

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, 2023

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)

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

(Address of principal executive offices)

98-0424072

(I.R.S. Employer Identification No.)

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.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

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\$39,940,224 (equivalent to US\$26,480,368) as of June 30, 2023.

There were 212,369,435 shares of the registrant's common stock, par value US\$0.0001 per share, outstanding as of February 20, 2024.

Documents incorporated by reference:

Certain information contained in the registrant's definitive Proxy Statement for the 2024 annual meeting of stockholders, to be filed with the SEC 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-30 of our Annual Report to Stockholders for the fiscal year ended December 31, 2023 (our "2023 Annual Report") is incorporated by reference in our response to Items 7, 7A, 8 and 9A of Part II. The 2023 Annual Report is filed as Exhibit 13 to this Annual Report on Form 10-K.

UNIVERSAL BIOSENSORS, INC.

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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 war or other military conflict and inflationary factors such as increases in the cost of various inputs in our supply chain, each of 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 majeure, 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 specialize in the design and development of electrochemical cells (strips) used in conjunction with point-of-use devices that are used in various industries such as healthcare (point-of-care), wine, food and agriculture. Our ambition is to build a multi-product stable of biosensors in large markets which generates ongoing revenue streams. UBI was incorporated as a Delaware corporation on September 14, 2001.

Key developments during 2023 include:

- Revenue from the sale of products increased 67% to \$5.64m
- Total revenue increased 47% to A\$6.63 million
- Gross profit increased 100% to A\$4.28 million
- Operating costs decreased as follows:
 - R&D expenses declined by 60% to A\$4.97 million
 - Total operating expenses declined by 43% to A\$20.97 million
- Net loss after tax and impairment of intangible assets improved by A\$20.11 million
- Completion of Xprecia Prime clinical trials and submission of 510K application to the US ("FDA")
- Global launch of Sentia's Fructose, Acetic Acid and Titratable Acidity tests
- Global launch of the Petrackr blood glucose product
- First sales of next generation Xprecia Prime in Europe
- Major tender win to supply Xprecia Prime in Italy
- Received regulatory approval and first order for Xprecia Prime in India and Malaysia
- Received regulatory approval for the sale of Xprecia Prime 4U directly to patients for self-testing in Europe
- The continuing development of our Oncology platform
-

Description of our business

Industry background

We operate in the high growth, point-of-care segment of the global in vitro diagnostics (IVD) industry, oenology (wine industry), veterinary blood glucose monitoring 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 continue to demonstrate the broader application of our technology platform for markets with significant commercial potential and have developed products in blood glucose, a coagulation Prothrombin Time International Normalized Ratio ("PT-INR") test and chemical tests for the wine industry.

We continue to invest an appropriate amount of resources into the development of new products and technologies across various industries including oncology, fertility, aptamers, per- and polyfluoroalkyl substances ("PFAS"), Sentia alcohol and heavy metals.

We use various channels to sell our products and they include direct sales and the engagement of distributors and agents.

Principal products and services

We are the manufacturer and distributor of PT-INR coagulation test strips and devices (Xprecia Stride and Xprecia Prime), used to monitor the effect of the anticoagulant therapy warfarin. Xprecia Stride and Xprecia Prime are medical devices.

We are the manufacturer and distributor of all the Sentia wine testing products which includes Free SO₂, Malic Acid, Glucose, Fructose, Total Acid and Titratable Acidity. Sentia is a non-medical device.

We are the manufacturer and distributor of the Petrackr which is a blood glucose test used in cats and dogs.

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 expires on December 31, 2025 with an option to renew the lease for two further terms of five years each.

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. HRL holds an ISO 13485:2016 certification.

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 Xprecia Stride, Xprecia Prime, Petrackr 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 Petrackr (animal device) and Sentia (non-medical) products are subject to regulation by product safety regulations by 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.

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 and the "PETRACKR" trademark which we use to market our blood glucose test to detect and monitor diabetes in non-humans.

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,	
	2023	2022
	A\$	A\$
Australia (home country)	4,823,076	4,978,712
Americas	1,913,892	1,387,556
Europe	2,295,455	2,841,678
Other	2,006,822	150,082
Total income	11,039,245	9,358,028

% of total revenue from products and services derived from major customers (revenue generated by customers having sales of more than 10% has been disclosed separately in the table below):

	Year Ended December 31,	
	2023	2022
Siemens	0%	13%
Other	100%	87%

Siemens rights to sell Xprecia products pursuant to the Commercial and Distribution agreement ended formally on March 31, 2023. We are not dependent on a single customer now.

We did not have any significant backlog orders as of December 31, 2023 and 2022.

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 20, 2024, the Company had approximately 80 employees located in Australia, Canada, the United States and Europe. Females represent 45% of our workforce, including 25% of senior management. 98% of our workforce are permanently employed to ensure throughput of growth and development. None of our employees are subject to a collective bargaining agreement.

The Company believes that success of its mission is realized by the engagement and empowerment of its employees. The CEO and Head of People Strategy & Culture regularly update the Company's Board of Directors ("the Board of Directors") and its committees on the status of the human capital trends and activities within the business. Our management and cross-functional teams work closely to evaluate human capital management issues such as staff retention, workplace safety, harassment and bullying, as well as to implement measures to mitigate these risks.

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. Further to monetary rewards, the Company provides a family-friendly environment where staff can organize hybrid work arrangements where required.

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. Training needs are identified at the start of each year when corporate and departmental objectives are communicated. Strategic talent reviews and succession planning discussions takes place annually, as an extension to annual performance reviews, across all business areas. The CEO and Head of People Strategy & Culture meet with senior management and the Board of Directors to review top enterprise talent. The Company continues to provide opportunities for employees to grow their careers with over half of the open management positions filled internally during 2023.

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 foster 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. Excluding senior management, staff to manager ratio is 16.2 – this enables effective and efficient management that supports optimum employee engagement.

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. During the year ended December 31, 2023, zero safety incidents were achieved. Separately, the Company views mental health as a fundamental part of our humanity and implemented a comprehensive Employee Assistance Program in 2021. The program offers a wide-ranging suite of online resources, including mental health coaching and training to help managers recognize and respond to signs of mental health issues.

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 States 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

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.

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.

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 the products that we develop, manufacture and distribute is ultimately dependent on the level of continued market acceptance and sales of such products. Continued market acceptance will depend on, amongst other things, the ability to provide and maintain evidence of safety, efficacy and cost effectiveness of our 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 the products that we develop, manufacture and distribute or are currently being marketed by our partners.

We cannot be sure that any other products that we develop, manufacture and distribute 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 develop, manufacture and distribute 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.

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.

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 generated from our products and services, 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 Euros 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 and Euro cash receipts into Australian dollars to fund our operations.

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 marketplace 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 and we may have to delay or modify our plans significantly. This may 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 sub-components thereof 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 capital raising, 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 2024 financial year, we expect to generate revenues from the sale of our Xprecia Stride and Xprecia Prime products, Sentia and Petrackr 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.

The effects of global climate change or other unexpected events, including global health crises, may disrupt our operations and have a negative impact on our business.

The effects of global climate change, such as extreme weather conditions and natural disasters occurring more frequently or with more intense effects, or the occurrence of unexpected events including wildfires, hurricanes, earthquakes, floods, tsunamis and other severe hazards or global health crises, such as the outbreak of Ebola or the global COVID-19 pandemic, or other actual or threatened epidemic, pandemic, outbreak and spread of a communicable disease or virus, in the countries where we operate or sell products and provide services, could adversely affect our operations and financial performance. Extreme weather, natural disasters, power outages, global health crises or other unexpected events could disrupt our operations by impacting the availability and cost of materials needed for manufacturing, causing physical damage and partial or complete closure of our manufacturing sites or distribution centers, loss of human capital, temporary or long-term disruption in the manufacturing and supply of products and services and disruption in our ability to deliver products and services to customers. These events and disruptions could also adversely affect our customers' and suppliers' financial condition or ability to operate, resulting in reduced customer demand, delays in payments received or supply chain disruptions. Further, these events and disruptions could increase insurance and other operating costs, including impacting our decisions regarding construction of new facilities to select areas less prone to climate change risks and natural disasters, which could result in indirect financial risks passed through the supply chain or other price modifications to our products and services.

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 or eliminate our existing commercialization opportunities. We also license other intellectual property from third parties as part of our other development efforts.

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

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 devices products we are involved in developing are subject to extensive regulation in all major markets. The Company submitted its full response to the FDA's "Request for Additional Information" in November 2023 for the Xprecia Prime product. Assuming there are no further queries, an FDA decision for the approval of Xprecia Prime for sale in United States is expected during Q1 2024. 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.

Any failure to prevent or mitigate security breaches and improper access to or disclosure of our data or our user data could result in the loss or misuse of such data, which could harm our business and reputation and diminish our competitive position.

Awareness and sensitivity to personal data breaches and cyber security threats is at an all-time high. Our computer systems and those of our contractors and consultants are vulnerable to damage from unauthorized access, computer viruses, telecommunications and electrical failures, and natural disasters. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption to our operations.

As part of our business model, we collect, retain, and transmit confidential information over public networks. We may be vulnerable to targeted or random personal data or security breaches, acts of vandalism, computer malware, misplaced or lost data, programming and/or human errors, or other similar events. Any misappropriation of our internal confidential or personal information gathered, stored or used by us, be it intentional or accidental, could have a material impact on the operation of our business, including severely damaging our reputation and our relationships with licensees, employees and investors. We may incur further significant costs implementing additional security measures to protect against new or enhanced data security or privacy threats, or to comply with current and new international, federal, and state laws governing the unauthorized disclosure of confidential and personal information which are continuously being enacted. We could also experience loss of revenues resulting from unauthorized use of proprietary information including our intellectual property. We could also face sizable fines, significant breach containment and notification costs to supervisory authorities and the affected data subjects, and increased litigation as a result of cyber security or personal data breaches.

The rapid evolution and increased adoption of artificial intelligence technologies may intensify our cybersecurity risks by making cyberattacks more difficult to detect, contain or mitigate. We believe we will continue to see, widespread vulnerabilities that could affect our or other third parties' data or systems. Mitigation and remediation recommendations continue to evolve, and addressing this and other critical vulnerabilities pertaining to widely used systems, platforms and infrastructure is a priority for us. Internal access management failures could result in the compromise or unauthorized exposure of confidential data. Moreover, hardware, software or applications we use may have inherent vulnerabilities or defects of design, manufacture or operations or could be inadvertently or intentionally implemented or used in a manner that could compromise information security. There can be no assurance that we or our vendors and other third parties will not be subject to additional cybersecurity threats and incidents that bypass our or their security measures, impact the integrity, availability or privacy of personal health information or other data subject to privacy laws or disrupt our or their information systems, devices or business. In such an event, we may incur substantial costs, including but not limited to, costs associated with remediating the effects of the cybersecurity incident, costs for security measures to guard against similar future incidents and costs to recover data. Further, consumer confidence in the integrity and security of personal information and critical operations data in the life sciences industry generally could be shaken to the extent there are successful cyberattacks at other companies, which could have a material, adverse effect on our business, financial position or results of operations.

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, 2023, we had A\$30,582,036 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, 2023. 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, 2022, our aggregate turnover was less than A\$20,000,000 and we received a tax incentive income of A\$4,495,137. Additionally, we will be eligible to make this claim for the year ended December 31, 2023, as our revenues are less than A\$20,000,000. We anticipate receiving a refundable tax offset of A\$3,774,343 in 2024 following the lodgment of our 2023 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.

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 or CDIs by us, and sales in the public market of the shares or CDIs 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 ("Viburnum"), as investment manager for its associated funds and entities holds a beneficial interest and voting power over approximately 26% 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
- our stockholders are prohibited from taking action by written consent, and all stockholder action is required to take place at a meeting of our stockholders.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation Law, or DGCL, which prevents interested stockholders, such as certain stockholders holding more than 15% of our outstanding common stock, from engaging in certain business combinations unless (i) prior to the time such stockholder became an interested stockholder, our board of directors approved the transaction that resulted in such stockholder becoming an interested stockholder, (ii) upon consummation of the transaction that resulted in such stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of our common stock, or (iii) following board approval, such business combination receives the approval of the holders of at least two-thirds of our outstanding common stock not held by such interested stockholder at an annual or special meeting of stockholders.

Any provision of our certificate of incorporation, bylaws, or Delaware law that has the effect of delaying, preventing, or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

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.

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 1C. Cybersecurity.

The Company's Board of Directors takes seriously both the responsibility to guard against cybersecurity threats and its compliance with the SEC Cybersecurity regulations adopted on July 26, 2023. Our Board of Directors has standing agenda to review and discuss on cybersecurity matters with management during each meeting. Management is updated on cybersecurity matters by the IT Senior Systems Administrator ("ITSSA").

Our cybersecurity risk management program leverages a combination of processes, technologies and personnel with expertise in cybersecurity to comply with applicable regulations and detect and respond to cyber-attacks, data breaches, security incidents, and compromises of personal information, as well as to regularly and promptly inform management and our Board of Directors of any significant cybersecurity risks and developments.

Our ITSSA, who has significant experience in managing cybersecurity risks is directly responsible for establishing cybersecurity strategies and structures and managing ongoing cybersecurity risk management activities, reports relevant information regarding cybersecurity threats and risks to management. Management can then further elevate matters to the full Board of Directors, as necessary or required.

The Company and the Board of Directors are committed to remaining updated on evolving cybersecurity regulations and best practices, as well as the development and amendment of processes to meet these changing demands.

The Company did not experience any cyber security incident during 2023.

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 1 Corporate Avenue will expire 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.

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 Depository 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 Depository Nominees Pty Ltd, or "CDN", and the shares are registered in the name of CDN and held by CDN on behalf of and for the benefit of the holders of CDIs. CDN is a wholly owned subsidiary of ASX.

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

Security details

As of February 20, 2024, there were 212,369,435 shares of our common stock issued and outstanding and 12,406,300 options and performance rights 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 Act. We have not agreed to register any of our shares of common stock for resale by security holders.

Holdings

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 20, 2024	2,590	8

Dividends

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

Recent Sales of Unregistered Securities

None.

Restricted Employee Shares Issued to Employees

Our Employee Share Plan was adopted 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. 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 three fiscal years and the balance of the restricted shares as of December 31, 2023, is nil.

There were no performance rights issued by the Company to employees during the year ended December 31, 2023.

There were 1,555,000 performance rights issued by the Company to select employees during the year ended December 31, 2022, of which nil shares vested during the year ended December 31, 2023. 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 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 2023 Annual Report under the caption “Management’s Discussion and Analysis of Financial Condition and Results of Operations” on pages F2 to F8.

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 2023 Annual Report under the following captions:

- Consolidated Balance Sheets
- Consolidated Statements of Comprehensive Income/(Loss)
- Consolidated Statements of Changes in Stockholders' Equity and Comprehensive Income/(Loss)
- Consolidated Statements of Cash Flows
- Notes to Consolidated Financial Statements
- Report of Independent Registered Public Accounting Firm (PCAOB ID 1379)

The items are included on pages F10 through F30 of the 2023 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, 2023, 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, 2023. 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, 2023, 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 29, 2024

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 within 120 days after December 31, 2023, in connection with our Annual Meeting of Stockholders in 2024 (the "2024 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 2024 Proxy Statement under the captions "Management of the Company – Compensation of Directors," "Executive Compensation" and "Management of the Company – Board Meetings and 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 2024 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 2024 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 2024 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-9 through F-30 of our Annual Report to Stockholders for the fiscal year ended December 31, 2023, as provided in Item 8 hereof:

Report of Independent Registered Public Accounting Firm (PCAOB ID 1379)	F-9
Consolidated Balance Sheets	F-10
Consolidated Statements of Comprehensive Income/(Loss)	F-11
Consolidated Statements of Changes in Stockholders' Equity and Comprehensive Income/(Loss)	F-12
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(a)(2) 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 Current Report on Form 8-K filed on March 7, 2022 as Exhibit 10.1.
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. Satesh Balak effective November 27, 2006.	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.8.
10.6	Amended and Restated Master Services and Supply Agreement (which amends and restates the Master Services and Supply Agreement by and between Universal Biosensors Pty. Ltd., Universal Biosensors, Inc., and LifeScan, Inc. dated October 29, 2007 filed on November 14, 2007 as Exhibit 10.1 to our Quarterly Report on Form 10-Q and the First Amendment to the Master Services and Supply Agreement filed on March 30, 2009 as Exhibit 10.14 to our Annual Report on Form 10-K).	Incorporated by reference to our Quarterly Report on Form 10-Q filed on August 7, 2009 as Exhibit 10.3. Confidentiality treatment has been granted for portions of this exhibit. These confidential portions have been omitted and were filed separately with the SEC.

10.7	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.
10.8	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.
10.9	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
10.10	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
10.11#	Employee Incentive Plan	Incorporated by reference to our Current Report on Form 8-K filed on September 17, 2021 as Exhibit 10.2.
10.12#	Award Agreement between Universal Biosensors, Inc. and Mr. Satesh 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.
10.13#	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.
10.14	Underwriting Agreement between Viburnum Funds Pty Ltd and Universal Biosensors, Inc.	Incorporated by reference to our Quarterly Report on Form 10-Q filed on August 10, 2022 as Exhibit 10.18.
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.
101	The following materials from the Universal Biosensors, Inc. Annual Report on Form 10-K for the financial year ended December 31, 2023 formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Comprehensive Income/(Loss), (iii) the Consolidated Statements of Changes in Stockholder's Equity and Comprehensive Income/(Loss), (iv) the Consolidated Statements of Cash Flows and (v) the Notes to Consolidated Financial Statements.	As provided in Rule 406T of Regulation S-T, this information is furnished herewith and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934.
104	Cover Page Interactive Data File (Formatted as Inline XBRL and contained in Exhibit 101.	
#	Indicates a management or compensatory plan.	

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 29, 2024

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:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ John Sharman</u> John Sharman	Chief Executive Officer (Principal Executive Officer)	February 29, 2024
<u>/s/ Salesh Balak</u> Salesh Balak	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 29, 2024
<u>/s/ Craig Coleman</u> Craig Coleman	Director	February 29, 2024
<u>/s/ Judith Smith</u> Judith Smith	Director	February 29, 2024
<u>/s/ David Hoey</u> David Hoey	Director	February 29, 2024
<u>/s/ Graham McLean</u> Graham McLean	Non-Executive Chairman and Director	February 29, 2024

Universal Biosensors, Inc.

2023 Annual Report

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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.

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 biosensor technology company focused on commercializing a range of biosensors using proprietary electrochemical cells (strips) and point-of-use devices. Our ambition is to build a multi-product stable of biosensors in large markets which generates ongoing revenue streams. Our products are sold to human health, oneology (wine) and the vet industries.

Key developments during 2023 include:

- Revenue from the sale of products increased 67% to \$5.64m
- Total revenue increased 47% to A\$6.63 million
- Gross profit increased 100% to A\$4.28 million
- Operating costs decreased as follows:
 - R&D expenses declined by 60% to A\$4.97 million
 - Total operating expenses declined by 43% to A\$20.97 million
- Net loss after tax and impairment of intangible assets improved by A\$20.11 million
- Completion of Xprecia Prime clinical trials and submission of 510K application to the US (“FDA”)
- Global launch of Sentia’s Fructose, Acetic Acid and Titrateable Acidity tests
- Global launch of the Petrackr blood glucose product
- First sales of next generation Xprecia Prime in Europe
- Major tender win to supply Xprecia Prime in Italy
- Received regulatory approval and first order for Xprecia Prime in India and Malaysia
- Received regulatory approval for the sale of Xprecia Prime 4U directly to patients for self-testing in Europe
- The continuing development of our Oncology platform

Results of Operations

Analysis of Consolidated Revenue

The financial results of the products and services we sold during the years ended December 31, 2023 and 2022 are as follows:

	Year Ended December 31,	
	2023	2022
	A\$	A\$
Revenue from products & services	6,632,838	4,524,962
Cost of goods sold and services	(2,347,901)	(2,385,931)
Gross profit	<u>4,284,937</u>	<u>2,139,031</u>

Total revenue and gross profit increased by 47% and 100%, respectively delivering a gross profit of \$4,284,937 in the year ended December 31, 2023.

Revenue from Products

The financial results of the products we sold during the years ended December 31, 2023 and 2022 are as follows:

	Year Ended December 31,	
	2023	2022
	A\$	A\$
Xprecia	2,607,506	2,366,331
Sentia	2,528,666	1,013,071
Petrackr	500,320	0
	5,636,492	3,379,402
Cost of goods sold	(2,032,452)	(1,386,889)
Gross profit	<u>3,604,040</u>	<u>1,992,513</u>

Our total revenue from products increased by 67% and our gross profit increased by 81%.

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

Revenue from coagulation testing products grew 10% but was negatively impacted by the “aggressive selling of stock” by Siemens as a result of its rights to sell Xprecia products ending formally on March 31, 2023.

Revenue from wine testing products increased by 150%. During 2022, our revenues from wine testing products were primarily from the sale of Sentia analyzers, Free SO₂ and Malic Acid test strips. During 2023, we began generating revenues from the sale of the following additional test products – Fructose, Glucose, Acetic Acid and Titratable Acidity.

Petrackr, launched in May 2023, generated revenue of A\$500,320.

Our gross profit has increased largely as a result of increased throughput taking into account largely the fixed cost nature of our business.

Revenue from Services

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

	Year Ended December 31,	
	2023	2022
	A\$	A\$
Laboratory testing services	996,346	1,145,560
Cost of services	(315,449)	(999,042)
Gross profit	<u>680,897</u>	<u>146,518</u>

Despite this decline in revenue, HRL business accelerated during the second half of the year ended December 31, 2023, which accounted for 69% of total revenue HRL business generated during the year ended December 31, 2023.

Product Support

Product support relates to post-market technical support provided by us for our products in the market. Product support has increased by 68% compared to the previous financial year as a result of the launch of new products.

Depreciation and Amortization Expenses

	Year Ended December 31,	
	2023	2022
	A\$	A\$
Depreciation	831,409	1,139,984
Amortization	129,504	1,645,651
Depreciation allocated to cost of goods sold & services	(4,638)	(135,964)
	<u>956,275</u>	<u>2,649,671</u>

Depreciation of fixed assets is calculated on a straight-line basis over the useful life of property, plant and equipment. Although our property, plant and equipment has increased, the decline in depreciation during the year ended December 31, 2023, compared to the previous financial year is due to certain assets not being currently depreciated as they are not available for use (currently in work in progress) and also as a result of certain assets fully depreciated during the year.

Amortization expense for the year ended December 31, 2023 represents the Company’s software. Amortization expense has declined during the year ended December 31, 2023 compared to the previous financial year as the intangible assets which were acquired in September 2019 pursuant to the Siemens acquisition were impaired as at December 31, 2022.

Impairment of Definite-Lived Intangible Assets

As part of a strategic review of the balance sheet UBI reviewed its intangible assets and recorded a A\$11,014,785 impairment charge for the year ended December 31, 2022. This charge relates solely to the previously capitalized Siemens agreement which ended September 2023.

Research and Development Expenses

The primary focus of the R&D activities during the year ended December 31, 2023 were developing the Company’s:

- Sentia wine testing platform (Fructose, Acetic Acid and Titratable Acidity tests all of which has now been launched) including further enhancement of certain Sentia tests;
- Xprecia Prime next generation PT-INR Coagulation platform including U.S. Food and Drug Administration (“FDA”) Clinical Trial programs. The submission to the FDA was made in March 2023 and response received from the FDA in June 2023. The Company submitted its full response to the FDA in November 2023 and assuming there are no further queries, an FDA decision is expected during Q1 2024;

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- Petrackr biosensor strip and meter to be used for the detection and monitoring of diabetes in non-humans. The Petrackr product was launched in May 2023;
- Oncology platform Tn Antigen biosensor used for the detection, staging and monitoring of cancer; and
- Aptamer based sensing platform including COVID-19 and female fertility testing.

As we finalize the development of our products, obtain the necessary regulatory approval required for such products and subsequently launch the same, our R&D activity relating to these developments is expected to reduce. During Q1 2023, we finalized the development of and launched the Sentia Fructose and Acetic Acid tests. The Titratable Acidity test was launched in April 2023. We submitted to the FDA our Xprecia Prime clinical trial results. Once approved by the FDA, we will be able to launch this product in the United States. We launched our Petrackr product in May 2023. As a result of these activities our R&D expenditure declined by 60% to A\$4,974,437 during the year ended December 31, 2023, from A\$12,291,750 during the year ended December 31, 2022.

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.

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 taxation services.

Selling, general and administrative expenses increased by 35% to A\$14,879,937 during the year ended December 31, 2023, from A\$10,984,316 during the year ended December 31, 2022 due to an investment in the Company's sales and marketing efforts. The Company now has multiple products in the market compared to the same period in the previous financial year and these products are supported by various marketing campaigns and awareness including sales personnel to support our pipeline of products, webinar series and focused direct marketing campaign.

Interest Income

Interest income increased by 92% during the year ended December 31, 2023, compared to the previous financial year. The increase in interest income is generally attributable to higher interest rates.

Interest Expense

Interest expense relates to interest being charged on the secured short-term borrowing initiated by the Company for the 2023 financial year and the interest expense on finance lease liabilities.

Financing Costs

Disclosed in this account is accretion expense which is associated with the Company's asset retirement obligations ("ARO"). Decrease in financing costs is as a result of change of estimate for the ARO liability.

Research and Development Tax Incentive Income

As of December 31, 2023 the aggregate turnover of the Company for the year ending December 31, 2023 was less than A\$20,000,000 and accordingly an estimated A\$3,774,343 has been recorded as research and development tax incentive income for the year then ended. Offset against this was an overstatement of research and development tax incentive income of A\$278,413 for the year ended December 31, 2022 and as a result the aggregate amount recognized as income is A\$3,495,930 for the year ended December 31, 2023. The decrease year on year is driven by the decrease in eligible research and development expenditure incurred during the year ended December 31, 2023 as compared to the previous financial year.

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

Research and development tax incentive income for the 2023 financial year has not yet been received and as such is recorded in “Research and development tax incentive income” in the consolidated balance sheets as current assets.

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 for the years ended December 31, 2023 and 2022 is as follows:

	Year Ended December 31,	
	2023	2022
	A\$	A\$
Federal and state government subsidies	20,000	42,713
Rental income	153,904	137,219
Other income	2,198	2,054
Sundry income	5,739,912	0
	<u>5,916,014</u>	<u>181,986</u>

Sundry income represents the following:

- Previously accrued marketing support payment of A\$2,896,764 derecognized.
- Previously accrued license fee payable to Siemens of A\$2,214,022 derecognized
- A\$629,126 as a result of change in estimates in ARO liability

Income tax benefit

For the year ended December 31, 2022, an income tax benefit had arisen after the deferred income tax liability was reversed as a result of the impairment of the definite-lived intangible assets.

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 research and development tax incentive income, stock-based compensation expenses and asset retirement obligations:

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

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 of December 31, 2023.

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 subject to 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.

Asset Retirement Obligations

ARO are legal obligations associated with the retirement and removal of long-lived assets. ARO reflects estimates of future costs directly attributable to remediating the liability, inflation, assumptions of risks associated with the future cash outflows, and the applicable risk-free interest rates for discounting future cash outflows. Changes in these factors can result in a change to the ARO recognized by the Company.

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 Cash/(Debt)

Our net cash position for the years ended December 31, 2023 and 2022 is shown below:

	Year Ended December 31,	
	2023	2022
	A\$	A\$
Cash and cash equivalents		
Cash and cash equivalents	10,240,429	25,977,703
Debt		
Short term debt/ loan	911,082	65,768
Net cash	9,329,347	25,911,935

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 Group has experienced net cash outflows over recent periods, predominantly in conducting research & development activities, product approval and registrations, launch of our products and support of the same in the marketplace. We continue to reduce research & development expenditure and other operating expenditure in the foreseeable future and focus on increasing our commercialization efforts. We are closely monitoring the success of our commercialization efforts in relation to the newly launched product portfolio and their impact on our cash position. Given the natural uncertainty that arises with the launch of new products, if we were to experience delays or encounter issues in these commercialization efforts, we would need and expect to adjust our operating expenditure accordingly, to ensure sufficient cash remains available to fund our operations for at least the next twelve months from the date of issuance. We do not have any external long-term debt obligations and are not subject to any covenant obligations.

Management's Discussion and Analysis of Financial Condition and Results of 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. 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 is 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. A financial asset is a non-physical asset whose value is derived from a contractual claim and in our case includes cash and cash equivalents, accounts receivables, fixed deposits and equity shares. There were no impairments recognized as at December 31, 2023 or for the year ended December 31, 2022.

Measures of Liquidity and Capital Resources

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

	Year Ended December 31,	
	2023	2022
	A\$	A\$
Cash and cash equivalents	10,240,429	25,977,703
Working capital	16,053,982	23,586,600
Ratio of current assets to current liabilities	3.70	2.80
Shareholders' equity per common share	0.09	0.12

The movement in cash and cash equivalents and working capital (calculated as current assets less current liabilities) during the years ended December 31, 2023 and 2022 was primarily the result of ongoing investment in our R&D and the general operations of the Company.

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

Summary of Cash Flows

	Year Ended December 31,	
	2023	2022
	A\$	A\$
Cash provided by/(used in):		
Operating activities	(14,619,044)	(14,702,153)
Investing activities	(1,473,367)	(1,565,144)
Financing activities	(82,839)	25,011,276
Net increase/(decrease) in cash, cash equivalents and restricted cash	(16,175,250)	8,743,979

Our net cash used in operating activities for the years ended December 31, 2023 and 2022 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. As our products capture increased market share, we expect our inflows from the receipt from our customers to eventually exceed the cash outflows from operating activities.

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. Included in accounts payable is an amount of A\$35,782 and A\$289,371 for the years ended December 31, 2023 and 2022, respectively for the acquisition of property, plant and equipment.

Our net cash decrease in financing activities for the year ended December 31, 2023 primarily represents repayment of the Canada Emergency Business Account unsecured loan of CAD\$40,000 and transaction costs sustained during our May 2022 capital raise. Our net cash increase in financing activities for the year ended December 31, 2022 is primarily the result of A\$26 million raised pursuant to a A\$20 million fully underwritten rights issue and a A\$6 million placement which occurred in May 2022.

Off-Balance Sheet Arrangement

As of December 31, 2023 and December 31, 2022, 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.

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

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.

Our operations are in Australia, US, Europe and Canada.

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 A\$, US\$, CAD\$ and Euros. The Company is currently using natural hedging to limit currency exposure, however the Company 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, 2023 and 2022. 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 losses of A\$30,177 and A\$115,515 for the years ended December 31, 2023 and 2022, respectively.

Interest Rate Risk

The majority of our investments are in cash and cash equivalents in 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, revenues, income and costs 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, 2023 and 2022, and the related consolidated statements of comprehensive income/(loss), of changes in stockholders' equity and comprehensive income/(loss), and of cash flows for the years then ended, including the related notes (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, 2023, and 2022, 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
Melbourne, Australia
February 29, 2024

We have served as the Company's auditor since 2006

Consolidated Balance Sheets

	December 31,	
	2023	2022
	A\$	A\$
ASSETS		
Current assets:		
Cash and cash equivalents	10,240,429	25,977,703
Inventories	4,377,933	3,142,181
Accounts receivable	2,125,500	974,323
Prepayments	1,200,188	489,800
Restricted cash	35,000	527,148
Research and development tax incentive receivable	3,774,343	4,736,106
Other current assets	249,540	824,870
Total current assets	22,002,933	36,672,131
Non-current assets:		
Property, plant and equipment	32,304,310	31,090,787
Less accumulated depreciation	(27,456,376)	(26,507,419)
Property, plant and equipment - net	4,847,934	4,583,368
Intangible assets	0	16,371,996
Less amortization of intangible assets	0	(5,357,211)
Less impairment of intangible assets	0	(11,014,785)
Intangible assets - net	0	0
Right-of-use asset - operating leases	2,662,885	4,422,303
Right-of-use asset - finance leases	49,074	58,421
Restricted cash	320,000	320,000
Other non-current assets	90,045	88,832
Total non-current assets	7,969,938	9,472,924
Total assets	29,972,871	46,145,055
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	1,240,902	268,074
Accrued expenses	2,056,929	5,888,380
Contingent consideration	0	2,214,022
Other liabilities	0	3,023,767
Contract liabilities	36,132	29,851
Lease liability - operating leases	825,475	755,125
Lease liability - finance leases	9,236	8,814
Employee entitlements liabilities	869,195	831,730
Short-term loan	911,082	65,768
Total current liabilities	5,948,951	13,085,531
Non-current liabilities:		
Asset retirement obligations	1,214,255	2,920,630
Employee entitlements liabilities	76,165	48,273
Lease liability - operating leases	3,179,294	3,943,517
Lease liability - finance leases	46,397	55,633
Total non-current liabilities	4,516,111	6,968,053
Total liabilities	10,465,062	20,053,584
Commitments and contingencies	0	0
Stockholders' equity:		
Preferred stock, US\$0.01 par value. Authorized 1,000,000 shares; issued & outstanding nil at December 31, 2023 (nil at December 31, 2022). Common stock, US\$0.0001 par value. Authorized 300,000,000 shares; issued & outstanding 212,369,435 shares at December 31, 2023 (211,844,435 at December 31, 2022)	21,237	21,184
Additional paid-in capital	119,239,087	119,040,784
Accumulated deficit	(92,678,783)	(65,824,231)
Current year loss	(6,741,564)	(26,854,552)
Accumulated other comprehensive loss	(332,168)	(291,714)
Total stockholders' equity	19,507,809	26,091,471
Total liabilities and stockholders' equity	29,972,871	46,145,055

See accompanying Notes to the Consolidated Financial Statements.

Consolidated Statements of Comprehensive Income/(Loss)

	Year Ended December 31,	
	2023	2022
	A\$	A\$
Revenue		
Revenue from products	5,636,492	3,379,402
Revenue from services	996,346	1,145,560
Total revenue	6,632,838	4,524,962
Operating costs and expenses		
Cost of goods sold	2,032,452	1,386,889
Cost of services	315,449	999,042
Total cost of goods sold and services	2,347,901	2,385,931
Gross profit	4,284,937	2,139,031
Other operating costs and expenses		
Product support	154,609	92,186
Depreciation and amortization	956,275	2,649,671
Impairment of definite-lived intangible assets	-	11,014,785
Research and development	4,974,437	12,291,750
Selling, general and administrative	14,879,937	10,984,316
Total operating costs and expenses	20,965,258	37,032,708
Loss from operations	(16,680,321)	(34,893,677)
Other income/(expense)		
Interest income	734,375	381,597
Interest expense	(20,386)	(18,151)
Financing costs	(156,999)	(199,370)
Research and development tax incentive income	3,495,930	4,757,741
Exchange loss	(30,177)	(115,515)
Other income	5,916,014	181,986
Total other income	9,938,757	4,988,288
Net loss before tax	(6,741,564)	(29,905,389)
Income tax benefit/(expense)	0	3,050,837
Net loss after tax	(6,741,564)	(26,854,552)
Net loss per share		
Net loss per share - basic and diluted	(0.03)	(0.14)
Average weighted number of shares - basic and diluted	212,369,435	198,724,910
Other comprehensive gain/(loss), net of tax:		
Foreign currency translation reserve	(40,454)	31,574
Other comprehensive income/(loss)	(40,454)	31,574
Comprehensive income/(loss)	(6,782,018)	(26,822,978)

See accompanying Notes to the Consolidated Financial Statements.

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

Year Ended December 31, 2023

	Ordinary shares		Additional paid-in capital	Accumulated deficit	Other comprehensive income/ (loss)	Total stockholders' equity
	Shares	Amount				
	A\$	A\$				
Balances at January 1, 2023	211,844,435	21,184	119,040,784	(92,678,783)	(291,714)	26,091,471
Net loss	0	0	0	(6,741,564)	0	(6,741,564)
Other comprehensive loss	0	0	0	0	(40,454)	(40,454)
Performance awards and exercise of stock options issued to employees	525,000	53	(53)	0	0	0
Stock-based compensation expense	0	0	198,356	0	0	198,356
Balances at December 31, 2023	212,369,435	21,237	119,239,087	(99,420,347)	(332,168)	19,507,809

Year Ended December 31, 2022

	Ordinary shares		Additional paid-in capital	Accumulated deficit	Other comprehensive income/ (loss)	Total stockholders' equity
	Shares	Amount				
	A\$	A\$				
Balances at January 1, 2022	177,828,504	17,783	93,737,565	(65,824,231)	(323,288)	27,607,829
Net loss	0	0	0	(26,854,552)	0	(26,854,552)
Issuance of common stock at A\$0.77 per share, net of issuance costs	33,775,931	3,377	24,728,289	0	0	24,731,666
Other comprehensive income	0	0	0	0	31,574	31,574
Performance awards and exercise of stock options issued to employees	240,000	24	43,876	0	0	43,900
Stock-based compensation expense	0	0	319,402	0	0	319,402
Capitalized stock-based compensation	0	0	211,652	0	0	211,652
Balances at December 31, 2022	211,844,435	21,184	119,040,784	(92,678,783)	(291,714)	26,091,471

See accompanying Notes to the Consolidated Financial Statements.

Universal Biosensors, Inc.
Notes to Consolidated Financial Statements

Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2023	2022
	A\$	A\$
Cash flows from operating activities:		
Net loss	(6,741,564)	(26,854,552)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	969,671	2,785,635
Impairment of definite-lived intangible assets	0	11,014,785
Stock-based compensation expense	198,356	319,402
Non-cash lease expense	57,814	160,321
Unrealized foreign exchange losses	28,046	159,175
Change in assets and liabilities:		
Other liabilities	(5,739,912)	0
Inventories	(1,235,752)	(998,677)
Accounts receivable	(1,176,493)	(472,844)
Prepayments and other assets	310,100	(1,107,213)
Other non-current assets	(1,214)	(50,410)
Contract liabilities	31,598	(33,895)
Employee entitlements	65,357	180,440
Accounts payable and accrued expenses	(1,385,051)	195,680
Net cash used in operating activities	<u>(14,619,044)</u>	<u>(14,702,153)</u>
Cash flows from investing activities:		
Purchases of property, plant and equipment	(1,473,367)	(1,565,144)
Net cash used in investing activities	<u>(1,473,367)</u>	<u>(1,565,144)</u>
Cash flows from financing activities:		
Proceeds from borrowings	1,056,059	1,002,404
Repayment of borrowings	(1,100,504)	(1,002,404)
Proceeds from issuance of common stock, net of issuance costs	(29,580)	24,972,897
Other	(8,814)	38,379
Net cash (used in)/provided by financing activities	<u>(82,839)</u>	<u>25,011,276</u>
Net decrease in cash, cash equivalents and restricted cash	(16,175,250)	8,743,979
Cash, cash equivalents and restricted cash at beginning of period	26,824,851	18,099,219
Effect of exchange rate fluctuations on the balances of cash held in foreign currencies	(54,172)	(18,347)
Cash, cash equivalents and restricted cash at end of period	<u><u>10,595,429</u></u>	<u><u>26,824,851</u></u>

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 or through reduction of costs. 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, impairment of definite-lived intangible assets 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, 2023. There were no new material accounting standards issued in 2023 that impacted the Company with the exception of the following:

- In December 2023, the FASB issued ASU No. 2023-09, Improvements to Income Tax Disclosures, which requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. The standard is intended to benefit investors by providing more detailed income tax disclosures that would be useful in making capital allocation decisions. The amendments in this ASU are effective for annual periods beginning on January 1, 2025, and should be applied on a prospective basis with the option to apply the standard retrospectively. Early adoption is permitted. This ASU will have no impact on the Company's consolidated financial condition or results of operations. The Company is currently evaluating the impact to its income tax disclosures.
- In November 2023, the FASB issued ASU No. 2023-07, Improvements to Reportable Segment Disclosures, which improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. In addition, the amendments enhance interim disclosure requirements, clarify circumstances in which an entity can disclose multiple segment measures of profit or loss, provide new segment disclosure requirements for entities with a single reportable segment, and contain other disclosure requirements. The purpose of the amendments is to enable investors to better understand an entity's overall performance and assess potential future cash flows. For public business entities, the amendments in this ASU are effective for annual periods beginning on January 1, 2024 and interim periods beginning on January 1, 2025, and should be applied on a retrospective basis for all periods presented. For entities other than public business entities, the ASU is effective for annual periods beginning after December 15, 2025. This ASU will have no impact on the Company's consolidated financial condition or results of operations. The Company is currently evaluating the impact to its segment disclosures.

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 A\$ for all years presented. The functional currencies of UBS LLC, HRL and UBS BV are US\$, CAD\$ and €, respectively, for all years presented.

Universal Biosensors, Inc.
Notes to Consolidated Financial Statements

The consolidated financial statements are presented using a reporting currency of A\$.

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, 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 collateral for facilities.

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 sheets 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.

Universal Biosensors, Inc.
Notes to Consolidated Financial Statements

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.

Other Current Assets

The Company's other current assets are primarily represented by sundry receivables.

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 long-lived assets, including property, plant and equipment and definite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss is recognized when the undiscounted future cash flows expected to result from the use of the asset is less than the carrying amount of the asset. Accordingly, we recognise an impairment loss based on the excess of the carrying value amount over the fair value of the asset.

Australian Goods and Services Tax, Canadian Harmonized Sales Tax, US Sales Tax and European Value Added Tax, 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

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. 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 twelve 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 and finance lease liabilities are classified as lease liabilities in the Company's consolidated balance sheets.

Universal Biosensors, Inc.
Notes to Consolidated Financial Statements

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 or finance 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 is incurred.

Asset Retirement Obligations

Asset retirement obligations 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 analyzers and test strips and the provision of laboratory 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.

<i>Products and services</i>	<i>Nature, timing of satisfaction of performance obligations and significant payment terms</i>
Coagulation testing products (“Xprecia”)	Our point-of-care coagulation testing products use electrochemical cell technology 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.
Laboratory testing services	HRL provides non-diagnostic laboratory services and performs these 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.
Wine testing products (“Sentia”)	Our Sentia wine analyzer is used to measure Free SO ₂ , Malic Acid, Glucose, Fructose, Total Sugar, Acetic Acid and Titratable Acidity levels in 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.
Veterinary diabetes product (“Petrackr”)	Our veterinary blood glucose product, Petrackr, is a blood glucose monitoring product for dogs and cats with diabetes. 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.

Universal Biosensors, Inc.
Notes to Consolidated Financial Statements

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 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 involved in eligible research and development ("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\$3,495,930 and A\$4,757,741 for the 2023 and 2022 financial year, respectively as the aggregated turnover of the Company did not exceed A\$20,000,000.

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.

Universal Biosensors, Inc.
Notes to Consolidated Financial Statements

Employee Benefit Costs

The Company contributes a portion of each employee's salary to standard defined contribution superannuation funds on behalf of all eligible UBS employees in line with legislative requirements. The contribution rate increased from 9.50% to 10.0% for the period commencing July 1, 2021 and increased to 10.5% on July 1, 2022 and 11.0% on July 1, 2023. 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 with 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.

401k Plan

The Company acts as a plan sponsor for a 401k plan for eligible UBS LLC employees. A 401k plan is a US-based defined-contribution pension account into which the employees can elect to have a percentage of their salary deducted and contributed to the plan. Their contributions are matched by the Company up to a maximum of 10% of their salary.

Employee Entitlements Liabilities

Employee entitlements to annual leave and long service leave are recognized when they accrue to employees. A provision is made for the estimated liability for annual leave and long-service leave as a result of services rendered by employees up to the balance sheet date.

Income Taxes

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

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

Pursuant to the 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.

Universal Biosensors, Inc.
Notes to Consolidated Financial Statements

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,	
	2023	2022
	A\$	A\$
Cash and cash equivalents	10,240,429	25,977,703
Restricted cash – current assets	35,000	527,148
Restricted cash – non-current assets	320,000	320,000
	<u>10,595,429</u>	<u>26,824,851</u>

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

	December 31,	
	2023	2022
	A\$	A\$
Performance guarantee (a) - current assets	0	527,148
Collateral for facilities (b) - current assets	35,000	0
Collateral for facilities (b) - non-current assets	320,000	320,000
	<u>355,000</u>	<u>847,148</u>

(a) The performance guarantee represented letter of credit issued in favour of Siemens pursuant to the 2019 Siemens Agreements expired on March 2023.

(b) Collateral for facilities represents letter of credit for A\$35,000 issued in favour of American Express Australia Ltd (current), bank guarantee of A\$250,000 for commercial lease of UBS' premises (non-current) and security deposit on Company's credit cards of A\$70,000 (non-current).

Interest earned on the restricted cash for years ended December 31, 2023 and 2022 was A\$14,347 and A\$27,534 respectively.

3. Inventories

	December 31,	
	2023	2022
	A\$	A\$
Raw materials	261,753	1,758,073
Work in progress	273,965	646,161
Finished goods	3,842,215	737,947
	<u>4,377,933</u>	<u>3,142,181</u>

4. Receivables

	December 31,	
	2023	2022
	A\$	A\$
Accounts receivable	2,125,500	974,323
Allowance for credit losses	0	0
	<u>2,125,500</u>	<u>974,323</u>

5. Property, Plant and Equipment

	December 31,	
	2023	2022
	A\$	A\$
Plant and equipment	22,962,369	21,543,134
Leasehold improvements	9,341,941	9,341,612
Capital work in process	0	206,041
	32,304,310	31,090,787
Accumulated depreciation	(27,456,376)	(26,507,419)
Property, plant & equipment - net	<u>4,847,934</u>	<u>4,583,368</u>

Universal Biosensors, Inc.
Notes to Consolidated Financial Statements

6. Leases

The Company's lease portfolio consists primarily of operating leases for office space and equipment with contractual terms expiring from December 2025 to February 2032. Lease contracts may include one or more renewal options that allow the Company to extend the lease term. 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 and Canada.

	December 31,	
	2023	2022
	A\$	A\$
Operating lease right-of-use assets:		
Non-current	2,662,885	4,422,303
Operating lease liabilities:		
Current	825,475	755,125
Non-current	3,179,294	3,943,517
Weighted average remaining lease terms (in years)	6.3	6.9
Weighted average discount rate	4.8%	4.8%

The components of lease income/expense were as follows:

	Year Ended December 31,	
	2023	2022
	A\$	A\$
Fixed payment operating lease expense	805,481	965,224
Short-term lease expense	0	3,262
Sub-lease income	133,900	137,219

The sublease income is 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:

	Year Ended December 31,	
	2023	2022
	A\$	A\$
Cost of goods sold	0	107,140
Cost of services	39,601	147,558
Research and development	138,340	273,823
Selling, general and administrative	627,540	436,703
	805,481	965,224

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

	Year Ended December 31,	
	2023	2022
	A\$	A\$
Operating cash outflows from operating leases	979,387	831,685

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

	Year Ended December 31,	
	2023	2022
	A\$	A\$
Right-of-use assets obtained in exchange for lease liabilities	28,353	3,023,907
Right-of-use asset modifications	0	0

Universal Biosensors, Inc.
Notes to Consolidated Financial Statements

Future lease payments are as follows:

	December 31, 2023
	A\$
1 year	488,262
2 years	998,418
3 years	1,022,251
4 years	407,413
5 years	416,427
Thereafter	1,807,808
Total future lease payments	5,140,579
Less: imputed interest	(1,135,810)
Total operating lease liabilities	4,004,769
Current	825,475
Non-current	3,179,294

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 January 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, 2023, the Company has not entered into any operating or finance 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:

	Year Ended December 31,			
	2023		2022	
	A\$	%	A\$	%
Loss before income taxes	(6,741,564)		(29,905,389)	
Computed by applying income tax rate of home jurisdiction	(1,685,391)	25	(7,476,347)	25
Effect of tax rates in foreign jurisdictions	300,584	(4)	200,505	(1)
Research and development tax incentive	1,225,577	(18)	1,257,265	(4)
Disallowed expenses/(income):				
Stock-based compensation	49,575	(1)	132,763	(0)
Amortization	0	0	2,344,621	(8)
Other	735,257	(11)	150,633	(1)
Change in valuation allowance	(625,602)	9	339,723	(1)
Income tax expense/(benefit)	0	(0)	(3,050,837)	10

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

	Year Ended December 31,	
	2023	2022
	A\$	A\$
Foreign	(4,204,348)	(3,653,169)
Domestic	(2,537,216)	(26,252,220)
	(6,741,564)	(29,905,389)

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Deferred Tax Assets and Liabilities

	Year Ended December 31,	
	2023	2022
	A\$	A\$
Deferred tax assets:		
Operating loss carry forwards	7,645,509	6,055,726
Depreciation and amortization	1,157,004	1,115,812
Asset retirement obligations	303,564	730,157
Employee entitlements	224,890	206,747
Accruals	268,214	2,056,550
Decline in value of patents	835,173	875,496
Unrealized exchange loss	116,259	34,875
Total deferred tax assets	10,550,613	11,075,363
Valuation allowance for deferred tax assets	(10,403,122)	(11,028,724)
Net deferred tax asset	147,491	46,639
Deferred tax liabilities:		
Other	147,491	46,639
Total deferred tax liabilities	147,491	46,639
Net deferred tax liabilities	0	0

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

At December 31, 2023 the Company has A\$30,582,036 (A\$24,222,902 as at December 31, 2022) 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, 2022) of non-refundable R&D tax offset as at December 31, 2023. 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.

A reconciliation of the valuation and qualifying accounts is as follows:

	Balance at Beginning of Period A\$	Additions A\$	Deductions A\$	Balance at end of Period A\$
Year ended December 31, 2023				
Deferred income tax valuation allowance	11,028,724	(625,602)	0	10,403,122
Year ended December 31, 2022				
Deferred income tax valuation allowance	10,689,001	339,723	0	11,028,724

8. Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2023	2022
	A\$	A\$
Legal, tax and accounting fees	443,833	527,523
Salary and related costs	663,978	387,047
Research and development costs	319,193	3,586,251
Patent fees	47,484	421,759
Inventory purchases	102,458	345,563
Legal, tax and accounting fees	443,833	527,523
Salary and related costs	663,978	387,047
Research and development costs	319,193	3,586,251
Patent fees	47,484	421,759
Inventory purchases	102,458	345,563
Sample collection site costs	148,741	135,373
Calibration costs	51,247	3,897
Public company costs	40,204	8,416
Freight	36,977	66,405
Royalties	35,775	0
Travel	32,329	2,953
Product design costs	22,420	19,724
Consultants	19,873	38,396
Warehouse expenses	17,554	5,664
Other	74,863	339,409
	2,056,929	5,888,380

9. Contingent Consideration

Pursuant to the Siemens Acquisition and the agreement dated September 2019, the Company had agreed to pay US\$1,500,000 (equivalent to A\$2,214,022) to Siemens within five days of Siemens achieving a pre-defined milestone. In an agreement dated June 2023 between Siemens and the Company, the Company is no longer required to pay this amount and therefore have measured the fair value of this liability as nil. This amount has been recognized as Other Income in the consolidated condensed statements of comprehensive income/(loss). See note 13 for further details.

10. Other Liabilities

Other liabilities represent a marketing support payment due to a third party and is payable in US dollars once supporting documentation has been provided to the Company. This amount has been long outstanding and was derecognized as at June 30, 2023 as supporting documentation has not been provided to the Company. This amount has been recognized as Other Income in the consolidated condensed statements of comprehensive income/(loss). See note 13 for further details.

11. Short-Term Loan

The unsecured loan was 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 was 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, 2023;
- if the Company chooses to repay at least CAD\$40,000 of the loan by December 31, 2023, the remaining balance will be forgiven;
- if the loan is not repaid by the above mentioned date, it will be converted into a 2-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 2-year term, the entire balance of the loan is due for repayment by December 31, 2025.

In December 2023, the Company repaid CDN\$40,000 of the loan and pursuant to the terms of the loan, the remaining CDN\$20,000 has been forgiven.

In January 2023, UBS entered into an arrangement with BOQF Cashflow Finance Pty Ltd to fund the Group's 2023 insurance premium. The total amount financed was A\$1,056,059 at inception and the short-term borrowing was fully repaid in September 2023. Interest was charged at an effective annual interest rate of 1.99%. The short-term borrowing was secured by proceeds of or payable under any insurance including proceeds or refunds from the cancellation or termination of any insurance.

In December 2023 the Company entered into a short-term loan facility to finance its 2024 Insurance Premium. The total amount available and drawn down under the facility is \$911,082. The facility is repayable in nine monthly instalments which commenced in January 2024 and has an effective annual interest rate of 1.99%. The short-term borrowing is secured by proceeds of or payable under any insurance including proceeds or refunds from the cancellation or termination of any insurance.

12. Revenue

Disaggregation of Revenue

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

	Year Ended December 31,	
	2023	2022
	A\$	A\$
Major product/service lines		
Coagulation testing products	2,607,506	2,366,331
Laboratory testing services	996,346	1,145,560
Wine testing products	2,528,666	1,013,071
Veterinary diabetes products	500,320	0
	<u>6,632,838</u>	<u>4,524,962</u>
Timing of revenue recognition		
Products and services transferred at a point in time	<u>6,632,838</u>	<u>4,524,962</u>

Contract Balances

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

	Year Ended December 31,	
	2023	2022
	A\$	A\$
Receivables	2,125,500	974,323
Contract liabilities	36,132	29,851

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.

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

	Year Ended December 31,	
	2023	2022
	A\$	A\$
Contract Liabilities - current		
Opening balance	29,851	38,431
Closing balance	36,132	29,851
Net increase/(decrease)	6,281	(8,580)

The Company expects all of the Company's contract liabilities to be realized by December 31, 2024.

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:

	Year Ended December 31,	
	2023	2022
	A\$	A\$
Federal and state government subsidies	20,000	42,713
Rental income	153,904	137,219
Other income	2,198	2,054
Sundry income	5,739,912	0
	5,916,014	181,986

Sundry income represents the following:

- Previously accrued marketing support payment of A\$2,896,764 derecognized
- Previously accrued license fee payable to Siemens of A\$2,214,022 derecognized
- A\$629,126 as a result of change in estimates in ARO liability

ARO reflects estimates of future costs directly attributable to remediating the liability, inflation, assumptions of risks associated with the future cash outflows, and the applicable risk-free interest rates for discounting future cash outflows. Changes in these factors can result in a change to the ARO recognized by the Company. As a result of a change in estimates of future costs, the Company's ARO liability decreased to A\$1,182,218 as at September 1, 2023 resulting in A\$629,126 recorded as Other Income in the consolidated condensed statements of comprehensive income/(loss).

14. Equity Incentive Schemes

In 2004, the Company adopted an employee option plan which was subsequently replaced in 2021 by the Equity Incentive Plan ("the Equity Incentive Plan") to cater for awards including options, performance rights, CDIs and restricted CDIs.

There were no securities awarded during the 2023 financial year pursuant to the Equity Incentive Plan. During the year ended December 31, 2022, the Company issued shares as a short-term incentive plan 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.

During the year ended December 31, 2022, the Company issued to Viburnum Funds Pty Ltd ("Viburnum") in connection with the Entitlement Offer, unlisted options to purchase 3,840,000 ordinary shares in two tranches. Refer to Note 18 for more details.

At December 31, 2023, total stock compensation expense recognized in the consolidated statements of comprehensive income/(loss) was A\$198,356 (2022: A\$319,402). A\$142,130 of the stock compensation expense as of December 31, 2023 has been recorded in selling, general and administrative expenses and the balance in research and development expenses.

(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.

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

The number of options granted pursuant to the Equity Incentive Plan in 2023 and 2022 were nil.

The number of options granted to parties other than those granted pursuant to the Equity Incentive Plan in 2023 and 2022 were nil and 3,840,000, respectively. See Note 18 to the Consolidated Financial Statements for details on the options granted to Viburnum.

Stock option activity during the current period is as follows:

	Number of options	Weighted average exercise price A\$
Balance at December 31, 2022	12,406,300	0.49
Lapsed	(756,000)	0.49
Balance at December 31, 2023	<u>11,650,300</u>	<u>0.49</u>

At December 31, 2023, the number of options vested and exercisable was 11,650,300 (2022: 12,406,300). At December 31, 2023 and 2022, total stock compensation expense for options recognized in the consolidated statements of comprehensive income/(loss) was nil.

The following table represents information relating to stock options outstanding under the plans as of December 31, 2023:

Exercise price A\$	Options	Weighted average remaining life in years	Options exercisable shares
0.50	216,300	0	216,300
0.20	2,364,666	0	2,364,666
0.25	2,364,667	1	2,364,667
0.30	2,364,667	1	2,364,667
0.30	500,000	1	500,000
0.92	1,920,000	1	1,920,000
1.00	1,920,000	1	1,920,000
	<u>11,650,300</u>		<u>11,650,300</u>

The table below sets forth the number of employee stock options exercised and the number of shares issued in the period from January 1, 2022. 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\$
2023	0	0.00	0
2022	90,000	0.49	43,900

As of December 31, 2023, there was no unrecognized compensation expense (2022: 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 2023 and 2022.

(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.

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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 2023 was 525,000 (2022: up to 1,555,555).

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:

	Oct-22	Nov-22
Exercise price A\$	0	0
Share price at grant date A\$	0.25	0.25
Volatility	66%	67%
Maximum life (years)	2.47	1.19
Risk-free interest rate	3.19%	3.16%
Fair value A\$	0.25	0.25

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, 2022	8,830,000	0.00
Issued as common stock	(525,000)	0.00
Lapsed	(805,000)	0.00
Balance at December 31, 2023	7,500,000	0.00

At December 31, 2022, there were 525,000 performance rights which vested and these performance rights were issued as common stock in January 2023. 805,000 performance rights granted in 2022 lapsed as the Company did not achieve the predetermined market and non-market conditions in 2023. At December 31, 2023, total stock compensation expense for performance rights recognized in the consolidated statements of comprehensive income/(loss) was A\$198,356 (2022: A\$319,402).

The following table represents information relating to the maximum quantity of performance rights outstanding under the plans as of December 31, 2023:

Exercise price A\$	Rights	Weighted average remaining life in years	Rights exercisable shares
0	7,500,000	1	0

As of December 31, 2023, there was unrecognized compensation expense of up to A\$5,158,773 (2022: A\$5,357,072). 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, 2023 would be recognized.

Universal Biosensors, Inc.
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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:

	<u>Before-Tax Amount</u>	<u>Tax (Expense)/ Benefit</u>	<u>Net-of-Tax Amount</u>
	A\$	A\$	A\$
Year Ended December 31, 2023			
Foreign currency translation reserve	(40,454)	0	(40,454)
Other comprehensive loss	(40,454)	0	(40,454)
Year Ended December 31, 2022			
Foreign currency translation reserve	31,574	0	31,574
Other comprehensive gain	31,574	0	31,574

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 Depository Interests ("CDIs"). Each CDI represents beneficial ownership in one underlying share. Legal title to the shares underlying CDIs is held by CHESS Depository Nominees Pty Ltd ("CDN"), a wholly owned subsidiary of ASX.

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

17. Net Loss per Share

The following table shows the computation of basic and diluted loss per share for 2023 and 2022:

	<u>Year Ended December 31,</u>	
	<u>2023</u>	<u>2022</u>
	A\$	A\$
Numerator:		
Net loss	(6,741,564)	(26,854,552)
Denominator:		
Weighted-average basic and diluted shares	212,369,435	198,724,910
Basic and diluted loss per share	(0.03)	(0.14)

The number of shares not included in the calculation of basic net loss per ordinary share because the impact would be anti-dilutive were 4,729,333 and 7,629,000 for the years ended December 31, 2023 and 2022, 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 Director of the Company and an Executive Chairman and Associate of Viburnum Funds Pty Ltd ("Viburnum"). Viburnum, as an investment manager for its associated funds, holds a beneficial interest and voting power over approximately 26% of UBI's shares.

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On April 20, 2022, the Company announced a fully underwritten non-renounceable rights issue of new CHESSE depositary interests over fully paid ordinary shares in UBI ("New CDIs") to raise approximately A\$20.00 million ("Entitlement Offer") at a ratio of 1 New CDI for every 6.85 existing CDIs held at the record date, being April 27, 2022.

In connection with the Entitlement Offer, on April 19, 2022, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Viburnum (the "Underwriter"). Pursuant to the terms of the Underwriting Agreement, the Underwriter agreed to take up its full entitlement under the Entitlement Offer and fully underwrite the Entitlement Offer, which meant that the Underwriter agreed to subscribe for or procure others to subscribe for all securities (if any) not subscribed for by the Company's eligible securityholders under the Entitlement Offer. Following the close of the Entitlement Offer, 25.9 million New CDIs were issued to Viburnum on May 27, 2022, which raised approximately A\$19.94 million.

The Company also agreed, subject to the approval of the stockholders of the Company, to issue to the Underwriter (or its nominee) unlisted options to purchase up to 3,840,000 ordinary shares, in two tranches, as its underwriting fee (the "Underwriter Options") in lieu of cash compensation. The Underwriter Options vested upon issue on May 27, 2022 and have an expiry date of 3 years from their date of issue. The exercise price in respect of half of the Underwriter Options is an amount equal to 120% of the Offer Price, or A\$0.92. The second half of the Underwriter Options have an exercise price equal to 130% of the Offer Price, or A\$1.00. The stockholders of the Company approved the issuance of the Underwriter Options at a special meeting of stockholders held on May 23, 2022.

In accordance with ASC 718, the fair value of the Underwriter Options granted were estimated at the date of the grant using the Trinomial Lattice mode. The key assumptions for the grant were:

	Tranche 1	Tranche 2
Exercise Price (\$A)	0.92	1.00
Share Price at Grant Date (A\$)	0.44	0.44
Volatility	64%	64%
Maximum Life (years)	3.00	3.00
Risk-Free Interest rate	2.78%	2.78%
Fair Value (A\$)	0.06	0.05

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.

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.

On May 27, 2022, Viburnum acquired from a member of management, unlisted options to purchase up to 1,000,000 ordinary shares. The options fully vested on March 25, 2020, have an exercise price of \$A0.20 and have an expiry date of March 24, 2024.

There were no material related party transactions or balances as at December 31, 2023 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, 2023 and December 31, 2022. Purchase commitments are entered into with various parties to purchase products and services such as equipment, technology and consumables used in R&D and commercial activities. Purchase commitments contracted for as at December 31, 2023 and December 31, 2022 were A\$3,484,474 and A\$6,581,876, 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.

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Our operations are in Australia, US, Europe and Canada. 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 (excluding sundry income) as disclosed in the Consolidated Statements of Comprehensive Income/(Loss).

	Year Ended December 31,	
	2023	2022
	A\$	A\$
Australia (home country)	4,823,076	4,978,712
Americas	1,913,892	1,387,556
Europe	2,295,455	2,841,678
Other	2,006,822	150,082
	11,039,245	9,358,028

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

	Year Ended December 31,	
	2023	2022
	A\$	A\$
Siemens	0%	13%
Other	100%	87%

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".

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.