ Coagulation Analyzer, or any of the other products in development, will gain market share in a timely fashion (or at all). Competitors such as Roche Diagnostics have well established brand recognition, sales and marketing forces, product development programs and have significant resources available to support their products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Operational Risks

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

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

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

Additionally, unanticipated clinical 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.

We are dependent on our suppliers.

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

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.

Our business strategy depends on our ability to manufacture our current and proposed products in sufficient quantities and on a timely basis so as to meet consumer demand, while adhering to product quality standards, complying with regulatory requirements and managing manufacturing costs. We are subject to numerous risks related to our manufacturing capabilities, including:

- quality or reliability defects in product components that we source from third-party suppliers;
- our inability to secure product components in a timely manner, in sufficient quantities and on commercially reasonable terms;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- implementing and maintaining acceptable quality systems while experiencing rapid growth;
- our failure to increase production of products to meet demand;
- our inability to modify production lines and expand manufacturing facilities to enable us to efficiently produce future products or implement changes in current products in response to consumer demand or regulatory requirements;
- our inability to manufacture multiple products simultaneously while utilizing common manufacturing equipment; and
- potential damage to or destruction of our manufacturing equipment or manufacturing facilities.

As demand for our products increases, and as the number of our commercial products expands, we will have to invest additional resources to purchase components, hire and train employees, and enhance our manufacturing processes and quality systems. We may also increase our utilization of third parties to perform contracted manufacturing services for us, and we may need to acquire additional custom designed equipment to support the expansion of our manufacturing capacity. In addition, although we expect some of our products under development to share product features and components with our current products, manufacturing of these products may require modification of our production lines, hiring of specialized employees, identification of new suppliers for specific components, qualifying and implementing additional equipment and procedures, obtaining new regulatory approvals, or developing new manufacturing technologies. Ultimately, it may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these products commercially viable.

If we fail to increase our production capacity to meet consumer demand while also maintaining product quality standards, obtaining and maintaining regulatory approvals, and efficiently managing costs, our revenues and operating margins could be negatively impacted, which would have an adverse impact on our financial condition and operating results.

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.

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

We have largely funded our operations and capital expenditures from our existing cash reserves and the sale of our products and provision of services and government grants and rebates including the research and development tax incentive income. The revenue from the sale of our products and provision of services has funded a relatively small portion of our operating expenses. For the 2022 financial year, we expect to generate revenues from the sale of our Xprecia Stride™ product, Sentia products and through the provision of services undertaken by HRL. If our revenues are not significant, we will continue to incur operating losses on an annual basis.

To implement our business strategy and achieve consistent profitability, we need to, among other things, increase sales of our products and the gross profit associated with those sales, maintain an appropriate customer service and support infrastructure, fund ongoing research and development activities, create additional efficiencies in our manufacturing processes while adding to our capacity, and obtain regulatory clearance or approval to commercialize our products currently under development. We expect our expenses will continue to increase as we pursue these objectives and make investments in our business. Additional increases in our expenses without commensurate increases in sales could significantly increase our operating losses.

The extent of our future operating losses and the timing of our profitability are highly uncertain in light of a number of factors, including the timing of the launch of new products and product features by us and our competitors, market acceptance of our products and competitive products and the timing of regulatory approval of our products and the products of our competitors. Any additional operating losses will have an adverse effect on our stockholders' equity, and we cannot assure you that we will be able to sustain profitability.

We may also require additional capital to fund our business operations, which may not be available on acceptable commercial terms, or at all.

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

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

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

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

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

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

Legal and Regulatory Risks

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

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

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

Much of our platform intellectual property rights are licensed to us from LifeScan. If we were to breach the license agreement and LifeScan were to validly terminate the agreement in response, it would seriously restrict or eliminate our ability to develop and commercialize our existing and future tests which would have a material adverse effect on us as it would restrict r 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.

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 some 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.

Risks associated with regulatory clearance and changes to regulation.

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

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

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

If we are found to have violated laws concerning the privacy and security of patient health information or other personal information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

There are a number of domestic and international laws protecting the privacy and security of personal information. These laws place limits on how we may collect, use, share and store medical information and other personal information, and they impose obligations to protect that information against unauthorized access, use, loss, and disclosure.

If we, or any of our service providers who have access to the personal data for which we are responsible, are found to be in violation of the privacy or security requirements, we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition and operating results. Although we utilize a variety of measures to secure the data that we control, even compliant entities can experience security breaches or have inadvertent failures despite employing reasonable practices and safeguards.

We may also face new risks relating to data privacy and security as the United States, individual U.S. states, E.U. member states, and other international jurisdictions adopt or implement new data privacy and security laws and regulations as we continue to commercialize our products worldwide. For example, the California Consumer Privacy Act, which took effect on January 1, 2020, may impose additional requirements on us and increase our regulatory and litigation risk. As we continue to expand, our business will need to adapt to meet these and other similar legal requirements.

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.

Tax Risks

Our ability to carry forward our Australian tax losses and certain other tax attributes may be impacted.

As of December 31, 2021, we had A$18,921,216 of accumulated tax losses available for carry forward against future earnings, which under Australian tax laws do not expire but may not be available under certain circumstances. The Company also has A$ 3,374,776 of non-refundable R&D tax offset as at December 31, 2021. 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.

To continue to offset our accumulated tax losses and the non-refundable R&D tax offset against future earnings, we have to meet the requirements of the Continuity of Ownership Test ("COT") and failing that the Same Business Test ("SBT"). A taxpayer generally satisfies the COT where the company can demonstrate at all times that the same persons (i.e. ultimate individual owners) beneficially held more than 50% of the voting power in the company; and the rights to more than 50% of the company's dividends; and the rights to more than 50% of the company's capital distributions, for the period commencing at the beginning of the loss year (i.e. the year that the relevant tax loss was incurred) to the end of the income year in which the company seeks to utilize the loss. In performing a SBT analysis, UBI would need to show that the activities undertaken by the business immediately prior to the COT breach is either the same or similar to the business activities undertaken in the loss recoupment year.

Our share ownership may change overtime and we may not be able to satisfy COT and we may venture into other businesses which are not similar to our existing activities hence we may not be able to utilize our losses for offset against future earnings which will negatively impact our cash flows.

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 year ended December 31, 2020, our aggregate turnover was less than A$20,000,000 and we received a tax incentive income of A$2,826,244. Additionally, we will be eligible to make this claim for the year-ended 2021 as our revenues are less than A$20,000,000. We anticipate receiving a refundable tax offset of A$3,897,543 in 2022 following the lodgment of our 2021 Australian company tax return.

Despite these, there can be no assurance that we will qualify and be eligible for such incentives or that the Australian Government will continue to provide incentives, offsets, grants and rebates on similar terms or at all.

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 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.

Risks Related to the Ownership of Our Shares

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

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

- the entry into, or termination of, key agreements, including collaboration and supply agreements and licensing agreements with key strategic partners;
- any inability to obtain additional financing on favorable terms to fund our operations and pursue our business plan if additional financing becomes necessary;
- future sales of our common stock or debt or convertible debt securities or other capital-raising activities, and the terms of those issuances of securities;
- time to market and future revenue streams from product sales, if any, by our collaborative partners, and the extent of demand for, and sales of, our products;

- the initiation of material developments in, or conclusion of disputes or litigation with our customers or partners or to enforce or defend any of our intellectual property rights or otherwise;
- our results of operations and financial condition, including our cash reserves, cash burn and cost level;
- general and industry-specific economic and regulatory conditions that may affect our ability to successfully develop and commercialize products;
- the loss of key employees;
- the introduction of technological innovations or other products by our competitors;
- sales of a substantial number of CDIs by our large stockholders;
- changes in estimates or recommendations by securities analysts, if any, who cover our common stock;
- issuance of shares by us, and sales in the public market of the shares issued, upon exercise of our outstanding warrants; and
- period-to-period fluctuations in our financial results.

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

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

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

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

In addition, our securities are "restricted securities" as that term is defined in Rule 144 under the 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 shares of common stock for resale by security holders.

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 16% of our shares. For details of our substantial stockholders and the interests of our directors, refer to "Part III, Item 12 — Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters".

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 of directors into classes whose terms expire at staggered intervals over a three year period and advance notice requirements for nominations to our board of directors 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.

Other Risks

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.

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 Form 10-K, 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 October 8, 2019 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 October 7, 2019, the liability of PwC Australia may be subject to the limitations set forth in predecessor schemes. The current NSW Accountants Scheme expires on October 7, 2024 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 October 8, 2013, a maximum liability for audit work of A$75 million; or
- in relation to matters occurring on or prior to October 7, 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.

General Risk Factors

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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

The Company 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 was terminated and a new lease entered into simultaneously in January 2021. The lease now expires on December 31, 2025 with an option to renew the lease for two further terms of five 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.

The Company leased approximately 482 square meters of office and laboratory facilities at 15(H) Wing, Second Floor, 711 Concession Street, Hamilton, Ontario which expired on January 31, 2022. On June 28, 2021, HRL entered a premises lease to occupy approximately 418 square meters of office and laboratory facilities at 44 Frid Street, Hamilton, Ontario, Canada. The lease commenced in February 2022, with a ten-year contractual period. HRL relocated to the new premises in February 2022. The lease does not include an option to renew the lease for a further term.

Item 3. Legal Proceedings.

There are no material pending legal proceedings to which the Company or any of its subsidiaries is a party or of which any of their property is the subject. There are no known contemplated material governmental proceedings pending against the Company.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market information

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

Our shares of common stock are traded on the ASX in the form of 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 18, 2022, there were 177,838,504 shares of our common stock issued and outstanding and 8,848,800 employee options that are exercisable for an equivalent number of shares of common stock. 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 shares of common stock for resale by security holders.

Holders

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

Date	Total Number of Registered Holders	Number of Registered Holders that are United States Residents
At February 18, 2022	2,538	8

Dividends

To date, we have not declared or paid any cash dividends on our shares or CDIs.

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 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$)
2021			
January	10,000	0.23	2,300
June	131,650	0.47	62,375
August	5,000	0.23	1,150
August	40,000	0.00	0
November	5,000	0.23	1,150
November	7,500	0.45	3,375
November	7,500	0.33	2,475
December	10,000	0.23	2,300
	216,650		**75,125**
2020			
December	**40,000**	**0.00**	**0**
2019			
February	210,000	0.00	0
April	20,000	0.17	3,400
May	73,334	0.00	0
November	25,000	0.00	0
	328,334		**3,400**

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

Restricted Employee Shares Issued to Employees

Our Employee Share Plan was adopted by the Board of Directors in 2009 which was subsequently amended in 2021 ("the Equity Incentive Plan"). The Equity Incentive 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 Equity Incentive 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.

There were no restricted shares issued by the Company within the past two fiscal years.

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

	Number of shares	Weighted average issue price (A$)
Balance at December 31, 2020	91,652	0.24
Release of restricted shares	(91,652)	0.24
Balance at December 31, 2021	0	0

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 registered under Section 12 of the Exchange Act made in the fourth quarter of the fiscal year covered by this Form 10-K by or on behalf of the Company or any affiliated purchaser (as defined in Rule 10b-18(a)(3) under the Exchange Act).

Item 6. [Reserved].

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 2021 Annual Report under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations" on pages F-2 to F-9.

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 7A.

Item 8. Financial Statements and Supplementary Data.

The information required by this item is incorporated by reference to our 2021 Annual Report under the following captions:

- Report of Independent Registered Public Accounting Firm (PCAOB ID 1379)
- 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
- Notes to Consolidated Financial Statements

The items are included on pages F-10 through F-35 of the 2021 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. As of the end of the period covered by this Form 10-K, the Company and its management evaluated the effectiveness of the design and operation of its disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e)). 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. John Sharman, Principal Executive Officer and Salesh Balak, Principal Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Mr. Sharman and Mr. Balak concluded that, as of the end of the period covered by this Form 10-K, the Company's disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting. During the quarter ended December 31, 2021, there were no changes in the Company's internal control over financial reporting 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 the Company's financial reporting (as defined in Rule 13a-15(f) and 15d – 15(f) under the Exchange Act). Our internal control over the Company's 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, 2021. 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, 2021, our internal control over financial reporting was effective.

/s/ John Sharman
John Sharman
Principal Executive Officer

/s/ Salesh Balak
Salesh Balak
Principal Financial Officer

February 24, 2022

Report of Independent Registered Public Accounting Firm on Internal Control over Financial Reporting.

This Annual Report does not include an attestation report of our Independent Registered Public Accounting Firm regarding internal control over financial reporting. We are an emerging growth company and are a non-accelerated filer under the SEC rules, and are exempt from the requirement to provide an auditor attestation report.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

Part III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 is incorporated by reference to our Definitive Proxy Statement to be filed with the SEC in connection with our Annual Meeting of Stockholders in 2022 (the "2022 Proxy Statement") under the captions "Management of the Company" and, if applicable, "Delinquent Section 16(a) Reports."

Item 11. Executive Compensation.

The information required by this Item 11 is incorporated by reference to the 2022 Proxy Statement under the captions “Management of the Company – Compensation of Directors,” “Executive Compensation” and “Management of the Company – Board Committees – Compensation Committee Interlocks and Insider Participation.”

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 is incorporated by reference to the 2022 Proxy Statement under the captions “Security Ownership of Certain Beneficial Owners and Management,” and “Executive Compensation – Equity Compensation Plan Information.”

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 is incorporated by reference to the 2022 Proxy Statement under the captions “Certain Relationships and Related Transactions,” and “Management of the Company.”

Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated by reference to the 2022 Proxy Statement under the caption “Independent Public Accountants – Audit Fees.”

Part IV

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Financial Statements

The following financial statements are incorporated by reference from pages F-10 through F-35 of our Annual Report to Stockholders for the fiscal year ended December 31, 2021, as provided in Item 8 hereof:

(a)(2) Financial Statement Schedules – Schedule II—Valuation and Qualifying Accounts (F-35). 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.
4.3	Description of Securities	Incorporated by reference to our Annual Report on Form 10-K filed on February 24, 2021 as Exhibit 4.3.
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 principal 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	CEO Option Plan.	Incorporated by reference to our Current Report on Form 8-K filed on September 17, 2021 as Exhibit 10.1.
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.

Exhibit Number	Description	Location
10.7	Manufacturing Initiation Payment Addendum to Master Services and Supply Agreement (which is an addendum to the Amended and Restated Master Services and Supply Agreement filed on August 7, 2009 as Exhibit 10.3 to our Quarterly Report on Form 10-Q).	Incorporated by reference to our Quarterly Report on Form 10-Q filed on August 7, 2009 as Exhibit 10.4. Confidentiality treatment has been granted for portions of this exhibit. These confidential portions have been omitted and were filed separately with the SEC.
10.8	Supply Agreement between Universal Biosensors Pty Ltd and Siemens Healthcare Diagnostics, Inc. dated September 20, 2012.	Incorporated by reference to our Quarterly Report on Form 10-Q/A filed on February 4, 2013 as Exhibit 10.2. Confidentiality treatment has been granted for portions of this exhibit. These confidential portions have been omitted and were filed separately with the SEC.
10.9	Supplemental Agreement – Reader Product Support Obligations and Responsibilities between Universal Biosensors Pty Ltd and Siemens Healthcare Diagnostics, Inc. dated September 20, 2012.	Incorporated by reference to our Quarterly Report on Form 10-Q/A filed on February 4, 2013 as Exhibit 10.3. Confidentiality treatment has been granted for portions of this exhibit. These confidential portions have been omitted and were filed separately with the SEC.
10.10	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.
10.11	Deed of Surrender and Lease between Universal Biosensors Pty Ltd and Bowmayne Pty Ltd	Incorporated by reference to our Current Report on Form 8-K filed on March 18, 2021 as Exhibit 10.1.
10.12	Employment agreement between Universal Biosensors Pty Ltd and Mr. John Sharman effective March 3, 2020.	Incorporated by reference to our Quarterly Report on Form 10-Q/A filed on May 1, 2020 as Exhibit 10.1
10.13	Definitive Agreements between Universal Biosensors Pty Ltd and Siemens Healthcare Diagnostics, Inc. dated September 18, 2019.	Incorporated by reference to our Quarterly Report on Form 10-Q filed on November 4, 2019 as Exhibit 10.23
10.14	Employee Incentive Plan	Incorporated by reference to our Current Report on Form 8-K filed on September 17, 2021 as Exhibit 10.2.
10.15	Employee Share Plan	Incorporated by reference to our Current Report on Form 8-K filed on March 18, 2021 as Exhibit 10.4.
10.16	Award Agreement between Universal Biosensors, Inc. and Mr. Salesh Balak, dated February 28, 2021	Incorporated by reference to our Current Report on Form 8-K filed on March 18, 2021 as Exhibit 10.2.
10.17	Award Agreement between Universal Biosensors, Inc. and Mr. John Sharman, dated February 28, 2021	Incorporated by reference to our Current Report on Form 8-K filed on March 18, 2021 as Exhibit 10.3.
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.
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.	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.

Exhibit Number	Description	Location
101	The following materials from the Universal Biosensors, Inc. Annual Report on Form 10-K for the financial year ended December 31, 2021 formatted in Inline Extensible Business Reporting Language (iXBRL): (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.
104	Cover Page Interactive Data File (embedded within the Inline XBRL and contained in Exhibit 101)	

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 Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 24, 2022

Universal Biosensors, Inc.
(Registrant)

By: /s/ John Sharman
John Sharman
Principal Executive Officer

Power of Attorney

Each person whose signature appears below hereby constitutes and appoints John Sharman 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 SEC, 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/ John Sharman John Sharman	Chief Executive Officer (Principal Executive Officer)	February 24, 2022
/s/ Salesh Balak Salesh Balak	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 24, 2022
/s/ Craig Coleman Craig Coleman	Non-Executive Chairman and Director	February 24, 2022
/s/ Judith Smith Judith Smith	Director	February 24, 2022
/s/ David Hoey David Hoey	Director	February 24, 2022

Exhibit 13.0

Universal Biosensors, Inc.

2021 Annual Report

Contents

Unless otherwise noted, references in 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"), its wholly owned US operating subsidiary, Universal Biosensors LLC ("UBS LLC") and UBS' wholly owned Canadian operating subsidiary, Hemostasis Reference Laboratory Inc. ("HRL") and wholly owned Dutch operating subsidiary, Universal Biosensors B.V. ("UBS BV"). 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$", "CAD$" and "€" are references to United States dollars, Canadian dollars and Euros respectively.

Universal Biosensors, Inc.

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

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 biosensors company focused on commercializing a range of biosensors in oenology (wine industry), human health including oncology, coagulation, COVID-19, women's health and fertility, non-human and environmental testing using our patented platform technology and hand-held point of use devices.

Key achievements during the year include:

- Revenue increased 80% (year on year);
- Receipts from customers increased 412%;
- Entering into a technology licensing deal that extends UBI's platform technology measuring range by 1 million times (+) on our hand-held platform device;
- Entering into a technology licensing deal for a cancer biomarker, Tn Antigen;
- Entering into a technology licensing deal using aptamer sensing for an Instant COVID-19 Test;
- The successful development and use of aptamer sensing technology on our hand-held platform device;
- The global launch and sale of Sentia's wine testing platform;
- The global launch of Sentia's Free Sulphur Dioxide product;
- The hiring of a Sentia direct sales force in the USA;
- Entering into 14 separate distribution agreements for the sale of Sentia's wine testing platform device in Australia, France, USA, Italy, Germany, Spain, Portugal, Switzerland, New Zealand, South Africa, Canada, Mexico, Chile, Austria and Greece;
- The completion of Sentia's new Malic Acid wine testing product;
- The further development of additional Sentia wine testing products including Total Sugars, Acetic Acid and Total Acid tests;
- The finalization of the development of UBI's next generation PT-INR Coagulation platform (Xprecia Prime);
- The commencement of clinical studies and the recruitment of "first patient" across 4 sites in the USA for Xprecia Prime;
- The submission to European regulatory authorities to have Xprecia Prime approved for sale in Europe;
- The entering into 16 new distribution agreements for the sale of Xprecia products around the world;
- Entering into various agreements for the development of our cancer Tn Antigen cancer biomarker with Peter MacCallum Cancer Centre, the Victorian Cancer Biobank and the internationally recognized Centre for Cooperative Research in Bioscience, CIC bioGUNE – BRTA (together with its clinical partner Basurto University Hospital, Spain);
- The commencement of an Investigational Clinical Study (300 patient/+) for our Tn Antigen biosensor used for the detection, staging and monitoring of cancer;
- The continued development of our diabetes detection and monitoring biosensor product in animals;
- 245% sales growth and record sales from our HRL laboratory business in Canada;
- Strong sales growth for Xprecia Stride products; and
- The establishment of operating subsidiary companies in the USA and Europe to support the global expansion of the Company's coagulation and wine testing product sales.

Results of Operations

Analysis of Consolidated Revenue

Our total revenue increased by 80% during the year ended December 31, 2021.

Revenue from our existing operations including coagulation and blood products grew by 47%.

Revenue from our new product Sentia was $1.15 million.

Receipts from customers was up 412%.

Revenue from Products

The financial results of the coagulation testing products and wine testing products we sold during the respective periods are as follows:

	Years Ended December 31,	
	2021	2020
	A$	A$
Revenue from products	3,815,397	2,565,747
Cost of goods sold	(2,367,084)	(1,715,538)
Gross profit	1,448,313	850,209
Gross profit margin	38%	33%

The Company benefited from a new revenue stream in 2021 following the successful global launch of our Sentia Free Sulphur Dioxide wine testing product and growth in the sales of coagulation products.

Revenue from Services

The financial results of the coagulation testing and other services we provided during the respective periods are as follows:

	Years Ended December 31,	
	2021	2020
	A$	A$
Coagulation testing services	1,962,354	568,528
Other services	0	68,334
	1,962,354	636,862
Cost of services	(1,304,973)	(863,985)
Gross profit/(loss)	657,381	(227,123)
Gross profit/(loss) margin	33%	(36%)

Revenue from coagulation testing increased by 245% during the year ended December 31, 2021 because of new contracts won and an expanded customer base.

Adjusted EBITDA

Adjusted EBITDA is net loss before interest, taxes, depreciation, amortization, accretion of asset retirement obligations and stock-based compensation expense. Adjusted EBITDA is a non-GAAP measurement. Management uses adjusted 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, U.S. GAAP. The most comparable GAAP measure is net loss. Consolidated adjusted EBITDA should not be considered in isolation or as a substitution for analysis of our results as reported under GAAP.

Adjusted EBITDA for the respective periods and a reconciliation of net loss to adjusted EBITDA is as follows:

	Years Ended December 31,	
	2021	2020
	A$	A$
Net loss	(10,506,935)	(7,638,024)
Interest income	(49,947)	(293,816)
Depreciation and amortization	2,566,719	2,430,941
Accretion expense	121,910	154,800
Stock-based compensation expense	92,432	173,232
Adjusted EBITDA	(7,775,821)	(5,172,867)

The decline in adjusted EBITDA during the year ended December 31, 2021, compared to the same period in the previous financial year is primarily a result of increased R&D expenditure that has resulted in an increase in the net loss between the respective periods.

Product Support

Product support relates to post-market technical support provided by us for the Xprecia Stride and Sentia test devices. Product support for the respective periods are as follows:

	Years Ended December 31,	
	2021	2020
	A$	A$
Product support	80.,007	25,212

Depreciation and Amortization Expenses

	Years Ended December 31,	
	2021	2020
	A$	A$
Depreciation:		
Charged to cost of goods sold and services	389,968	204,001
Charged to other operating costs and expenses	540,448	586,154
	930,416	790,155
Amortization:		
Charged to other operating costs and expenses	1,636,303	1,640,786
Total depreciation and amortization	2,566,719	2,430,941

Depreciation of fixed assets is calculated on a straight-line basis over the useful life of property, plant and equipment. Depreciation is allocated to cost of goods sold and R&D based on output. The increase in depreciation charged to cost of goods sold and services during the year ended December 31, 2021, compared to the same period in the previous financial year is due to depreciation charges allocated to the Sentia product launched in the 2021 financial year. Depreciation has increased overall as a result of the Company's investment in property, plant and equipment during the 2021 financial year, primarily being used for R&D and commercial production.

Amortization expense represents intangible assets amortized over their estimated useful lives. These intangible assets were acquired in September 2019 pursuant to the Siemens Acquisition and are being amortized on a straight-line basis over ten years.

Research and Development Expenses

R&D expenditure principally reflects the effort required in product development of the tests we are developing.

The primary focus of the R&D activities during 2021 were developing the Company's:

- additional tests on our wine testing platform (Malic Acid, Glucose and Fructose, Acetic Acid and Total Acid);
- next generation PT-INR Coagulation platform including FDA Clinical Trial programs;
- Tn Antigen biosensor used for the detection, staging and monitoring of cancer;
- biosensor strip and meter to be used for the detection and monitoring of diabetes in non-humans; and
- Aptamer based sensing platform including a COVID-19 test.

R&D expenditure increased by 84% during the year ended December 31, 2021, compared to the same period in the previous financial year because of the increased development activities noted above.

The timing and cost of any development program is dependent upon a number of factors including achieving technical objectives, which are inherently uncertain and subsequent regulatory approvals. We have project plans in place for all our development programs which we use to plan, manage and assess our projects. As part of this procedure, we also undertake commercial assessments of such projects to optimize outcomes and decision making.

Additionally, R&D expenses are related to the development of new technologies and products based on the electrochemical cell platform.

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

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

- consultant and employee related expenses, which include consulting fees, salaries and benefits;
- materials and consumables acquired for the research and development activities;
- verification and validation work on the various R&D projects including clinical trials;
- 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.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist principally of salaries and related costs, including stock-based compensation expense for certain personnel. Other selling, general and administrative expenses include sales and marketing costs to support our products in the market, shipping and handling costs incurred when fulfilling customer orders, repairs and maintenance, insurance, facility costs not otherwise included in R&D expenses, consultancy fees and professional fees including legal services and maintenance fees incurred for patent applications, audit and accounting services.

General and administrative expenses decreased by 5% during the year ended December 31, 2021, compared to the same period in the previous financial year primarily due to overall cost management.

Interest Income

Interest income decreased by 83% during the year ended December 31, 2021, compared to the same period in the previous financial year. The decrease in interest income is attributable to the lower amount of funds available for investment and lower interest rates.

Financing Costs

Disclosed in this account is accretion expense which is associated with the Company's asset retirement obligations ("ARO").

Research and Development Tax Incentive Income

As at December 31, 2021 the aggregate turnover of the Company for the year ending December 31, 2021 was less than A$20,000,000 and accordingly an estimated A$3,875,908 has been recorded as research and development tax incentive income for the year then ended. The increase year on year is driven by the increase in eligible research and development expenditure incurred in 2021 as compared to the same period in 2020.

Research and development tax incentive income for the 2021 financial year has not yet been received and as such is recorded in "Other current assets" in the consolidated balance sheet.

Exchange Gain/(Loss)

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

Other Income

Other income is as follows for the relevant periods:

	Years Ended December 31,	
	2021	2020
	A$	A$
Insurance recovery	2,262	674,083
Federal and state government subsidies	153,001	1,265,149
Rental income	163,397	180,631
Other income	112,052	2,988
	430,712	2,122,851

Insurance recovery for the year ended December 31, 2020 includes A$600,000 of partial reimbursement of our legal costs which was incurred during mediation with Siemens.

Federal and state government subsidies which primarily include Australian JobKeeper payments and Canada Emergency Wage Subsidy, represent assistance provided by government authorities as a stimulus during COVID-19. The Company was ineligible to receive Australian JobKeeper payments in relation to the 2021 financial year and became ineligible to receive Canadian Emergency Wage Subsidy payments in H1 2021.

Certain Uncertainties

Depending on the duration of the COVID-19 crisis and continued negative impacts on economic activity, the Company may experience negative impacts in 2022 which cannot be predicted.

Critical Accounting Estimates and Judgments

The preparation of financial statements and related disclosures in conformity with U.S. generally accepted accounting principles and the Company's discussion and analysis of its financial condition and operating results require the Company's management to make judgments, assumptions and estimates that affect the amounts reported. Significant items subject to such estimates and assumptions include deferred income taxes, research and development tax incentive income and stock-based compensation expenses:

Deferred Income Taxes

We compute our deferred income taxes based on the statutory tax rates, future forecasts and tax planning opportunities. Judgement is required in determining our future forecasts and evaluating our tax positions.

Our estimates are made based on the best available information at the time we prepare our consolidated financial statements. In making our estimates, we consider the impact of legislative and judicial developments. As these developments evolve, we update our estimates, which, in turn, may result in adjustments to our effective tax rate.

We anticipate realization of a significant portion of our deferred tax assets through the reversal of existing deferred tax liabilities. Although realization is not assured, management believes it is more likely than not that our deferred tax assets, net of valuation allowances, will be realized.

Uncertain tax positions taken or expected to be taken in a tax return are recognized (or derecognized) in the financial statements when it is more likely than not that the position would be sustained on its technical merits upon examination by tax authorities, taking into account available administrative remedies and litigation. Assessment of uncertain tax positions requires significant judgments relating to the amounts, timing and likelihood of resolution.

Stock-based Compensation Expenses

Probability of attaining vesting conditions and the fair value of the stock-based compensation is highly subjective and requires judgement, and results could change materially if different estimates and assumptions were used. The probability assumptions are critically examined by management each reporting period and reviewed by the board of directors for reasonableness. See note 14 to the Consolidated Financial Statements for additional information including the unrecognized compensation expense as at December 31, 2021.

Research and Development 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 its eligible research and development activities and expenditures. The calculation of the refundable tax offset requires judgement as to what is eligible research and development activity and expenditure and the outcome will change if different assumptions were used.

Note 1, "Summary of Significant Accounting Policies," of the Notes to Consolidated Financial Statements in Part II, Item 8 of this Form 10-K describes in further detail the significant accounting policies and methods used in the preparation of the Company's consolidated financial statements. Management bases its estimates on historical experience and on various other assumptions it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recognition of revenue and expenses. Actual results may differ from these estimates.

Financial Condition, Liquidity and Capital Resources

Net Financial Assets

Our net financial assets position is shown below:

	December 31,	
	2021	2020
	A$	A$
Financial assets		
Cash and cash equivalents	15,318,201	23,561,807
Accounts receivable	476,164	73,073
Total financial assets	15,794,365	23,634,880
Debt		
Short and long-term debt/ loan	64,900	40,741
Net financial assets	15,729,465	23,594,139

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

The decline in our net financial assets position is primarily a result of ongoing investment in our R&D activities and the general operations of the Company.

We believe we have sufficient cash and cash equivalents to fund our operations for at least the next twelve months from the date of issuance. Liquidity risk is the risk that the Company may encounter difficulty meeting obligations associated with financial liabilities. The Company manages liquidity risk through the management of its capital structure. The purpose of liquidity management is to ensure that there is sufficient cash to meet all the financial commitments and obligations of the Company as they come due. In managing the Company's capital, management estimates future cash requirements by preparing a budget and a multi-year plan for review and approval by the Board of Directors ("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.

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

We regularly review all our financial assets for impairment. There were no impairments recognized as at December 31, 2021 or for the year ended December 31, 2020.

The Company is continuing to monitor the potential impact of COVID-19, if any, on the Company's business and financial position.

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, 2021 and 2020, we did not have any assets or liabilities that utilize Level 3 inputs.

We had no derivatives or outstanding contracts in place through the years ended December 31, 2021 and December 31, 2020.

Measures of Liquidity and Capital Resources

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

	December 31,	
	2021	2020
	A$	A$
Cash and cash equivalents	15,318,201	23,561,807
Working capital	15,448,181	22,433,054
Ratio of current assets to current liabilities	2.64	3.50
Shareholders' equity per common share	0.16	0.21

The movement in cash and cash equivalents and working capital (calculated as current assets less current liabilities) during the above periods was primarily the result of ongoing investment in our R&D activities and the general operations of the Company.

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

Summary of Cash Flows

	Years Ended December 31,	
	2021	2020
	A$	A$
Cash provided by/(used in):		
Operating activities	(9,896,620)	(8,291,139)
Investing activities	(664,584)	(372,204)
Financing activities	95,621	43,644
Net decrease in cash, cash equivalents and restricted cash	(10,465,583)	(8,619,699)

Our net cash used in operating activities for all periods represents receipts offset by payments for our R&D projects including efforts involved in establishing and maintaining our manufacturing operations and selling, general and administrative expenditure. Cash outflows from operating activities primarily represent the ongoing investment in our R&D activities and the general operations of the Company.

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

Our net cash increase in financing activities for the year ended December 31, 2021 represents CAD$20,000 received in the form of a long-term unsecured government guaranteed loan which was introduced in the Canadian Federal Government's COVID-19 Economic Response Plan and funds received in relation to the exercise of stock options issued to employees.

In January 2022 the Company entered into a short-term loan facility to finance its 2022 Insurance Premium. The total amount available and drawn down under the facility is $1,002,404. The facility is repayable in nine monthly instalments which commenced in January 2022 and has an effective annual interest rate of 1.49%. The short-term borrowing is secured by the insurance premium refund.

Off-Balance Sheet Arrangement

As of December 31, 2021 and December 31, 2020, we did not have any off-balance sheet arrangements, as such term is defined under Item 303 of Regulation S-K, that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Segments

We operate in one segment. We are a specialist biosensors company focused on the development, manufacture and commercialization of a range of point of use devices for measuring different analytes across different industries.

We operate predominantly in one geographical area, being Australia.

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

Recent Accounting Pronouncements

See Note 1, Summary of Significant Accounting Policies – Recent Accounting Pronouncements.

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 where we deem appropriate. These practices may change as economic conditions change.

Foreign Currency Market Risk

We transact business in various foreign currencies, including US$, CAD$ and Euros. The Company is currently using natural hedging to limit currency exposure, however has an established foreign currency hedging program available where forward contracts are used to hedge the net projected exposure for each currency and the anticipated sales and purchases in U.S. dollars where required. The goal of this hedging program is to economically guarantee or lock-in the exchange rates on our foreign exchange exposures. No forward contracts were entered by the Company for the years ended December 31, 2021 and 2020. 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 has recorded foreign currency transaction gains/(losses) of A$274,857 and (A$167,952) for the years ended December 31, 2021 and 2020, respectively.

Interest Rate Risk

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

Inflation

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

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying Consolidated Balance Sheets of Universal Biosensors, Inc. and its subsidiaries (the “Company”) as of December 31, 2021 and 2020, and the related Consolidated Statements of Comprehensive Income/(Loss), Consolidated Statements of Changes in Stockholders’ Equity and Comprehensive Income/(Loss), and the Consolidated Statements of Cash Flows for the years then ended, including the related notes and schedule of valuation and qualifying accounts for the years then ended 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, 2021 and 2020, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ PricewaterhouseCoopers

Newcastle, Australia

February 24, 2022

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

Universal Biosensors, Inc.

Consolidated Balance Sheets

	December 31, 2021 A$	December 31, 2020 A$
ASSETS		
Current assets:		
Cash and cash equivalents	15,318,201	23,561,807
Inventories	2,143,504	1,879,853
Accounts receivable	476,164	73,073
Prepayments	399,290	107,511
Restricted cash	1,968,814	2,174,806
Other current assets	4,544,273	3,598,596
Total current assets	24,850,246	31,395,646
Non-current assets:		
Property, plant and equipment	29,622,945	29,339,380
Less accumulated depreciation	(25,523,265)	(24,984,001)
Property, plant and equipment - net	4,099,680	4,355,379
Intangible assets	16,371,996	16,371,996
Less amortization of intangible assets	(3,720,908)	(2,084,605)
Intangible assets - net	12,651,088	14,287,391
Right-of-use asset	2,050,336	4,024,962
Restricted cash	812,204	2,318,507
Other non-current assets	38,421	0
Total non-current assets	19,651,729	24,986,239
Total assets	44,501,975	56,381,885
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	436,763	447,523
Accrued expenses	2,800,815	1,152,008
Contingent consideration	2,067,255	1,947,546
Other liabilities	2,823,322	2,659,534
Contract liabilities	38,431	1,628,426
Lease liability	500,284	524,844
Employee entitlements liabilities	670,295	602,711
Short-term loan - unsecured	64,900	0
Total current liabilities	9,402,065	8,962,592
Non-current liabilities:		
Asset retirement obligations	2,721,260	2,734,800
Long-term loan - unsecured	0	40,741
Employee entitlements liabilities	29,268	20,960
Deferred income tax liability	3,050,837	3,050,837
Lease liability	1,690,716	3,594,531
Total non-current liabilities	7,492,081	9,441,869
Total liabilities	16,894,146	18,404,461
Commitments and contingencies	0	0
Stockholders' equity:		
Preferred stock, US$0.01 par value. Authorized 1,000,000 shares; issued and outstanding nil at December 31, 2021 (nil at December 31, 2020)		
Common stock, US$0.0001 par value. Authorized 300,000,000 shares; issued and outstanding 177,828,504 shares at December 31, 2021 (177,611,854 at December 31, 2020)	17,783	17,761
Additional paid-in capital	93,737,565	93,570,030
Accumulated deficit	(55,317,296)	(47,679,272)
Current year loss	(10,506,935)	(7,638,024)
Accumulated other comprehensive loss	(323,288)	(293,071)
Total stockholders' equity	27,607,829	37,977,424
Total liabilities and stockholders' equity	44,501,975	56,381,885

See accompanying Notes to the Consolidated Financial Statements.

Universal Biosensors, Inc.

Consolidated Statements of Comprehensive Income/(Loss)

	Years Ended December 31,	
	2021	2020
	A$	A$
Revenue		
Revenue from products	3,815,397	2,565,747
Revenue from services	1,962,354	636,862
Total revenue	5,777,751	3,202,609
Operating costs and expenses		
Cost of goods sold	2,367,084	1,715,538
Cost of services	1,304,973	863,985
Total cost of goods sold and services	3,672,057	2,579,523
Gross profit	2,105,694	623,086
Other operating costs and expenses		
Product support	80,007	25,212
Depreciation and amortization	2,176,751	2,226,940
Research and development	9,281,928	5,044,613
Selling, general and administrative	5,605,092	5,884,504
Total operating costs and expenses	17,143,778	13,181,269
Loss from operations	(15,038,084)	(12,558,183)
Other income/(expense)		
Interest income	49,947	293,816
Financing costs	(121,910)	(154,800)
Research and development tax incentive income	3,897,543	2,826,244
Exchange gain/(loss)	274,857	(167,952)
Other income	430,712	2,122,851
Total other income	4,531,149	4,920,159
Net loss before tax	(10,506,935)	(7,638,024)
Income tax benefit/(expense)	0	0
Net loss	(10,506,935)	(7,638,024)
Loss per share		
Net loss per share - basic and diluted	(0.06)	(0.04)
Average weighted number of shares - basic and diluted	177,714,201	177,574,046
Other comprehensive gain/(loss), net of tax:		
Foreign currency translation reserve	(30,217)	48,671
Other comprehensive income/(loss)	(30,217)	48,671
Comprehensive loss	(10,537,152)	(7,589,353)

See accompanying Notes to the Consolidated Financial Statements.

Universal Biosensors, Inc.

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

	Ordinary shares		Additional Paid-in Capital	Accumulated Deficit	Other comprehensive Income/(Loss)	Total Stockholders' Equity
	Shares	Amount				
		A$	A$	A$	A$	A$
Balances at January 1, 2020	177,571,854	17,757	93,396,802	(47,679,272)	(341,742)	45,393,545
Net loss	0	0	0	(7,638,024)	0	(7,638,024)
Other comprehensive gain	0	0	0	0	48,671	48,671
Exercise of stock options issued to employees	40,000	4	(4)	0	0	0
Stock-based compensation expense	0	0	173,232	0	0	173,232
Balances at December 31, 2020	177,611,854	17,761	93,570,030	(55,317,296)	(293,071)	37,977,424
Net loss	0	0	0	(10,506,935)	0	(10,506,935)
Other comprehensive loss	0	0	0	0	(30,217)	(30,217)
Exercise of stock options issued to employees	216,650	22	75,103	0	0	75,125
Stock-based compensation expense	0	0	92,432	0	0	92,432
Balances at December 31, 2021	177,828,504	17,783	93,737,565	(65,824,231)	(323,288)	27,607,829

See accompanying Notes to the Consolidated Financial Statements.

Universal Biosensors, Inc.

Consolidated Statements of Cash Flows

	Years ended December 31,	
	2021	2020
	A$	A$
Cash flows from operating activities:		
Net loss	(10,506,935)	(7,638,024)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,566,719	2,430,941
Stock-based compensation expense	92,432	173,232
Loss/(gain) on fixed assets disposal	1,765	(45)
Unrealized foreign exchange (gains)/losses	(592,230)	370,322
Change in assets and liabilities:		
Inventories	(263,651)	(801,790)
Accounts receivable	(408,827)	43,553
Prepayments and other assets	(1,129,077)	(127,703)
Other non-current assets	(87,659)	0
Contract liabilities	(1,395,483)	(2,475,658)
Employee entitlements	75,892	(191,186)
Accounts payable and accrued expenses	1,750,434	(74,781)
Net cash used in operating activities	(9,896,620)	(8,291,139)
Cash flows from investing activities:		
Proceeds from sale of property, plant and equipment	0	45
Purchases of property, plant and equipment	(664,584)	(387,046)
Proceeds from government grants and insurance recovery	0	14,797
Net cash used in investing activities	(664,584)	(372,204)
Cash flows from financing activities:		
Proceeds from borrowings	20,496	43,644
Proceeds from exercise of stock options issued to employees	75,125	0
Net cash provided by financing activities	95,621	43,644
Net decrease in cash, cash equivalents and restricted cash	(10,465,583)	(8,619,699)
Cash, cash equivalents and restricted cash at beginning of period	28,055,120	37,192,907
Effect of exchange rate fluctuations on the balances of cash held in foreign currencies	509,682	(518,088)
Cash, cash equivalents and restricted cash at end of period	18,099,219	28,055,120

See accompanying Notes to the Consolidated Financial Statements.

Universal Biosensors, Inc.

Notes to Consolidated Financial Statements

1. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP" or "GAAP").

Unless otherwise noted, references in 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") , its wholly owned US operating subsidiary, Universal Biosensors LLC ("UBS LLC") and UBS' wholly owned Canadian operating subsidiary, Hemostasis Reference Laboratory Inc. ("HRL") and wholly owned Dutch operating subsidiary, Universal Biosensors B.V. ("UBS BV"). 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$", "CAD$" and "€" are references to United States dollars, Canadian dollars and Euros respectively.

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

Unless otherwise stated, the accounting policies adopted are consistent with those of the previous year.

Principles of Consolidation

The consolidated financial statements include the financial statements of the Company and its wholly owned subsidiaries, UBS, UBS LLC, HRL and UBS BV. 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 deferred income taxes, research and development tax incentive income and stock-based compensation expenses. Actual results could differ from those estimates.

Recent Accounting Pronouncements

The Company assesses the adoption impacts of recently issued accounting standards by the Financial Accounting Standards Board on the Company's financial statements as well as material updates to previous assessments, if any, from the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021. There were no new material accounting standards issued in 2021 that impacted the Company.

Net Loss per Share and Anti-dilutive Securities

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

Foreign Currency

Functional and Reporting Currency

Items included in the financial statements of each of the Company'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 Australian dollars ("AUD" or "A$") for all years presented. The functional currencies of UBS LLC, HRL and UBS BV are United States dollars ("US$"), Canadian dollars ("CAD$") and Euros ("€"), respectively, for all years presented.

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

Transactions and Balances

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

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/(Loss).

Fair Value of Financial Instruments

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

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

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

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

Concentration of Credit Risk and Other Risks and Uncertainties

Cash, cash equivalents and restricted cash 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, cash equivalents and restricted cash 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, cash equivalents and restricted cash to the extent of the amount recorded on the consolidated balance sheets. The Company has not experienced any losses on its deposits of cash, cash equivalents and restricted cash. The Company has not identified any collectability issues with respect to receivables.

Cash, Cash Equivalents and Restricted Cash

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

The Company maintains cash and restricted cash, which includes performance guarantee issued in favor of a customer, tenant security deposits and credit card security deposits.

Inventory

Inventories are stated at the lower of cost or net realizable value. Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and estimated costs necessary to dispose. Inventories are principally determined under the average cost method which approximates cost. Cost comprises direct materials, direct labour and an appropriate portion of variable and fixed overhead expenditure, the latter being allocated on the basis of normal operating capacity. Costs of purchased inventory are determined after deducting rebates and discounts. The Company recognizes inventory on the consolidated balance sheet when they have concluded that the substantial risks and rewards of ownership, as well as the control of the asset, have been transferred.

Receivables

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The allowance for credit losses 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 credit losses, if any, is recorded within selling, general and administrative expenses in the consolidated statements of comprehensive income/(loss). Account balances are charged against the allowance when it is probable the receivable will not be recovered.

Prepayments

Prepaid expenses represent expenditures that have not yet been recorded by the Company as an expense, but have been paid for in advance. The Company's prepayments are primarily represented by insurance premiums paid annually in advance and fees partially paid in advance in relation to the development activities being carried out for the biosensor test used for the detection and monitoring of diabetes in non-humans.

Other Current Assets

The Company's other current assets is primarily represented by the estimated receivable in relation to the research and development tax incentive income.

Property, Plant and Equipment

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

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

Impairment of Long-Lived Assets

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

Intangible Assets

The intangible assets, having finite useful lives, are amortized over their estimated useful lives. Finite life intangible assets are amortized over the shorter of their contractual or useful economic lives. The intangible assets comprise of distribution rights and are amortized on a straight-line basis over ten years.

Impairment of Intangible Assets

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

Australian Goods and Services Tax ("GST"), Canadian Harmonized Sales Tax ("HST"), US Sales Tax and European Value Added Tax ("VAT"), collectively "Sales Tax"

Revenues, expenses and assets are recognized net of the amount of associated Sales Tax, unless the Sales Tax 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 Sales Tax receivable or payable. The net amount of Sales Tax recoverable from, or payable to, the taxation authority is included with other current assets or accrued expenses in the consolidated balance sheets dependent on whether the balance owed to the taxation authorities is in a net receivable or payable position.

Leases

On January 1, 2020, the Company adopted the requirements of Accounting Standards Update ("ASU") No. 2016-02, "Leases (Topic 842)" ("ASU No. 2016-02"), using the modified retrospective method and used the effective date as the date of initial application. As a result of this adoption, the following accounting policies were implemented or changed.

At contract inception, the Company determines if the new contractual arrangement is a lease or contains a leasing arrangement. If a contract contains a lease, the Company evaluates whether it should be classified as an operating or a finance lease. Currently, all of the Company's leases have been classified as operating leases. Upon modification of the contract, the Company will reassess to determine if a contract is or contains a leasing arrangement.

The Company records lease liabilities based on the future estimated cash payments discounted over the lease term, defined as the non-cancellable time period of the lease, together with all the following:

- periods covered by an option to extend the lease if the Company is reasonably certain to exercise the extension option; and
- periods covered by an option to terminate the lease if the Company is reasonably certain not to exercise the termination option.

Leases may also include options to terminate the arrangement or options to purchase the underlying lease property. The Company does not separate lease and non-lease components of contracts. Lease components provide the Company with the right to use an identified asset, which consist of the Company's real estate properties and office equipment. Non-lease components consist primarily of maintenance services.

As an implicit discount rate is not readily determinable in the Company's lease agreements, the Company uses its estimated secured incremental borrowing rate based on the information available at the lease commencement date in determining the present value of future lease payments. For certain leases with original terms of 12 months or less, the Company recognizes lease expense as incurred and does not recognize any lease liabilities. Short-term and long-term portions of operating lease liabilities are classified as lease liabilities in the Company's consolidated balance sheets.

A right-of-use ("ROU") asset is measured as the amount of the lease liability with adjustments, if applicable, for lease incentives, initial direct costs incurred by the Company and lease prepayments made prior to or at lease commencement. ROU assets are classified as operating lease right-of-use assets, net of accumulated amortization, on the Company's consolidated balance sheets. The Company evaluates the carrying value of ROU assets if there are indicators of potential impairment and performs the analysis concurrent with the review of the recoverability of the related asset group. If the carrying value of the asset group is determined to not be fully recoverable and is in excess of its estimated fair value, the Company will record an impairment loss in its consolidated statements of income and comprehensive income/(loss).

Lease payments may be fixed or variable, however, only fixed payments or in-substance fixed payments are included in the Company's lease liability calculation. Variable lease payments are recognized in operating expenses in the period in which the obligation for those payments are incurred.

As part of the adoption of ASU No. 2016-02, the Company elected the following practical expedients:

1) lease vs. non-lease components relating to the real estate asset class;
2) the short-term lease exemption; and
3) the package of practical expedients, which permits the Company to not reassess prior conclusions about lease identification, lease classification and initial direct costs under the new standard. In addition, the Company elected not to adopt the practical expedient related to hindsight.

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.

Revenue Recognition

The Group recognizes revenue predominantly from the sale of coagulation and wine testing devices and the provision of coagulation testing services based on the provisions of ASC 606 Revenue from Contracts with Customers. In accordance with this provision, to determine whether to recognize revenue, the Group follows a five-step process:

a) Identifying the contract with a customer;
b) Identifying the performance obligations within the customer contract;
c) Determining the transaction price;
d) Allocating the transaction price to the performance obligation; and
e) Recognizing revenue when/as performance obligations are satisfied.

Nature of goods and services

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

Products and services	*Nature, timing of satisfaction of performance obligations and significant payment terms*
Coagulation testing products	Our point-of-care coagulation testing products use electrochemical cell to measure Prothrombin Time (PT/INR), a test used to monitor the effect of the anticoagulant therapy warfarin. The performance obligation for the sale of these products is satisfied at a point-in-time when the Company transfers control of the products to its customer. The point of transfer of control of the products is dictated by individual terms contained within a customer agreement, as are the payment terms. The transaction price is fixed.
Coagulation testing services	HRL provides non-diagnostic laboratory services and performs coagulation testing services on behalf of customers. The performance obligation for the services is satisfied when the testing has been finalized and results have been reported to the customer. In some cases, the performance obligations will be satisfied as predetermined milestones have been achieved by the Company. Standard payment terms are generally 30-60 days upon invoice date. The transaction price is fixed.
Wine testing products	Our Sentia wine analyzer is used to measure free SO_2 levels in post-fermentation wine. The performance obligation for the sale of this product is satisfied at a point-in-time when the Company transfers control of the products to its customer. The point of transfer of control of the products is dictated by the individual terms contained within a customer agreement, as are the individual payment terms. The transaction price is fixed.

See Note 12 to the Consolidated Financial Statements for a disaggregation of revenue.

Interest Income

Interest income is recognized as it accrues, taking into account the effective yield and consists primarily of interest earned on cash, cash equivalents and restricted cash in interest-bearing accounts.

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. Subject to meeting a number of conditions, an entity which is an R&D entity involved in eligible R&D activities may claim research and development tax incentive income as follows:

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

(2) as a 38.5% non-refundable tax offset if aggregate turnover of the entity is more than A$20,000,000.

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

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

The Company has recorded research and development tax incentive income of A$3,897,543 and A$2,826,244 for the 2021 and 2020 financial year, respectively as the aggregated turnover of the Company did not exceed A$20,000,000.

Federal and State Government Subsidies

In response to the COVID-19 pandemic, governments in the countries in which we operate implemented government assistance measures to assist in mitigating some of the impact of the pandemic on our results and liquidity. To the extent appropriate, we applied for such government grants in Australia and Canada and recognize the grants at their fair value as other income when there is reasonable assurance that we have complied with all conditions attached to them.

Research and Development Expenditure

R&D expenses consist of costs incurred to further the Company'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. R&D costs are expensed as incurred as they fall in the scope of ASC 730 'Research and Development'.

Clinical Trial Expenses

Clinical trial costs are a component of R&D 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.

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 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

For periods ending on or before June 30, 2021, the Company contributed 9.50% of each employee's salary to standard defined contribution superannuation funds on behalf of all eligible UBS employees. For period commencing July 1, 2021, in line with legislative updates, the rate increased to 10%. Superannuation is an Australian compulsory savings program plan for retirement 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/(loss) as the expense is incurred.

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 RRSP. The Company contributes 1% to 2% of the employee's base earnings towards the DPSP. The DPSP contributions are vested immediately.

Benefit Plan

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

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 U.S. tax reform rules, UBI is subject to regulations addressing Global Intangible Low-Taxed Income ("GILTI"). 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 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 Australia, Canada, the Netherlands and the United States. Tax returns up to and including the 2020 financial years have been filed in Australia, Canada and the United States for UBI (Australian consolidated group), HRL and UBI (US parent entity). Tax returns for the 2021 financial year will be filed for UBI, HRL, UBS, UBS LLC and UBS BV in 2022.

2. Cash, cash equivalents and 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.

	December 31,	
	2021	2020
	A$	A$
Cash and cash equivalents	15,318,201	23,561,807
Restricted cash – current assets	1,968,814	2,174,806
Restricted cash – non-current assets	812,204	2,318,507
	18,099,219	28,055,120

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

	December 31,	
	2021	2020
	A$	A$
Performance guarantee (a) - current assets	1,968,814	2,174,806
Collateral for facilities (b) - non-current assets	320,000	320,000
Performance guarantee (a) - non-current assets	492,204	1,998,507
	2,781,018	4,493,313

(a) Performance guarantee represents letter of credit issued in favour of Siemens pursuant to the 2019 Siemens Agreements. The performance guarantee was initially issued for US$5,000,000 and the same reduces in equal quarterly amounts over the 42 months with effect from September 18, 2019.
(b) Collateral for facilities represents bank guarantee of A$250,000 for commercial lease of UBS' premises and security deposit on Company's credit cards of A$70,000.

Interest earned on the restricted cash for years ended December 31, 2021 and 2020 was A$8,668 and A$44,830 respectively.

3. Inventories

	December 31,	
	2021	2020
	A$	A$
Raw materials	1,207,077	761,279
Work in progress	410,731	640,885
Finished goods	525,696	477,689
	2,143,504	1,879,853

4. Receivables

	December 31,	
	2021	2020
	A$	A$
Receivables	476,164	73,073
Allowance for credit losses	0	0
	476,164	73,073

5. Property, Plant and Equipment

	December 31,	
	2021	2020
	A$	A$
Plant and equipment	20,183,757	20,171,121
Leasehold improvements	9,271,033	9,168,259
Capital work in process	168,155	0
	29,622,945	29,339,380
Accumulated depreciation	(25,523,265)	(24,984,001)
Property, plant & equipment - net	4,099,680	4,355,379

6. Leases

The Company's lease portfolio consists primarily of operating leases for office space and equipment with contractual terms expiring from November 2021 to December 2025. Lease contracts may include one or more renewal options that allow the Company to extend the lease term, typically from three years per each renewal option. The exercise of lease options is generally at the discretion of the Company. None of the Company's leases contain residual value guarantees, substantial restrictions, or covenants. The Company's leases are substantially within Australia.

	December 31, 2021	December 31, 2020
	A$	A$
Operating lease right-of-use assets:		
Non-current	2,050,336	4,024,962
Operating lease liabilities:		
Current	500,284	524,844
Non-current	1,690,716	3,594,531
Weighted average remaining lease terms (in years)	4.0	7.0
Weighted average discount rate	5.0%	6.0%

The components of lease income/expense were as follows:

	Years ended December 31, 2021	Years ended December 31, 2020
	A$	A$
Fixed payment operating lease expense	715,086	771,693
Short-term lease expense	0	100,361
Sub-lease income	163,397	180,631

The sub-lease income was deemed an operating lease.

The components of the fixed payment operating and short-term lease expense as classified in the Consolidated Statements of Comprehensive Income/(Loss) are as follows:

	Years ended December 31, 2021	Years ended December 31, 2020
	A$	A$
Cost of goods sold	119,437	141,291
Cost of services	104,344	100,266
Research and development	360,159	511,227
Selling, general and administrative	131,146	119,270
	715,086	872,054

Supplemental cash flow information related to the Company's leases was as follows:

	Years ended December 31, 2021	Years ended December 31, 2020
	A$	A$
Operating cash outflows from operating leases	716,247	488,382

Supplemental noncash information related to the Company's leases was as follows:

	Years ended December 31, 2021	Years ended December 31, 2020
	A$	A$
Right of use assets obtained in exchange for lease liabilities	0	4,324,727
Right of use asset modifications	(1,392,953)	0

Future lease payments are as follows:

	December 31, 2021
	A$
2022	598,564
2023	594,392
2024	608,443
2025	623,654
2026	0
Thereafter	0
Total future lease payments	2,425,053
Less: imputed interest	(234,053)
Total operating lease liabilities	2,191,000
Current	500,284
Non-current	1,690,716

On January 1, 2021, the lease for 1 Corporate Avenue was terminated and a new lease entered into simultaneously. The lease expires on December 31, 2025 with an option to renew the lease for two further terms of five years each. The renewal option periods have not been included in the lease term as the Company is not reasonably certain that they will be exercised.

On June 28, 2021, HRL entered into a premises lease, which commenced in February 2022, with a ten-year contractual period. The lease does not include an option to renew the lease for a further term.

On October 22, 2021, UBS entered into a lease arrangement to install solar panels and inverters ("panels"). The lease commenced in January 2022 upon installation of the panels. The panels were installed at the Company's 1 Corporate Avenue premises. The lease has a term of seven years and an option to buy at the end of the term.

As of December 31, 2021, the Company has not entered into any other lease agreements that have not yet commenced.

7. Income Taxes

Provision for Income Taxes

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

	Years Ended December 31,			
	2021		2020	
	A$	%	A$	%
Loss before income taxes	(10,506,935)		(7,638,024)	
Computed by applying income tax rate of home jurisdiction	(3,152,081)	30	(2,291,407)	30
Effect of tax rates in foreign jurisdictions	76,914	(1)	17,122	0
Research and development tax incentive	1,518,698	(15)	1,103,924	(14)
Disallowed expenses/(income):				
Stock-based compensation	27,730	0	51,970	(1)
Amortization expense	(490,891)	5	(625,381)	8
Other	49,441	0	12,011	0
Change in valuation allowance	1,970,189	(19)	1,731,761	(23)
Income tax expense/(benefit)	0	0	0	0

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

	Years Ended December 31,	
	2021	2020
	A$	A$
Foreign	52,186	(489,187)
Domestic	(10,559,121)	(7,148,837)
	(10,506,935)	(7,638,024)

Deferred Tax Assets and Liabilities

	Years Ended December 31,	
	2021	2020
	A$	A$
Deferred tax assets:		
Operating loss carry forwards	5,676,365	5,232,734
Depreciation and amortization	1,366,666	2,030,293
Asset retirement obligations	816,378	820,440
Employee entitlements	204,712	181,222
Accruals	1,692,194	1,082,516
Decline in value of patents	1,070,959	1,121,593
Unrealized exchange loss	56,706	(88,319)
Other	(3,750)	(4,423)
Total deferred tax assets	10,880,230	10,376,056
Valuation allowance for deferred tax assets	(10,689,001)	(9,693,936)
Net deferred tax asset	191,229	682,120
Deferred tax liabilities:		
Intangible assets	3,242,066	3,732,957
Total deferred tax liabilities	3,242,066	3,732,957
Net deferred tax liabilities	3,050,837	3,050,837

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, 2021 the Company has A$18,921,216 (A$17,315,505 as at December 31, 2020) of accumulated tax losses available for carry forward against future earnings, which under Australian tax laws do not expire but may not be available under certain circumstances. The Company also has A$3,374,776 (A$3,374,776 at December 31, 2020) of non-refundable R&D tax offset as at December 31, 2021. 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, 2021 (nil as of December 31, 2020). HRL has Canadian tax losses available for carry forward against future earnings of CAD$120,376 and CAD$779,887 as at December 31, 2021 and 2020, respectively.

8. Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2021	2020
	A$	A$
Legal, tax and accounting fees	52,982	254,348
Salary and related costs	348,657	231,290
Research and development costs	1,052,814	462
Patent fees	395,420	314,802
Inventory purchases	268,317	188,720
Occupancy expenses	345	111,142
Other	682,280	51,244
	2,800,815	1,152,008

9. Contingent Consideration

Pursuant to the Siemens Acquisition and the agreement dated September 2019, the Company has agreed to pay US$1,500,000 to Siemens within five days of Siemens achieving a pre-defined milestone. The Company has the discretion of advising Siemens when the milestone is to be achieved but from the date notification is sent by the Company, Siemens has 90 days to fulfill this milestone. Notification has not yet been issued to Siemens. Once the milestone is achieved, it will enable the Company to use Siemens proprietary reagent which will allow the Company to access markets in certain jurisdictions.

10. Other Liabilities

Other liabilities represents a marketing support payment due to one of our partners and is payable in US dollars. The balance will be paid once supporting documentation has been provided to the Company.

11. Borrowings

The unsecured loan is a government guaranteed loan called Canada Emergency Business Account (CEBA) of CAD$60,000 to help eligible businesses with operating costs. CAD$40,000 was received by the Company in 2020 and CAD$20,000 in 2021. This is among the business support measures introduced in the Canadian Federal Government's COVID-19 Economic Response Plan, with the following terms:

- the loan is interest-free and no principal repayment is required before December 31, 2022;
- if the Company chooses to repay at least CAD$40,000 of the loan by December 31, 2022, the remaining balance will be forgiven;
- if the loan is not repaid by the above mentioned date, it will be converted into a 3-year term loan and will be charged an interest rate of 5% per annum. Interest-only payments are required each month; and
- at the end of the 3-year term, the entire balance of the loan is due for repayment by December 31, 2025.

In January 2022 the Company entered into a short-term loan facility to finance its 2022 Insurance Premium. The total amount available and drawn down under the facility is $1,002,404. The facility is repayable in nine monthly instalments which commenced in January 2022 and has an effective annual interest rate of 1.49%. The short-term borrowing is secured by the insurance premium refund.

In January 2022 the Company entered into a long-term loan facility to finance the installation of solar panels at the Company's Rowville premises. The total amount available and drawn down under the facility is $65,000. The facility is repayable in eighty-seven monthly instalments which commence in April 2022 and has an effective annual interest rate of 6.85%.

12. Revenue

Disaggregation of Revenue

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

	Years Ended December 31	
	2021	2020
	A$	A$
Major product/service lines		
Coagulation testing products	2,667,541	2,565,747
Coagulation testing services	1,962,354	568,528
Other services	0	68,334
Wine testing products	1,147,856	0
	5,777,751	3,202,609
Timing of revenue recognition		
Products and services transferred at a point in time	5,777,751	3,202,609
	5,777,751	3,202,609

Contract Balances

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

	December 31, 2021	2020
	A$	A$
Receivables	476,164	73,073
Contract liabilities	38,431	1,628,426

The Company's contract liabilities represent the Company's obligation to transfer products to customers for which the Company has received consideration from customers, but the transfer has not yet been completed.

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

	Years Ended December 31, 2021	2020
	A$	A$
Contract Liabilities - Current		
Opening balance	1,628,426	2,682,404
Closing balance	38,431	1,628,426
Net increase/(decrease)	(1,589,995)	(1,053,978)
Contract Liabilities - Non-Current		
Opening balance	0	1,421,680
Closing balance	0	0
Net increase/(decrease)	0	(1,421,680)

The Company expects all of the Company's contract liabilities to be realized by December 31, 2022.

13. Other Income

Other income is recognized when there is reasonable assurance that the income will be received and the consideration can be reliably measured.

Other income is as follows for the relevant periods:

	Years Ended December 31 2021	2020
	A$	A$
Insurance recovery	2,262	674,083
Federal and state government subsidies	153,001	1,265,149
Rental income	163,397	180,631
Other income	112,052	2,988
	430,712	2,122,851

Insurance recovery for the year ended December 31, 2020 represents A$600,000 of partial reimbursement of our legal costs which was incurred during mediation with Siemens.

Federal and state government subsidies which primarily include Australian JobKeeper payments and Canada Emergency Wage Subsidy, represent assistance provided by government authorities as a stimulus during COVID-19. The Company was ineligible to receive Australian JobKeeper payments in relation to the 2021 financial year.

14. Employee Incentive Schemes

In 2004, the Company adopted an employee option plan which was subsequently amended in 2021 ("the Equity Incentive Plan").

During the year ended December 31, 2021, the Company granted stock options and performance rights to select employees under the Equity Incentive Plan. During the year ended December 31, 2020, the Company granted stock options to select employees under the Equity Incentive Plan. All stock options and performance rights granted under the Equity Incentive Plan require eligible recipients to complete a requisite service period.

At December 31, 2021, total stock compensation expense recognized in the consolidated statements of comprehensive income was A$92,432 (2020: A$173,232).

(a) Stock Options

Stock options ("options") may be granted pursuant to the Equity Incentive 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 Equity Incentive 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 Equity Incentive Plan. Options granted to date have had a term up to ten years and generally vest in tranches up to three years.

An option holder is not permitted to participate in a bonus issue or new issue of securities in respect of an option held prior to the issue of shares to the option holder pursuant to the exercise of an option. If the Company changes the number of issued shares through or as a result of any consolidation, subdivision, or similar reconstruction of the issued capital of the Company, the total number of options and the exercise price of the options (as applicable) will likewise be adjusted. The terms of the awards include a variety of market, performance and service conditions.
The number of options granted in 2021 and 2020 were up to 250,000 and 7,594,000 respectively.

In accordance with ASC 718, the fair value of the options granted in January 2021 were estimated on the date of each grant using the Trinomial Lattice model. The key assumptions for these grants were:

Exercise Price (A$)	0.50	0.50	0.50
Share Price at Grant Date (A$)	0.29	0.29	0.29
Volatility	62%	62%	62%
Maximum Life (years)	2.0	3.0	4.0
Risk-Free Interest rate	0.19%	0.19%	0.19%
Fair Value (A$)	0.05	0.06	0.07

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

Share Price and Exercise Price at Valuation Date

The value 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 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 Equity Incentive Plan have a maximum ten 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 options	Weighted average exercise price A$
Balance at December 31, 2020	9,398,450	0.29
Granted	250,000	0.50
Exercised	(216,650)	0.35
Lapsed	(553,000)	0.48
Balance at December 31, 2021	8,878,800	0.29

At December 31, 2021, the number of options vested and exercisable was 8,878,800 (2020: 8,898,450). At December 31, 2021, total stock compensation expense for options recognized in the consolidated statements of comprehensive income was A$3,780 (2020: A$173,232).

The following table represents information relating to stock options outstanding under the plans as of December 31, 2021:

Exercise price A$	Options	Weighted average remaining life in years	Options exercisable shares
0.23	20,000	0	20,000
0.45	37,500	1	37,500
0.50	861,000	1	861,000
0.33	52,000	2	52,000
0.50	234,300	2	234,300
0.20	2,364,666	2	2,364,666
0.25	2,364,667	3	2,364,667
0.30	2,364,667	3	2,364,667
0.30	500,000	3	500,000
0.50	80,000	0	80,000
	8,878,800		8,878,800

The table below sets forth the number of employee stock options exercised and the number of shares issued in the period from January 1, 2020. 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 A$	Proceeds Received (A$)
2020	40,000	0.00	0
2021	216,650	0.35	75,125

As of December 31, 2021, there was no unrecognized compensation expense (2020: nil).

(b) Restricted Shares

The Equity Incentive Plan permits our Board to grant shares of our common stock to our employees and directors (although our Board has determined not to issue equity to non-executive directors). The number of shares able to be granted is limited to the amount permitted to be granted at law, the ASX Listing Rules and by the limits on our authorized share capital in our certificate of incorporation. All our employees are eligible for shares under the Employee Share Plan. The Company has in the past issued A$1,000 worth of restricted shares of common stock to employees of the Company, but no more frequently than annually. The restricted shares have the same terms of issue as our existing shares of common stock but are not able to be traded until the earlier of three years from the date on which the shares are issued or the date the relevant employee ceases to be an employee of the Company or any of its associated group of companies. There were no restricted shares issued by the Company during 2021 and 2020.

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

	Number of shares	Weighted average issue price A$
Balance at December 31, 2020	91,652	0.24
Release of restricted shares	(91,652)	0.24
Balance at December 31, 2021	0	

(c) Equity

Equity may be granted pursuant to the Equity Incentive 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 performance right issued gives the holder the right to subscribe for one share of common stock. The total number of performance rights that may be issued under the Equity Incentive Plan is such maximum amount permitted by law and the Listing Rules of the ASX.

Such equity granted does not involve the payment of an exercise price. Equity generally vests in tranches up to four years.

The terms of the awards include a variety of market, performance and service conditions. The number of performance rights granted in 2021 was up to 7,425,000 (2020: nil).

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

	Feb-21	Aug-21	Dec-21
Exercise Price (A$)	0	0	0
Share Price at Grant Date (A$)	0.41	0.77	0.81
Volatility	63%	64%	63%
Maximum Life (years)	0.92	3.60	1.07
Risk-Free Interest rate	0.25%	0.12%	0.57%
Fair Value (A$)	0.39	0.77	0.81

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

Share Price and Exercise Price at Valuation Date

The value of the performance rights 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 performance rights. 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 performance rights granted under our Equity Incentive Plan have a maximum four 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.

Performance rights activity during the current period is as follows:

	Number of rights	Weighted average exercise price A$
Balance at December 31, 2020	0	
Granted	7,425,000	0.76
Exercised	0	
Lapsed	(150,000)	0.39
Balance at December 31, 2021	7,275,000	0.76

At December 31, 2021, there were no performance rights vested or exercisable. At December 31, 2021, total stock compensation expense for performance rights recognized in the consolidated statements of comprehensive income was A$88,652 (2020: nil).

The following table represents information relating to the maximum quantity of performance rights outstanding under the plans as of December 31, 2021:

Exercise price A$	Rights	Weighted average remaining life in years	Rights exercisable shares
0	150,000	0	0
0	6,750,000	3	0
0	375,000	1	0
	7,275,000		0

As of December 31, 2021, there was unrecognized compensation expense of up to A$5,471,098 (2020: nil). The issuance of the equity under the Equity Incentive Plan is subject to the Company achieving predetermined market and non-market conditions. In the event that the predetermined market and non-market conditions are met, the unrecognized compensation expense as at December 31, 2021 would be recognized.

15. 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	Tax (Expense)/ Benefit	Net-of-Tax Amount
	A$	A$	A$
Year Ended December 31, 2021			
Foreign currency translation reserve	(30,217)	0	(30,217)
	(30,217)	0	(30,217)
Year Ended December 31, 2020			
Foreign currency translation reserve	48,671	0	48,671
	48,671	0	48,671

16. 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.

17. Net Loss per Share

The following table shows the computation of basic and diluted loss per share for 2021 and 2020:

	Years Ended December 31, 2021	2020
	A$	A$
Numerator:		
Net loss	(10,506,935)	(7,638,024)
Denominator:		
Weighted-average basic and diluted shares	177,714,201	177,574,046
Basic and diluted loss per share	(0.06)	(0.04)

The number of shares not included in the calculation of basic net loss per ordinary share because the impact would be anti-dilutive were 9,028,800 and 4,844,333 for the years ended December 31, 2021 and 2020, respectively.

Basic and diluted net loss per share was computed by dividing the net loss applicable to common stock by the weighted-average number of common stock outstanding during the period.

18. 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:

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 16% of our shares.

There were no material related party transactions or balances as at December 31, 2021 other than as disclosed above.

19. 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, 2021 and December 31, 2020. Purchase commitments contracted for as at December 31, 2021 and December 31, 2020 were A$881,134 and A$369,779, respectively.

Refer to Note 9 for details of the Company’s Contingent Consideration.

20. Segment Information

We operate in one segment. We are a specialist biosensors Company focused on the development, manufacture and commercialization of a range of point of use devices for measuring different analytes across different industries.

We operate predominantly in one geographical area, being Australia. The chief operating decision maker of the Company is the Chief Executive Officer.

The Company’s material long-lived assets are predominantly based in Australia.

Our total income as disclosed below is attributed to countries based on location of customer. Location has been determined generally based on contractual arrangements. Total income includes revenue from products and services, interest income, research and development tax incentive income and other income as disclosed in the Consolidated Statements of Comprehensive Income/(Loss).

	Years Ended December 31,	
	2021	2020
	A$	A$
Australia (home country)	4,580,741	5,003,332
Americas	1,419,436	681,806
Europe	3,905,621	2,760,382
Other	250,155	0
Total income	10,155,953	8,445,520

% of total revenue from products and services derived from major customers:

	Years Ended December 31,	
	2021	2020
	A$	A$
Siemens	30%	77%
Bayer	16%	2%
Other	54%	21%

21. 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 ASIC Corporations (Wholly-owned Companies) Instrument 2016/785.

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".

22. Guarantees and Indemnifications

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

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

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

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

No liability has arisen under these indemnities as of December 31, 2021 and 2020.

23. Subsequent Events

In January 2022 the Company entered into a short-term loan facility to finance its 2022 Insurance Premium. The total amount available and drawn down under the facility is $1,002,404. The facility is repayable in nine monthly instalments which commenced in January 2022 and has an effective annual interest rate of 1.49%. The short-term borrowing is secured by the insurance premium refund.

There has been no other matter or circumstance that has occurred subsequent to period end that has significantly affected, or may significantly affect, the operations of the Company, the results of those operations or the state of affairs of the Company or in subsequent financial periods.

Universal Biosensors, Inc.

Schedule ii – Valuation and Qualifying Accounts

	Balance at Beginning of Period	Additions		Deductions	Balance at end of Period
		Charged to Costs and Expenses	Charged to Other Accounts		
	A$	A$	A$	A$	A$
Year Ended December 31, 2021					
Deferred income tax valuation allowance	9,693,936	1,970,189	(349,743)	(625,381)	10,689,001
Year Ended December 31, 2020					
Deferred income tax valuation allowance	8,220,770	1,731,761	(258,595)	0	9,693,936

Exhibit 21

List of subsidiaries

Subsidiary of Universal Biosensors Inc.	Jurisdiction of Incorporation
Universal Biosensors Pty Ltd.	Australia
Hemostasis Reference Laboratory Inc.	Canada
Universal Biosensors B.V.	The Netherlands
Universal Biosensors LLC	Delaware, U.S.

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, John Sharman, 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 24, 2022

/s/ John Sharman

John Sharman
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 24, 2022

/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, 2021, 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 24, 2022.

/s/ John Sharman
John Sharman
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.