



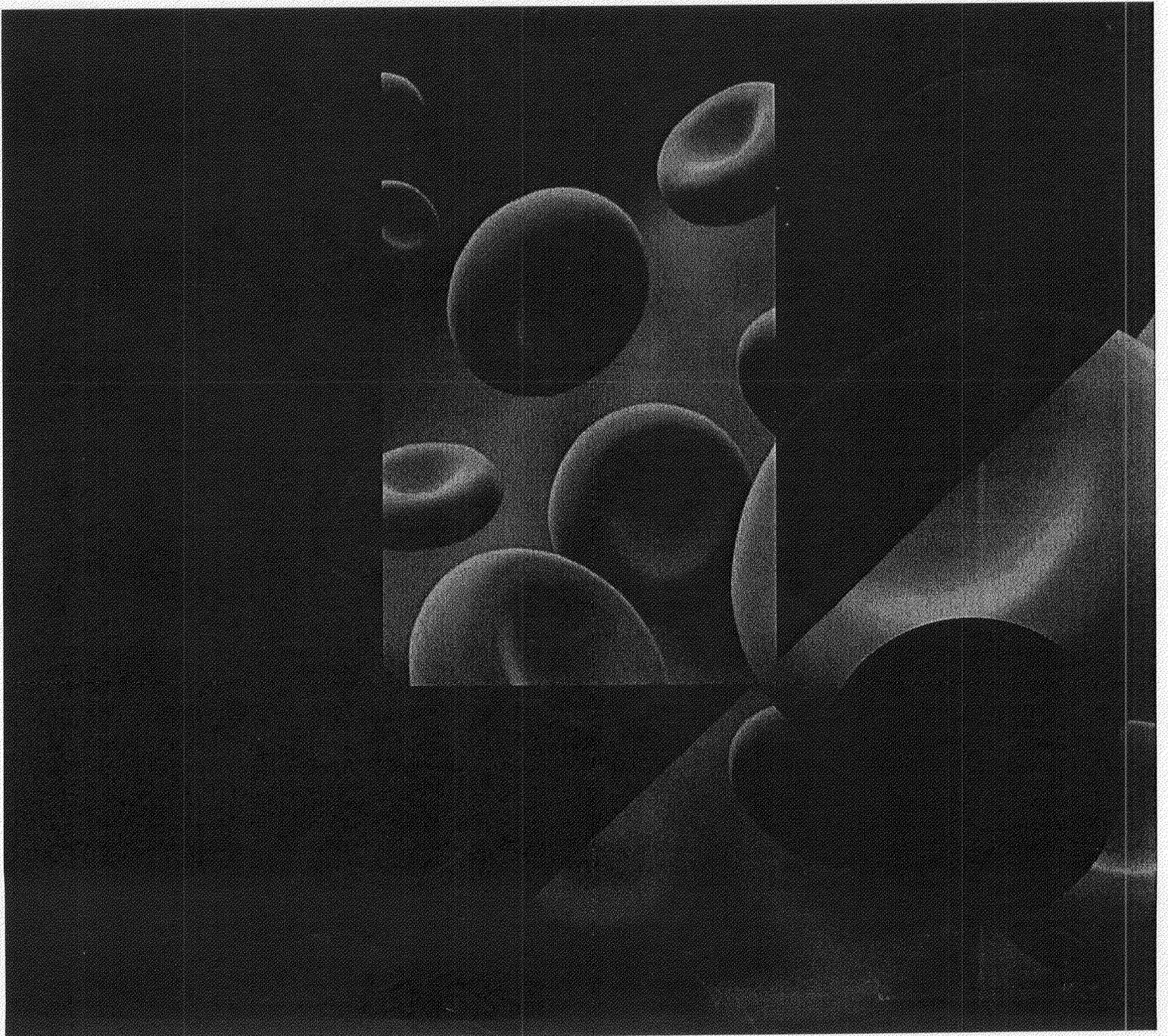
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Universal Biosensors

# Annual Report

Universal Biosensors, Inc.  
Annual Report for the Year Ended December 31, 2011



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## Chairman's Letter

2011 has been a transitional year for UBI as it moved from a technology start-up company to a company whose technology platform has been validated through the launch of LifeScan's OneTouch® Verio™ blood glucose product across Australia, Europe and North America, and the formation of a strategic partnership with Siemens Healthcare Diagnostics, Inc. for the development and commercialisation of products for the point-of-care coagulation testing market.

Our world class capabilities have again been validated by entering into a further agreement with LifeScan for the development of what will hopefully be their next generation of products for the diabetes market.

Over 2011 the company has significantly reduced the technical risk of the products it is developing through the hard work of our devoted management and staff.

I remain disappointed that the company's share price has not in my view reflected the value created by the company achieving significant commercial and technical milestones and does not in my view reflect the inherent value in the company.

The company and its management are focused on maximizing value to shareholders and will be striving to do this.

I would like to thank the Board and the entire UBI team for their efforts during the 2011 financial year and thank you, our shareholders for your continued support of our company.

Yours faithfully

**Andrew Denver**  
Chairman



## CEO Report

2011 was an important year in the ongoing transition of UBI from technology innovator to commercial enterprise. UBI's blood glucose testing technology is now being sold in all major world markets under the OneTouch® Verio™ brand by LifeScan and a new worldwide partnership is in place with Siemens for point-of-care coagulation testing. We ended the year with a solid cash balance, growing product volumes and exciting new opportunities ahead.

2011 was a year of great progress in the development of the UBI business as we continued to execute against important elements of our strategy.

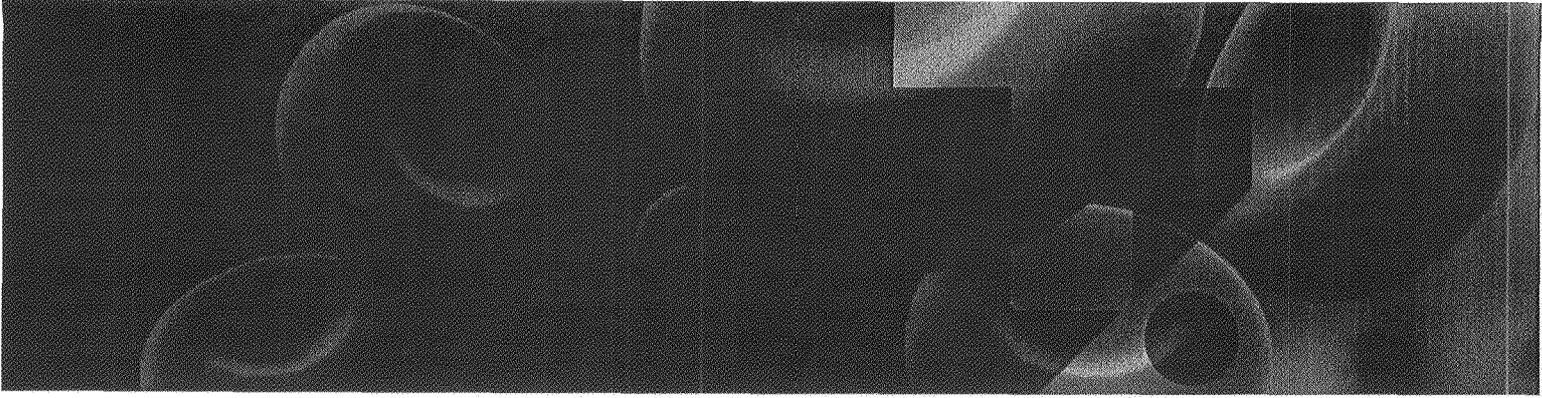
LifeScan continued to demonstrate commitment to the Verio technology with the continued roll-out of the OneTouch Verio across Australia, Europe and North America. With global strip sales accelerating, LifeScan continues to invest in the development of new meter technology to complement the UBI test strip and ensure that their customers receive the features and benefits they are looking for. Looking beyond Verio, 2011 also saw the start of an exciting new R&D initiative with LifeScan that demonstrates UBI's potential as a source of breakthrough innovation in glucose testing.

2011 also saw UBI step beyond the diabetes market with the signing of an important new partnership with Siemens Healthcare Diagnostics – the world leader in diagnostics and coagulation testing in particular. The culmination of an intensive business development effort, UBI is delighted to have partnered with Siemens in the area of point-of-care coagulation testing worldwide. A strong business and technical relationship has already been developed with collaborative R&D activity underway on several fronts. This major step forward for UBI further validates our technology, our business model and our capabilities.

The diabetes-focused part of our business delivered a positive gross margin to UBI in 2011, while we continued to invest R&D resources in developing the coagulation testing products and new platform technologies that will underpin future earnings. Our financial performance in 2011 reflected the volatility inherent in the early stages of a new product launch

with quarterly product revenues fluctuating significantly. We ended the year with a solid fourth quarter of manufacturing volume, taking us out of the interim costing arrangement with LifeScan and into profitable manufacturing. Although LifeScan have begun to manufacture Verio strips in their Inverness facility, we expect that UBI's manufacturing volumes in 2012 will nevertheless increase over 2011 levels, reflecting the growing demand for the OneTouch Verio product. 2011 Service Revenues were down on 2010 due to a slow down in R&D projects during the first part of the year, but the new technology feasibility program with LifeScan will see a return to historical levels. Against this backdrop, the company ended the year with a solid cash balance and the prospect of improved Verio-based revenues, and R&D milestone payments in 2012.

As we look to the future, we continue to see exciting opportunities in the point-of-care diagnostics field. There are two primary customer needs that are satisfied by point-of-care diagnostics. Firstly, the need for rapid diagnosis to support a timely medical intervention and, secondly, the improved convenience required to conduct frequent testing to monitor or manage a chronic disease or an ongoing therapy. The emergence of new, cost-effective technologies that support these needs is fuelling the growth of the point-of-care market which is projected to grow at double digit rates for the foreseeable future. Leading diagnostics companies are embracing the potential of point-of-care diagnostics, which has been an area of high corporate activity internationally, and significant investment is being made across the globe to find appropriate technology solutions. We believe that UBI has an important role to play in this field.



Against this backdrop, it is important that UBI continues to invest its limited resources in the science, engineering and business process that will drive and accelerate our future product revenues. Looking ahead, UBI will continue to pursue the rapid exploitation of our platform electrochemical sensor technology. In partnering with Siemens, UBI has retained its rights to pursue the emerging market for patient self-testing of PT-INR. In 2012, we will look to leverage the investment we have already made in PT-INR testing in this growth market. In addition to the important development work we are undertaking with LifeScan and Siemens, our internal R&D focus for 2012 will be on demonstrating our immunoassay testing capability, and further developing our concepts for a point-of-care molecular diagnostics product. These are important initiatives that will broaden the range of potential tests that can be performed using our sensors.

In summary, 2012 will see UBI:

- begin to benefit from continued growth in Verio manufacturing volumes and quarterly service fees from market expansion and accelerating Verio sales
- continue to innovate in partnership with LifeScan, delivering on our \$4.5M new technology feasibility program
- deliver on our first milestones in creating world-leading point-of-care coagulation testing products with Siemens
- advance our plans for entering the PT-INR patient self-test market
- achieve important technical milestones in broadening our immunoassay and molecular capabilities

2011 was an important year for UBI, in which the company delivered on a range of key commercial milestones. I believe 2012 will be another exciting year for the team at UBI as we continue our transition from innovative R&D organisation to commercial success story.

Yours faithfully



**Paul Wright**  
Chief Executive Officer

Form 10-K

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, 2011

OR

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

Commission File Number: 000-52607

Universal Biosensors, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of  
incorporation or organization)

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

Australia

(Address of principal  
executive offices)

98-0424072

(I.R.S. Employer  
Identification Number)

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:

Name of each exchange on which registered

Title of each class

None

Not applicable

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

Title of each class

Shares of common stock, par value US\$0.0001

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act: Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

The approximate aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant was A\$85,662,946 (equivalent to US\$91,993,437) as of June 30, 2011.

The number of shares outstanding of each of the registrant's classes of common stock as of March 6, 2012:

Title of Class	Number of Shares
Common Stock, US\$.0001 par value	159,146,213

Documents incorporated by reference:

Certain information contained in the registrant's definitive Proxy Statement for the 2011 annual meetings of stockholders, to be filed not later than 120 days after the end of the fiscal year covered by this report, is incorporated by reference into Part III hereof.

Information contained on pages F-2 through F-36 of our Annual Report to Stockholders for the fiscal year ended December 31, 2011 is incorporated by reference in our response to Items 7, 7A, 8 and 9A of Part II.

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Unless otherwise noted, references on this Form 10-K to "Universal Biosensors" the "Company," "Group," "we," "our" or "us" means Universal Biosensors, Inc. a Delaware corporation and, when applicable, its wholly owned Australian operating subsidiary, Universal Biosensors Pty Ltd. Our principal place of business is located at 1 Corporate Avenue, Rowville, Victoria 3178, Australia. Our telephone number is +61 3 9213 9000. Unless otherwise noted, all references in this Form 10-K to "\$", "A\$" or "dollars" and dollar amounts are references to Australian dollars. References to "US\$" are references to United States dollars.

## FORWARD-LOOKING STATEMENTS

This Form 10-K contains forward-looking statements that involve known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. All statements, other than statements of historical facts, are forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our business and product development strategies;
- our expectations with respect to corporate collaborations or strategic alliances;
- 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, approvals, 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 and our need for additional financing.

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

## PART I

### ITEM 1. BUSINESS.

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

#### **Business overview**

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

We were incorporated in the State of Delaware on September 14, 2001 and our shares of common stock in the form of CHES Depositary Interests ("CDIs") have been quoted on the Australian Securities Exchange ("ASX") since December 13, 2006. Our securities are not currently traded on any other public market. Our wholly owned subsidiary and primary operating vehicle, Universal Biosensors Pty Ltd ("UBS") was incorporated as a proprietary limited company in Australia on September 21, 2001. UBS conducts our research, development and manufacturing activities in Melbourne, Australia.

Our principal place of business is 1 Corporate Avenue, Rowville, Victoria 3178, Australia. Our principal telephone number in Australia is +61 3 9213 9000. Our agent for service in the United States is Corporation Service Company of 2711 Centerville Road, Suite 400, Wilmington, County of New Castle, Delaware, United States. We also maintain a web site at [www.universalbiosensors.com](http://www.universalbiosensors.com). The information contained in, or that can be accessed through, our web site is not part of this Form 10-K.

We have rights to an extensive patent portfolio, with certain patents owned by UBS and a number licensed to UBS under a license agreement between LifeScan, Inc. ("LifeScan") and UBS ("License Agreement"). LifeScan has granted us a worldwide, royalty free, exclusive license, with a right to sub-license certain electrochemical cell technologies in all fields of use excluding the field of diabetes and blood glucose management generally, the rights to which are retained by LifeScan pursuant to the License Agreement. Unless otherwise noted, references to "LifeScan" in this document are references collectively or individually to LifeScan, Inc., and/or LifeScan Europe, a division of Cilag GmbH International, both affiliates of Johnson and Johnson.

We are using our electrochemical cell technology platform to develop tests for a number of different markets. Our current focus is as set out below:

- *Blood glucose* — UBS provides services and acts as a non-exclusive manufacturer of test strips for LifeScan's "OneTouch® Verio™", pursuant to a Master Services and Supply Agreement with LifeScan ("Master Services and Supply Agreement"). LifeScan continues its global rollout of the OneTouch Verio product which is currently available in North America, major European markets and Australia. We also undertake research and development work for LifeScan pursuant to a development and research agreement ("Development and Research Agreement").
- *Coagulation testing market* — UBS is working with Siemens Healthcare Diagnostics, Inc. ("Siemens") to develop a range of test strips and reader products for the point-of-care coagulation market, pursuant to a collaboration agreement ("Collaboration Agreement").
- *Other electrochemical-cell based tests* — we are working on proving the broader applicability of our technology platform for other immunoassay and molecular diagnostic point-of-care tests. We will seek to enter into collaborative arrangements or strategic alliances with respect to any tests arising from this work.

## **Our Strategy**

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

- extending our electrochemical cell technology and proving the broader applicability of our technology platform for markets with significant commercial potential;
- seeking to enter into collaborative arrangements or strategic alliances with other life sciences companies or other industry participants to complete the development and commercialization of specific tests or in specific fields;
- undertaking research and development work for our customers and partners;
- manufacturing test strips for our customers and partners as required;
- providing post market support services to our customers and partners.

## **Plan of Operations for the Remainder of the Fiscal Year Ending December 2012**

Our plan of operations over the remainder of the fiscal year ending December 2012 is to:

- continue to undertake research and development work for our customers and partners;
- manufacture test strips to satisfy our customers and partners demand requirements;
- provide the necessary post-market support for our customers and partners;
- prove the broader applicability of our technology platform for markets with significant commercial potential, focusing initially on immunoassay and molecular diagnostic point-of-care tests;
- seek to enter into collaborative arrangements or strategic alliances with other life sciences companies or other industry participants to complete the development and commercialization of specific tests or in specific fields.

## **Financial information about segments**

We operate in one segment. Our principal activities are the research, development and manufacture of in vitro diagnostic test devices for consumer and professional point-of-care use. Although our products are intended for sale worldwide, we operate predominantly in one geographical area, that being Australia. For details of our revenues, profit and loss and total assets for financial years ending December 31, 2011, 2010, 2009, 2008 and 2007 refer to "Item 6. Selected Financial Data".

## **Description of our business**

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

### ***Industry background***

We operate in the high growth, point-of-care segment of the global in vitro diagnostics (IVD) industry. A large proportion of biological testing has historically been performed by trained scientists at dedicated or centralized testing sites including hospital laboratories and commercial pathology laboratories. Significant interest has developed in techniques and technologies that allow testing to be performed proximate (in time and location) to the patient. Point-of-care testing can be segmented into consumer testing or testing of patients by one of a variety of medical or laboratory professionals in locations such as clinics, physician's office laboratories and emergency departments. While not all tests are suited to being performed at the point-of-care, we believe our electrochemical cell technology could be a suitable platform for adapting a number of relevant central laboratory tests to a point-of-care format.

### ***Point-of-care tests in development and partnering strategy***

Our strategy is to apply the electrochemical cell technology to different fields and biomarkers and then to enter into collaborative arrangements or strategic alliances with third parties to complete the development and commercialization of the products for those fields. We have developed a blood glucose test with LifeScan and are working with Siemens to develop a range of test strip and reader products for the point-of-care coagulation market. We are also working to prove the broader applicability of our technology platform for markets with significant commercial potential, focusing initially on immunoassay and molecular diagnostic point-of-care tests.

### ***Facilities***

Universal Biosensors Pty Ltd leases approximately 5,000 square meters of office, research and development and manufacturing facilities at 1 Corporate Avenue, Rowville in Melbourne, Australia. We have had ISO 13485 certification continuously at that site since May 2007. The lease for 1 Corporate Avenue expires on March 31, 2014 with two options to renew the lease for successive five year periods.

### ***Raw materials***

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

### ***Distribution***

We do not currently intend to be responsible for the distribution and marketing of any product we develop. Our strategy is for our partners to be responsible for the commercialization and distribution of the applicable products.

### ***Regulatory clearances***

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

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

Our customers and partners are generally responsible for obtaining and maintaining all applicable regulatory approvals and determining the location and timing for submissions for regulatory clearance. We may provide a supporting role in this process.

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

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

Our point-of-care tests in development draw upon an extensive portfolio of patents and patent applications as well as know-how either owned by UBS or licensed to UBS by LifeScan. 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 by LifeScan in the manufacture of the point-of-care diagnostic tests being developed by us and to enable us to grant rights to our customers and partners to commercialize products that we may develop.

Our owned and licensed patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends upon the type of patent, the scope of its coverage and the availability of legal remedies in the country. Based on current product sales and our projects, the owned and licensed patents and patent applications that we consider most significant in relation to our business together with the last of the patents to expire within the patent family are set forth in the table below.

<u>Patent</u>	<u>Expiration Year</u>
<i>Apparatus and Method for Electrochemical Protease Sensor</i> (this patent family relates to a sensor to detect cleavage of an electrochemical substrate for use in measuring blood or plasma coagulation in assays such as prothrombin time and thrombin potential)	Refer Note 1
<i>Electrochemical On-Board Control Detection</i> (this patent family relates to an on-board control system of a sensor, wherein the control system can test/verify the viability of the sensor)	Refer Note 1
<i>Electrochemical Cell</i> (this patent family relates to a method and an electrochemical biosensor for determining the concentration of an analyte in a carrier)	2022
<i>Electrochemical Method</i> (this patent family provides an improved method and biosensor for determination of the concentration of an analyte in a carrier which provides improved accuracy, reliability and speed over prior techniques)	2024
<i>Electrochemical Cell</i> (this patent family relates to an electrochemical cell for determining the concentration of an analyte in a carrier)	2016
<i>Electrochemical Method for Measuring Chemical Reaction Rates</i> (this patent family relates to the measurement of the progress of a chemical reaction that generates an electroactive reaction product that is subsequently detected at an electrode amperometrically or coulometrically)	2023
<i>Electrochemical Cell Connector</i> (this patent family relates to a connector to provide electrical connection between an electrochemical cell of a strip type sensor and meter circuitry)	2026
<i>Method and Apparatus for Rapid Electrochemical Analysis</i> (this patent application relates to an improved method and apparatus for electrochemical analysis)	Refer Note 1
<i>Methods and Apparatus for Analyzing a Sample in the Presence of Interferents</i> (this patent application relates to methods and apparatus for determining analyte concentrations in a rapid and accurate manner)	Refer Note 1
<i>Systems and Methods for Discriminating Control Solution from a Physiological Sample</i> (this patent application relates to systems and methods for discriminating between a control solution and blood sample)	Refer Note 1
<i>Systems and Methods of Discriminating Control Solution from a Physiological Sample</i> (this patent application relates to systems and methods for discriminating between a control solution and a blood sample based on a summation of current values and comparing reference values to threshold values)	Refer Note 1

1. The patent application is either pending, allowed, or published

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

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

Our ability to build and maintain our proprietary position for our technology and products will depend on our success in obtaining effective claims and those claims being enforced once granted and, with respect to

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

***Seasonality***

We do not expect sales of the diagnostic tests we develop to be materially impacted by seasonality.

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

We commenced manufacture in our facility in Corporate Avenue, Rowville, Melbourne, in December 2009. We deal with our inventory and the supply of products in accordance with our contractual obligations to our customers and partners.

***Dependence on single customer.***

As shown in the table below, we currently receive a significant portion of our revenue from LifeScan.

	Years Ended December 31,		
	2011	2010	2009
	A\$	A\$	A\$
Revenue from products .....	12,063,582	11,760,009	132,733
Revenue from services .....	2,632,870	6,420,027	2,850,071
Research and development income .....	—	—	1,337,125
Milestone payment .....	—	—	17,722,641
Interest income .....	683,323	1,192,889	809,459
Fee income .....	—	—	—
Total income .....	<u>15,379,775</u>	<u>19,372,925</u>	<u>22,852,029</u>
Revenue from LifeScan as a % of total income .....	96%	94%	96%

Our dependence on LifeScan for a significant proportion of our revenue is likely to continue until we start to receive meaningful revenues from other collaborative arrangements or strategic alliances with third parties.

***Competitive conditions of our business***

Our revenue is currently highly dependent on the success of the One-Touch Verio® blood glucose product we have developed with LifeScan. One-Touch Verio® was first launched in the Netherlands in January 2010 and has subsequently been launched in Australia, major European markets and North America. LifeScan is responsible for all sales and marketing decisions and any decision to introduce the product to new territories and the timing of those decisions.

The global diabetes market place is intensely competitive and dominated by multinationals such as LifeScan, Roche, Abbott and Bayer. Although One-Touch Verio® has been well received in the jurisdictions in which it has been launched, we do not yet know if the product will be successful, the extent to which LifeScan will promote One-Touch Verio® when compared to its existing diabetes products, whether customers will prefer

it over competitive offerings, nor the rate at which it might be adopted. During 2012 we will continue to manufacture blood glucose test strips for LifeScan as a non-exclusive manufacturer under the Master Services and Supply Agreement. We anticipate that in the future LifeScan will manufacture all or a large proportion of its own requirements of any blood glucose test strip. If we are unable to compete effectively with LifeScan's own manufacturing capacity, we may not be able to win a manufacturing commitment from LifeScan and therefore be faced with surplus capacity in our manufacturing operations.

Our research and development expenditure during the last three fiscal years were as follows:

	<b>Years Ended December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>
	<b>A\$</b>	<b>A\$</b>	<b>A\$</b>
Research and development expenses .....	<u>9,812,396</u>	<u>6,482,150</u>	<u>14,898,072</u>

We expect that the range of test strip and reader products for the point-of-care coagulation market that we are developing with Siemens will compete with existing point-of-care technologies from competitors such as Roche Diagnostics, Alere Inc. and Abbott Point of Care. The test will also have to compete with the central laboratory which includes systems marketed by Siemens AG, Diagnostica Stago, Abbott Laboratories and Beckman Coulter, Inc. All of these companies have well established brand recognition, sales and marketing forces, and have significant resources available to support their product.

Core to our business strategy is to extend our intellectual property platform to enable other tests currently done in the central laboratory to be migrated to the point-of-care settings. Our belief is that much testing done in the central lab can more efficiently and profitably be performed at the point-of-care. With the exception of blood glucose testing, most point-of-care testing is currently conducted in professional settings. The health care professional has a choice and can request tests from a central laboratory, or services provider, or choose to have the test performed at the point-of-care. Thus we face competition not just from other companies active in the point-of-care space, but also the providers of testing who operate in centralized settings.

***Employees***

At March 6, 2012, we had 111 full time employees in our Melbourne facility, spanning production, engineering, quality and regulatory, research and development and administration.

**Financial information about geographic areas**

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

**Available Information**

We file annual and quarterly reports, proxy statements and other information with the SEC. Stockholders may read and copy any reports, statements or other information that we file at the SEC's public reference rooms in Washington, D.C., New York, New York, and Chicago, Illinois. Please call the SEC at 1-800-SEC-0330 for further information about the public reference rooms. Our public filings are also available from commercial document retrieval services and at the Internet Web site 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, Cameron Billingsley at +612 8115 9801 or write us at 1 Corporate Avenue, Rowville VIC 3178. You may also send an email to us at [companysecretary@universalbiosensors.com](mailto:companysecretary@universalbiosensors.com). Our Annual Report on Form 10-K and our other filings with the SEC, including the exhibits, are also available for free on our Internet site (<http://universalbiosensors.com>) and the SEC's Internet site (<http://www.sec.gov>).

## **ITEMS 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.*

### ***Our products may not be successful in the marketplace.***

Success of products that we are involved in developing is ultimately dependent on the level of market acceptance and sales of those products. Market acceptance will depend on, amongst other things, the ability to provide and maintain evidence of safety, efficacy and cost effectiveness of the products, the advantages and profile over competing products, the level of support from clinicians, the relative convenience and ease of use, cost-effectiveness compared to other products, the availability of reimbursement from national health authorities, the timing of 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.

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

The blood glucose test strips for the One Touch Verio® product was first launched in January 2010. While initial market acceptance for One Touch Verio® has been positive, there is no guarantee that the product will receive a positive acceptance in all countries in which the product will be launched, including in the key jurisdiction of the United States, or that market acceptance will be maintained or will secure adequate market share.

Further, we cannot be sure that any future products we are involved in developing with our customers and partners, such as the test strip and reader products for the point-of-care coagulation market that we are developing with Siemens, will be successful in the marketplace or will secure adequate market share.

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

### ***We are currently dependent on LifeScan for our income.***

We are at an early stage of our development as a specialist medical devices company. The vast majority of our income is currently derived from LifeScan and our business is therefore dependent on the level of services we provide to LifeScan, the number of test strips we manufacture for LifeScan and the sales of the blood glucose test strips for the One Touch Verio® product. Any changes in LifeScan's requirements and the level of test strip sales will directly affect our business.

To date, we have funded our operations primarily through the issue of shares, from payments received from LifeScan, including revenue from products and services and research and development income, and from Australian state and federal grants received by UBS. We do not currently have, and may never have, any products or services that generate substantial revenues.

We act as a non-exclusive manufacturer of the blood glucose test strips we developed with LifeScan. In the future we expect that LifeScan will manufacture all or a large proportion of its own requirements. If our manufacturing capacity is not fully utilized or not utilized at all, we will be faced with surplus capacity in our manufacturing operations and our revenues will decline. If the Master Services and Supply Agreement with LifeScan was terminated as a result of either party defaulting on its material obligations, becoming insolvent, or

as a result of other factors detailed in the Master Services and Supply Agreement we would cease to have the potential to receive service fee revenues from the sale of blood glucose strips. In addition, LifeScan has the ability to terminate the obligation to pay service fees to us by paying us a lump sum amount, but may only do so once it has paid us a certain level of service fees (we do not expect this level of service fees will be achieved until worldwide sales volumes have increased significantly) or as a result of other factors detailed in the Master Services and Supply Agreement. The service fee revenue is an ongoing amount LifeScan is obligated to pay to us based on the number of strips sold by LifeScan regardless of who manufactures the strips. If LifeScan was able to and did terminate the service fees, although we would receive a large lump sum payment, we would cease to receive ongoing service fee revenue and our ongoing future business would be adversely affected.

Our customers and partners may choose to utilize less of our research and development services. If the development and research work we undertake was materially reduced or ceased, we would lose an ongoing source of income which would have a material adverse effect on our business and financial position.

***Our business strategy and revenue relies on our ability to enter collaborative arrangements with other companies and there is a risk that we will not be able to enter into collaborative arrangements or strategic alliances with respect to our products.***

Our business strategy involves proving the broader applicability of our technology platform for a number of different products/technologies and then entering into collaborative arrangements, licensing agreements or strategic alliances with other life sciences companies or other industry participants for these products/ technologies. We have not established any internal product sales and marketing capacity and to achieve commercial success we must enter into and maintain successful arrangements with others to sell, market and distribute products that we are involved in developing. In seeking a collaborative arrangement, we need to compete against hundreds of technology companies for the attention of the limited pool of global multinationals. We may not be able to enter into such collaborative arrangements or strategic alliances in a timely fashion and on acceptable terms, if at all. An inability to enter such arrangement would be detrimental to our strategy, business and financial position.

Our ability to enter into collaborative arrangements or strategic alliances will suffer if the performances of the technologies developed by us are not perceived as being comparable or superior to established laboratory methods or other products. Other competitive factors may also act as obstacles in our ability to enter into partnership arrangements for certain opportunities.

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

***Entering collaborative arrangements with respect to our products will expose us to risks and uncertainties related to those collaborations and alliances.***

To the extent we are able to enter into collaborative arrangements or strategic alliances with respect to our products, we will be exposed to risks and uncertainties related to those collaborations and alliances. The customer or partner will generally makes the key decisions on product choice, regulatory approvals, product launch, product manufacture and marketing and promotion. Decisions made by our partner with respect to the commercialization of the products we develop with them will significantly affect the extent and timing of revenues to us. For example, our partner may choose not to launch new products we develop, may choose to launch the products in a limited number of jurisdictions, may delay the launch of products, may undertake only limited sales and marketing efforts to commercialize the products, all of which would have a material adverse effect on our business and financial position. Collaborative arrangements, licensing agreements or strategic alliances will subject us to a number of risks, including the risk that:

- we do not control the amount and timing of resources that our strategic partners may devote to our products;
- we do not control the decision to pursue a product, the timing of product launches and extent of marketing and sales activities;

- our strategic partners may experience financial difficulties;
- we may be required to relinquish important rights such as marketing and distribution rights;
- business combinations or significant changes in a partner's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- a collaborator could independently move forward with a competing product developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our products.

***Allegedly defective design or the manufacture of allegedly defective test strips could potentially expose us to substantial costs, write-offs and reputational damage.***

Allegedly defective designs or manufacture of allegedly defective products exposes us to the risk of product liability claims and product recalls, resulting in substantial costs, write-offs and potential delays in our shipment of product to customers, decreased demand for products, 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. While we will seek to mitigate our loss by obtaining appropriate insurances, if we are unable to maintain our insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities. This may harm our business and compromise the performance of our obligations to our customers and would have a material adverse effect on our business and financial results and may result in claims by our customers or partners and may trigger the dissolution of partnerships or collaborative relationships. Any claim for damages by our customers or other claim against us could be substantial.

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

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

Our margins may be reduced and costs increased which would have a material adverse effect on our business and financial position. The two primary factors that pose this risk include increased manufacturing costs or 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 manufacture 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. While the majority of our cash reserves and expenses are in Australian dollars, we continue to deal in other currencies, particularly in the United States and Europe, which may increase costs and decrease revenues incurred in foreign currencies. Additionally, we use, from time to time, financial instruments, primarily foreign currency forward contracts to hedge certain forecasted foreign currency commitments arising from trade accounts receivables, trade accounts payable and fixed purchase obligations. These hedging activities are largely dependent upon the accuracy of our forecasts and as such, our foreign currency forward contracts may not cover our full exposure to exchange rate fluctuations. Although we believe our foreign exchange policies are reasonable and prudent under the circumstances, we may experience losses from un-hedged currency fluctuations, which could be significant. If our costs increase or our margins decrease, it would have an adverse effect on our business and financial position.

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

The design and development of different tests on our platform takes a number of years to complete, is costly and the outcomes are uncertain. Although development risk generally reduces the further a test is developed, the tests we develop have a significant degree of technical risk, and irrespective of the stage of development, design

and development work and product validation, the development of the test may be unsuccessful or not warrant product commercialization. If development activities are unsuccessful, we may need to delay, reduce the scope of or eliminate some or all of our development programs and significant monies and management time invested may be rendered unproductive and worthless.

Our agreements with our customers generally contain milestone based payments, many of which are payable upon the achievement of technical development milestones. In the event we are not successful in achieving the development milestone, we will not receive the milestone payments which would have a material adverse effect on our revenue and financial position. Furthermore, if we are unable to develop a product for a customer, it may eliminate an important revenue stream for us which may result in us not being profitable, or trigger dissolution of partnerships or collaborative relationships.

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

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

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

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

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

Our diagnostic tests are based predominantly on intellectual property rights that have been 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 eliminate our existing commercialization opportunities.

LifeScan has a considerable degree of control in 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 a large portion 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. Our business would be harmed if the licensed patents were infringed or misappropriated. Prosecuting third parties and defending ourselves against third-party claims would be costly, time consuming and divert management's attention from our business, potentially leading to delays in our development or commercialization efforts. Additionally, if third parties made successful claims, we may be liable for substantial damages or license fees, be required to stop marketing the infringing product or take other actions that are adverse to our business.

***Risks associated with regulatory clearance and changes to regulation.***

The products we are involved in developing are medical devices and therefore subject to extensive regulation in all major markets. The process of obtaining regulatory clearance is costly and time consuming and there can be no assurance that the required regulatory clearances will be obtained. Products cannot be

commercially sold without regulatory clearance. 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 which could be detrimental to our business.

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

***Risks associated with suppliers.***

Similar to most major manufacturers in our industry, we are dependent upon our suppliers for certain raw materials and components. We have preferred suppliers, making us vulnerable to supply disruption, which could harm our business and delay manufacturing operations. We seek to enter into long term contractual arrangements with certain of our suppliers, however we may not always be able to do so on acceptable terms. 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.

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

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

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

***We may face intense competition in development, marketing and selling point-of-care tests.***

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

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

***We face risks manufacturing product for partners.***

There are technical challenges 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 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.

***Adverse economic conditions may harm our business.***

Market and economic conditions have been challenging worldwide. Continuing concerns have led to increased market volatility and diminished expectations for world economies. These factors may 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. Continued turbulence in the US and 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.

***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 credit if and when required. If we are unable to raise capital or secure 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.

***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. The competition for qualified employees in scientific research and medical diagnostic industries is particularly intense and there are a limited number of persons with the necessary skills and experience.

***Our primary 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. We take precautions to safeguard our facility, including security, health and safety protocols and maintain applicable insurance. However, we may be impacted by industrial action or operating equipment and facilities may not operate as intended or be available 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 event may restrict our ability to supply product, could cause substantial delays in our operations, damage or destroy our manufacturing equipment or inventory, and cause us to incur additional expenses. The insurance we maintain against fires, floods, earthquakes and other natural disasters may not be adequate to cover our losses in any particular case.

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

The receipt of dividends by Australian tax resident security holders and any subsequent disposal of our securities by 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.

***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. These fluctuations may be due to factors specific to us, to changes in analysts' recommendations and earnings estimates, or to factors affecting the life sciences industry or the securities markets in general. For example, from the initial quotation of our shares in the form of CDIs on the Australian Securities Exchange on December 13, 2006 until March 6, 2012, the closing price per share of our shares ranged from a low of A\$0.41 during February 2009 to a high of A\$2.02 during the first quarter of the 2010 fiscal year and was A\$0.80 on March 6, 2012. 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 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, a substantial number of our shares are "restricted securities" and resale of these shares to "U.S. Persons" as defined in Regulation S of the Securities Act of 1933 may only occur in a limited number of specified circumstances.

***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 Securities Exchange Act of 1934 as amended ("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. Additionally, as an "accelerated" filer with the SEC, our independent auditors must attest to our internal controls. We must perform the system and process evaluation and testing (and any necessary remediation) required to comply with the management certification and, when applicable, auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. If we are not able to continue to satisfy the requirements of Section 404 adequately, we may be subject to sanctions or investigation by regulatory authorities, including the SEC. Any action of this type could adversely affect our financial results, investors' confidence in our company and our ability to access capital markets, and could cause our stock price to decline.

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

Single stockholders with significant holdings or relatively small groups of stockholders have the power to influence matters requiring the approval of stockholders. Approximately 11.7% of our outstanding shares of common stock are owned by The Principals Cornerstone Fund Pty Ltd, an Australian company, which holds shares on trust for our directors, Messrs Denver, Hanley and Dr. Adam. These directors also hold shares directly and through other vehicles. In addition, a company called PFM Cornerstone Limited, an Australian company, of which Messrs Denver, Hanley and Dr. Adam are directors, holds approximately 7.6% of our shares. Mr. Andrew Jane is one of our directors and a director of CM Capital Investments Pty Ltd which holds approximately 11.2% of our shares. As directors, these individuals have the power to influence significantly all matters requiring the approval of our stockholders, including the election of directors and the approval of other significant resolutions, and their interests may conflict with those of the other stockholders. In addition, control of a significant amount of our common stock by insiders could adversely affect the market price of shares. Based on the latest Amendment to Schedule 13G filed on January 25, 2012, Johnson and Johnson Development Corporation (a venture capital wholly owned subsidiary of Johnson & Johnson) beneficially held 14,915,400 shares in the Company as at December 31, 2011 which represents approximately 9.4% of the Company's shares. For details of our substantial stockholders and the interests of our directors, refer to "Item 12 — Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters".

***We have never paid a dividend and we do not intend to pay dividends in the foreseeable future which means that holders of shares of common stock and CDIs may not receive any return on their investment from dividends.***

To date, we have not declared or paid any cash dividends on our shares or CDIs and currently intend to retain any future earnings, if any, for funding growth. We do not anticipate paying any dividends in the foreseeable future.

***Our holders of CDIs are not stockholders and do not have stockholder rights.***

The main difference between holding CDIs and holding our underlying shares is that a CDI holder has beneficial ownership of the equivalent number of shares instead of legal title. CDIs are exchangeable, at the option of the holder, into shares of our common stock at a ratio of 1:1. Legal title is held by CHESSE Depository Nominees Pty Ltd ("CDN") and the shares are registered in the name of CDN and held by CDN on behalf of and for the benefit of CDI Holders. CDN is a wholly owned subsidiary of ASX. CDI holders will be entitled to all the economic benefits of the shares underlying their CDIs, such as dividends (if any), bonus issues or rights issues. CDN as a stockholder of record will receive notice of stockholder meetings and be entitled to attend and vote at stockholder meetings. CDI holders will likewise be sent notices of stockholder meetings and are entitled to attend stockholder meetings but are not permitted to vote other than by giving directions on how to vote to CDN or as a proxy holder for CDN.

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

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

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

- the division of our Board into classes whose terms expire at staggered intervals over a three year period and advance notice requirements for nominations to our Board and proposing matters that can be acted upon at shareholder meetings;
- the requirement that actions by our stockholders by written consent be unanimous;
- the ability of our Board to issue preferred stock.

***Limitation on Independent Registered Public Accounting Firm's Liability.***

The Australian accounting firm we utilize for audit reports on our financial statements is subject to limitations on liability with respect to claims arising out of their audit reports, in accordance with professional standards legislation. This legislation may limit the liability of our accountant's for damages with respect to certain civil claims arising directly or vicariously from anything done or omitted in the performance of their professional services to us, including to the lesser of (in the case of audit services) ten times the reasonable charge for the service provided and a maximum liability for audit work of A\$75 million or, in relation to matters occurring prior to October 7, 2007, A\$20 million. The limit does not apply to claims for breach of trust, fraud or dishonesty.

These limitations of liability may limit recovery upon the enforcement in Australian courts of any judgment under US or other foreign laws rendered against our Australian accountants based on or related to their audit report on our financial statements. Substantially all of our accountant's assets are located in Australia. However, the professional standards legislation has not been subject to judicial consideration and therefore how the limitation will be applied by the courts and the effect of the limitation on the enforcement of foreign judgments are untested.

**ITEM 1B. UNRESOLVED STAFF COMMENTS.**

None.

**ITEM 2. PROPERTIES.**

Universal Biosensors Pty Ltd leases approximately 5,000 square meters of office, research and development and manufacturing facilities at 1 Corporate Avenue, Rowville in Melbourne, Australia. The lease for the premises at 1 Corporate Avenue Rowville expires on March 31, 2014 with two options to renew the lease for successive five year periods.

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 partners, we will need to secure additional or alternative facilities and establish additional large scale equipment sufficient to future manufacturing requirements.

**ITEM 3. LEGAL PROCEEDINGS.**

There are no material legal or arbitration proceedings pending against us or Universal Biosensors Pty Ltd.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable

**PART II**

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

**Market information**

Our shares of common stock are not currently traded on any established United States public trading market. We have not determined whether we will seek the quotation of our shares of common stock on any United States public trading market. We cannot assure you that we will seek to be quoted on any United States public trading market or that we would meet any applicable listing requirements.

Our shares of common stock are traded on the ASX in the form of CHESS 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 companies, such as us, that are domiciled in countries whose laws do not recognize uncertificated holdings or electronic transfer of legal title. 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).

**High and low sale prices of our CDIs on the ASX**

The sale prices of our shares traded in the form of CDIs are quoted on the ASX in Australian dollars. Our CDIs were first quoted on the ASX on December 13, 2006. Twenty minute delayed trading prices of our CDIs are available through the ASX at [www.asx.com.au](http://www.asx.com.au).

The following tables sets forth, for the periods indicated, the highest and lowest market prices in Australian dollars for our CDIs reported on the ASX:

	<u>High A\$</u>	<u>Low A\$</u>
Fiscal Year 2011		
First Quarter .....	A\$1.59	A\$1.23
Second Quarter .....	A\$1.40	A\$0.90
Third Quarter .....	A\$1.19	A\$.083
Fourth Quarter .....	A\$0.94	A\$0.72
Fiscal Year 2010		
First Quarter .....	A\$2.02	A\$1.60
Second Quarter .....	A\$1.75	A\$1.30
Third Quarter .....	A\$1.68	A\$1.40
Fourth Quarter .....	A\$1.65	A\$1.35

### Security details

As of March 6, 2012, there were 159,146,213 shares of our common stock issued and outstanding and 11,258,290 employee options that are exercisable for an equivalent number of shares of common stock (7,854,111 of which were exercisable or exercisable within 60 days thereafter). All of our issued and outstanding shares of common stock are fully paid.

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

### Rule 144(b)

Because there is no public trading market for the shares in the United States, no sales in the United States under Rule 144 other than Rule 144(b)(1)(i) are likely to occur. Under Rule 144(b)(1)(i), a person who is not deemed to have been an affiliate of ours at any time during the 90 days preceding a sale, and who has beneficially owned the shares proposed to be sold for between six months and one year may sell so long as the public information requirements of Rule 144 are satisfied, and, after one year, such person is entitled to sell the shares without having to comply with the manner of sale, public information or provisions of Rule 144. A person who is deemed an affiliate during the 90 days preceding the sale who has beneficially owned the shares proposed to be sold for at least six months may sell so long as the conditions of Rule 144 are met, including the manner of sale, public information, volume limitation and notice filing provisions of Rule 144.

### Holders

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

<u>Date</u>	<u>Total Number of Registered Holders</u>	<u>Number of Holders that are United States Residents</u>
At March 6, 2012 .....	1,507	8

### Dividends

To date, we have not declared or paid any cash dividends on our shares or CDIs and currently intend to retain any future earnings, if any, for funding growth. We do not anticipate paying any dividends in the foreseeable future.

**Securities authorized for issuance under equity compensation plans**

Set out below are details of our Employee Option Plan as at December 31, 2011.

<u>Plan Category</u>	<u>Equity Compensation Plan Information</u>		
	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights</u>	<u>Weighted average exercise price of outstanding options, warrants and rights</u> (A\$)	<u>Number of Securities remaining for future issuance</u>
Equity compensation plans approved by security holders .....	11,417,536	1.02	(1)
Equity compensation plans not approved by security holders .....	<u>—</u>	<u>—</u>	(1)
Total .....	<u>11,417,536</u>	<u>1.02</u>	

- (1) The number of employee options 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. The Listing Rules of ASX generally prohibit companies whose securities are quoted on the ASX from issuing securities exceeding 15% of issued share capital in any 12 month period, without stockholder approval.

## Recent Sales of Unregistered Securities; Use of Proceeds from Registered Securities

### *Exercise of Employee Stock Options*

The table below sets forth the number of employee stock options exercised and the number of shares of common stock issued in the period from January 1, 2009 to December 31, 2011. We issued these shares in reliance upon exemptions from registration under Regulation S under the Securities Act of 1933, as amended.

<u>Period Ending</u>	<u>Number of Options Exercised and Corresponding Number of Shares Issued</u>	<u>Option Exercise Price</u>	<u>Proceeds Received (A\$)</u>
<b>2009</b>			
August, 2009 .....	36,248	A\$0.31	11,221
September, 2009 .....	25,374	A\$0.31	7,853
November, 2009 .....	13,332	A\$0.89	11,865
November, 2009 .....	25,373	A\$0.28	7,059
November, 2009 .....	8,000	A\$0.70	5,600
November, 2009 .....	30,000	A\$1.18	35,400
	<u>138,327</u>		<u>78,998</u>
<b>2010</b>			
February, 2010 .....	23,333	A\$0.89	20,766
February, 2010 .....	20,000	A\$0.94	18,800
February, 2010 .....	4,000	A\$0.50	2,000
February, 2010 .....	18,124	US\$0.26	5,104
February, 2010 .....	13,332	A\$1.18	15,732
February, 2010 .....	18,124	US\$0.22	4,489
February, 2010 .....	33,333	Nil	—
March, 2010 .....	6,666	A\$0.89	5,933
March, 2010 .....	6,666	A\$0.70	4,666
March, 2010 .....	2,000	A\$0.94	1,880
May, 2010 .....	12,500	Nil	—
June, 2010 .....	6,667	A\$0.94	6,267
June, 2010 .....	20,000	US\$0.22	4,040
August, 2010 .....	25,374	US\$0.26	8,381
August, 2010 .....	20,000	A\$1.18	23,600
August, 2010 .....	13,332	A\$0.89	11,865
August, 2010 .....	6,667	A\$0.94	6,267
September, 2010 .....	13,333	A\$0.94	12,533
September, 2010 .....	8,000	A\$0.70	5,600
September, 2010 .....	16,666	A\$1.20	19,999
September, 2010 .....	3,333	A\$0.94	3,133
October, 2010 .....	960,560	US\$0.26	256,018
October, 2010 .....	45,000	A\$1.18	53,100
October, 2010 .....	100,000	A\$0.89	89,000
November, 2010 .....	181,238	US\$0.26	47,430
November, 2010 .....	28,000	A\$1.18	33,040
November, 2010 .....	40,000	A\$0.89	35,600
November, 2010 .....	21,333	A\$0.94	20,053
	<u>1,667,581</u>		<u>715,296</u>

**2011**

January, 2011 .....	50,000	A\$0.89	44,500
January, 2011 .....	13,333	A\$0.50	6,667
January, 2011 .....	26,667	Nil	—
January, 2011 .....	6,666	A\$0.94	6,266
March, 2011 .....	40,000	US\$0.22	8,694
May, 2011 .....	6,667	A\$0.70	4,667
May, 2011 .....	2,333	A\$0.94	2,193
August, 2011 .....	8,000	A\$0.50	4,000
November, 2011 .....	10,000	US\$0.26	2,518
November, 2011 .....	18,333	Nil	—
	<u>181,999</u>		<u>79,504</u>

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

***Restricted Employee Shares Issued to Employees***

Our Employee Share Plan was adopted by the Board of Directors in 2009. The Employee Share Plan permits our Board to grant shares of our common stock to our employees and directors. The number of shares able to be granted is limited to the amount permitted to be granted at law, the ASX Listing Rules and by the limits on our authorized share capital in our certificate of incorporation. All our employees are eligible for shares under the Employee Plan. The Company currently proposes to issue A\$1,000 worth of restricted shares of common stock to employees of the Company on a recurring basis, but no more frequently than annually. The restricted shares have the same terms of issue as our existing shares of common stock but are not able to be traded until the earlier of three years from the date on which the shares are issued or the date the relevant employee ceases to be an employee of the Company or any of its associated group of companies. We issue these shares in reliance upon exemptions from registration under Regulation S under the Securities Act of 1933, as amended.

The table below sets forth the restricted shares issued by the Company:

	<u>Number of Restricted Shares Issued</u>	<u>Market Value of Restricted Shares Issued</u>
November, 2009 .....	40,670	A\$69,952
May, 2010 .....	581	A\$ 999
November, 2010 .....	47,400	A\$74,892
November, 2011 .....	86,471	A\$76,959

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

	<u>Number of shares</u>	<u>Weighted average issue price A\$</u>
Balance at December 31, 2010 .....	<u>82,841</u>	<u>1.64</u>
Granted .....	86,471	0.89
Release of restricted shares .....	<u>(11,549)</u>	<u>1.64</u>
Balance at December 31, 2011 .....	<u>157,763</u>	<u>1.23</u>

***Purchases of Equity Securities by the Issuer and Affiliated Purchasers***

There were no repurchases of equity securities in 2011.

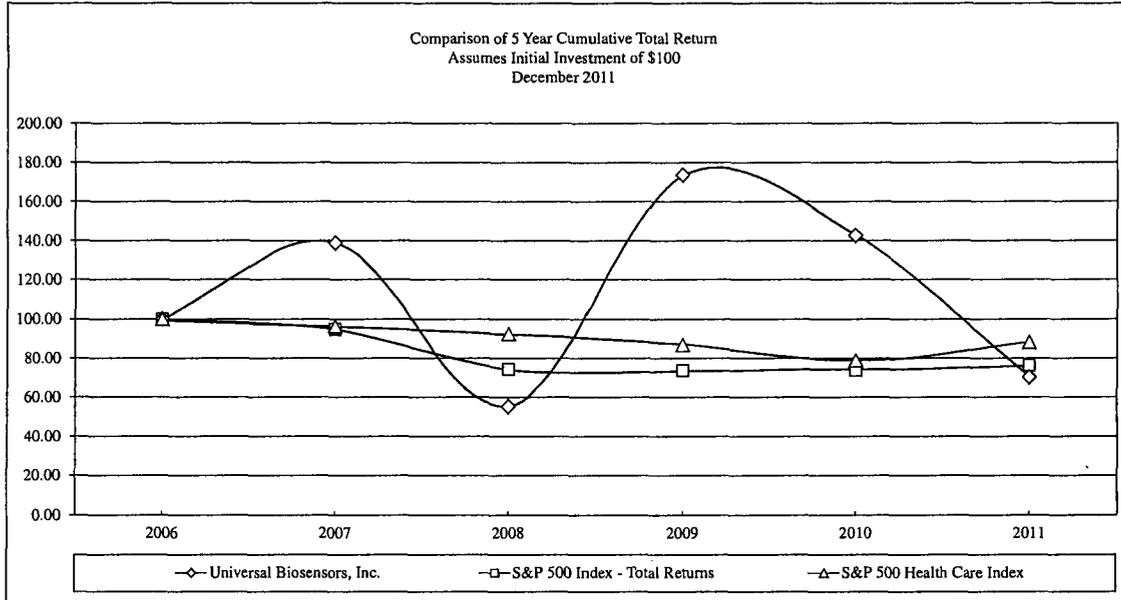
**ITEM 6. SELECTED FINANCIAL DATA.**

The following table represents our selected financial data for the dates and periods indicated.

	Years Ended December 31,				
	2011	2010	2009	2008	2007
	A\$	A\$	A\$	A\$	A\$
<b>Revenue</b>					
Revenue from products	\$ 12,063,582	\$ 11,760,009	\$ 132,733	\$ —	\$ —
Revenue from services	2,632,870	6,420,027	2,850,071	3,121,754	—
Research and development income	—	—	1,337,125	1,170,190	1,192,015
Milestone payment	—	—	17,722,641	—	—
Total revenue	14,696,452	18,180,036	22,042,570	4,291,944	1,192,015
<b>Operating costs &amp; expenses</b>					
Cost of goods sold	12,310,302	10,801,062	458,162	—	—
Cost of services	708,149	1,481,674	169,241	3,121,754	—
Research and development	9,812,396	6,482,150	14,898,072	11,585,258	7,157,216
General and administrative	7,271,488	7,185,550	5,635,569	5,510,127	4,226,757
Total operating costs & expenses	30,102,335	25,950,436	21,161,044	20,217,139	11,383,973
Profit/(loss) from operations	(15,405,883)	(7,770,400)	881,526	(15,925,195)	(10,191,958)
<b>Other income/(expense)</b>					
Interest income	683,323	1,192,889	809,459	2,542,060	1,440,102
Interest expense	—	—	(9,636)	(9,489)	—
Fee income	—	—	—	1,131,222	—
Other	30,443	(33,014)	(250,886)	265,310	(210,382)
Total other income/(expense)	713,766	1,159,875	548,937	3,929,103	1,229,720
Net profit/(loss) before tax	(14,692,117)	(6,610,525)	1,430,463	(11,996,092)	(8,962,238)
Income tax benefit/(expense)	—	—	—	206	145,000
Net profit/(loss)	<u>\$ (14,692,117)</u>	<u>\$ (6,610,525)</u>	<u>\$ 1,430,463</u>	<u>\$ (11,995,886)</u>	<u>\$ (8,817,238)</u>
Basic net profit/(loss) per share	\$ (0.09)	\$ (0.04)	\$ 0.01	\$ (0.08)	\$ (0.07)
Average weighted number of shares —					
basic	159,017,777	157,584,044	157,013,578	156,970,679	129,637,286
Diluted net profit/(loss) per share	\$ (0.09)	\$ (0.04)	\$ 0.01	\$ (0.08)	\$ (0.07)
Average weighted number of shares —					
diluted	159,017,777	157,584,044	161,354,802	156,970,679	129,637,286
<b>Years Ended December 31,</b>					
	2011	2010	2009	2008	2007
	A\$	A\$	A\$	A\$	A\$
<b>Balance Sheet Data:</b>					
Cash and cash equivalents	15,089,209	23,271,766	31,291,011	28,334,864	41,958,285
Total assets	45,216,467	53,837,949	56,083,468	52,505,321	63,512,160
Long-term debt	—	—	—	—	—
Convertible preference shares	—	—	—	—	—
Total stockholders' equity	35,022,606	47,219,079	51,314,002	48,703,230	59,749,624

**Total Return Stock Performance Graph**

The following line graph compares the cumulative total stockholder return on our common stock from December 31, 2006 through December 31, 2011 with the cumulative total return of a major market index and a published industry index. The graph below assumes an investment of A\$100.00 on December 31, 2006 in our common stock, and compares its performance with the Standard and Poor's 500 Index and the Standard and Poor's 500 Health Care Index. We paid no dividends on our common stock during the period covered by the graph. The Indices included in the graph reflect a cumulative total return based upon the reinvestment of dividends of the stocks included in those indices. Measurement points are December 31, 2006 and the last trading day of each subsequent year end through December 31, 2011.



The comparisons shown in the graph above are based upon historical data. The stock price performance shown in the graph is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock. This graph shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that section, and will not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**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 2011 Annual Report under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations" on pages F-2 to F-10.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The information required by this item is incorporated by reference to our 2011 Annual Report under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations — Financial Risk Management" on page F-10.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

We refer you to the “Consolidated Balance Sheets”, “Consolidated Statements of Operations”, “Consolidated Statements of Stockholders’ Equity and Comprehensive Income”, “Consolidated Statements of Cash Flows”, and “Notes to Consolidated Financial Statements”, on pages F-13 through F-36, and “Report of Independent Registered Public Accounting Firm” on pages F-11 through F-12 of our Annual Report to Stockholders for the fiscal year ended December 31, 2011, which sections are incorporated by reference herein.

**Supplementary Financial Information**

The following is a summary of the unaudited quarterly results of operations:

	Year ended December 31, 2011			
	Quarter Ended March 31	Quarter Ended June 30	Quarter Ended September 30	Quarter Ended December 31
	A\$	A\$	A\$	A\$
<b>Revenue</b>				
Revenue from products .....	\$ 3,319,401	\$ 2,267,766	\$ 2,153,518	\$ 4,322,897
Revenue from services .....	245,920	476,129	318,869	1,591,952
Research and development income .....	—	—	—	—
Milestone payment .....	—	—	—	—
Total revenue .....	<u>3,565,321</u>	<u>2,743,895</u>	<u>2,472,387</u>	<u>5,914,849</u>
<b>Operating costs &amp; expenses</b>				
Cost of goods sold .....	3,492,052	2,694,792	2,314,082	3,809,376
Cost of services .....	63,519	140,987	61,257	442,386
Research and development .....	1,747,507	2,969,982	2,317,556	2,777,351
General and administrative .....	1,405,358	1,800,900	2,029,467	2,035,763
Total operating costs & expenses .....	<u>6,708,436</u>	<u>7,606,661</u>	<u>6,722,362</u>	<u>9,064,876</u>
Profit/(loss) from operations .....	(3,143,115)	(4,862,766)	(4,249,975)	(3,150,027)
<b>Other income/(expense)</b>				
Interest income .....	224,875	179,444	145,228	133,776
Interest expense .....	—	—	—	—
Fee income .....	—	—	—	—
Other .....	(128,992)	(226,486)	749,727	(363,806)
Total other income/(expense) .....	95,883	(47,042)	894,955	(230,030)
Net profit/(loss) before tax .....	(3,047,232)	(4,909,808)	(3,355,020)	(3,380,057)
Income tax benefit/(expense) .....	—	—	—	—
Net profit/(loss) .....	<u>\$ (3,047,232)</u>	<u>\$ (4,909,808)</u>	<u>\$ (3,355,020)</u>	<u>\$ (3,380,057)</u>
Basic and diluted net loss per share .....	\$ (0.02)	\$ (0.03)	\$ (0.02)	\$ (0.02)
Average weighted number of shares used as denominator .....	158,952,569	159,012,414	159,022,118	159,082,531
Diluted net profit/(loss) per share .....	\$ (0.02)	\$ (0.03)	\$ (0.02)	\$ (0.02)
Average weighted number of shares used as denominator .....	158,952,569	159,012,414	159,022,118	159,082,531

	Year ended December 31, 2010			
	Quarter Ended	Quarter Ended	Quarter Ended	Quarter Ended
	March 31	June 30	September 30	December 31
	A\$	A\$	A\$	A\$
<b>Revenue</b>				
Revenue from products .....	\$ 1,524,813	\$ 1,359,584	\$ 3,202,873	\$ 5,672,739
Revenue from services .....	1,893,133	1,403,779	1,785,331	1,337,784
Research and development income .....	—	—	—	—
Milestone payment .....	—	—	—	—
Total revenue .....	3,417,946	2,763,363	4,988,204	7,010,523
<b>Operating costs &amp; expenses</b>				
Cost of goods sold .....	1,538,436	1,936,716	3,136,390	4,189,520
Cost of services .....	246,064	247,190	376,398	612,022
Research and development .....	1,554,227	1,799,551	1,543,482	1,584,890
General and administrative .....	1,469,609	1,788,984	1,675,868	2,251,089
Total operating costs & expenses .....	4,808,336	5,772,441	6,732,138	8,637,521
Profit/(loss) from operations .....	(1,390,390)	(3,009,078)	(1,743,934)	(1,626,998)
<b>Other income/(expense)</b>				
Interest income .....	305,019	327,949	289,296	270,625
Interest expense .....	—	—	—	—
Fee income .....	—	—	—	—
Other .....	(10,291)	153,984	(47,473)	(129,234)
Total other income/(expense) .....	294,728	481,933	241,823	141,391
Net profit/(loss) before tax .....	(1,095,662)	(2,527,145)	(1,502,111)	(1,485,607)
Income tax benefit/(expense) .....	—	—	—	—
Net profit/(loss) .....	<u>\$ (1,095,662)</u>	<u>\$ (2,527,145)</u>	<u>\$ (1,502,111)</u>	<u>\$ (1,485,607)</u>
Basic and diluted net loss per share .....	\$ (0.01)	\$ (0.02)	\$ (0.01)	\$ (0.01)
Average weighted number of shares used as denominator .....	157,229,023	157,307,199	157,378,290	158,403,507

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

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

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

*Changes in Internal Control Over Financial Reporting.* During the fiscal quarter ended December 31, 2011, there were no changes in the Company's internal control over financial reporting identified in connection with the evaluation of such referred to above in this Item 9A that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

## MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

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

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

Our management, with the participation of the Principal Executive Officer and Principal Financial Officer, assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2011. 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.

Based on this evaluation, our management, with the participation of the Principal Executive Officer and Principal Financial Officer, concluded that, as of December 31, 2011, our internal control over financial reporting was effective.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2011 has been audited by PricewaterhouseCoopers, an independent registered public accounting firm, as stated in their report, which appears in the "Report of Independent Registered Public Accounting Firm" on pages F-11 to F-12 of the Annual Report, which is incorporated herein by reference and filed as Exhibit 13 to this Report on Form 10-K.

/s/ Paul Wright

Paul Wright  
Principal Executive Officer

/s/ Salesh Balak

Salesh Balak  
Principal Financial Officer

March 13, 2012

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

We refer you to “Report of Independent Registered Public Accounting Firm” on pages F-11 to F-12 of our Annual Report to Stockholders for the fiscal year ended December 31, 2011, which are incorporated by reference herein, for the Independent Registered Public Accounting Firm’s report with respect to the effectiveness of internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None.

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.**

The information required by this item regarding our directors and executive officers is incorporated by reference to our Definitive Proxy Statement to be filed with the Securities and Exchange Commission in connection with our Annual Meeting of Stockholders in 2012 (the "2012 Proxy Statement") under the caption "Management of the Company."

The information required by this item regarding "Compliance with Section 16(a) of the Exchange Act" is incorporated by reference to the 2012 Proxy Statement under the caption "Other Matters — Section 16(a) Beneficial Ownership Reporting Compliance."

We have adopted our Code of Ethics for Senior Financial Officers, a code of ethics that applies to our Principal Executive Officer and Principal Financial Officer. This code of ethics may be accessed and reviewed through our website at [www.universalsbiosensors.com](http://www.universalsbiosensors.com). We intend to satisfy any disclosure requirement under item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of the Code of Ethics for our Principal Executive Officer and Principal Financial Officer, by posting such information on our website at [www.universalsbiosensors.com](http://www.universalsbiosensors.com)

The information regarding the procedures by which security holders may recommend nominees to our Board of Directors is incorporated by reference to the 2012 Proxy Statement under the caption "Management of the Company — Board Committees — Remuneration and Nomination Committee." There have been no material changes to the procedures by which security holders may recommend nominees to our Board of Directors.

The information required by this item regarding our Audit Committee is incorporated by reference to the 2012 Proxy Statement under the caption "Management of the Company — Board Committees — Audit and Compliance Committee."

**ITEM 11. EXECUTIVE COMPENSATION.**

The information required by this item is incorporated by reference to the 2012 Proxy Statement under the captions "Management of the Company — Compensation of Directors", "Executive Compensation" and "Management of the Company — Board Committees — Compensation Committee Interlocks and Insider Participation."

Discussions on the frequency of the shareholder advisory votes on executive compensation are incorporated by reference to the 2012 Proxy Statement under the caption "Executive Compensation".

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

The information regarding the security ownership of certain beneficial owners and management is incorporated by reference to the 2012 Proxy Statement under the caption "Security Ownership of Certain Beneficial Owners and Management."

The information regarding "Securities Authorized for Issuance under Equity Compensation Plans" is incorporated by reference to our 2012 Proxy Statement under the caption "Executive Compensation — Equity Compensation Plan Information."

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

The information required by this item is incorporated by reference to the 2012 Proxy Statement under the caption "Certain Relationships and Related Transactions," and "Management of the Company."

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.**

The information required by this item is incorporated by reference to the 2012 Proxy Statement under the caption "Independent Public Accountants — Audit Fees."

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENTS AND SCHEDULES.**

(a)(1) Financial Statements

*The following financial statements are incorporated by reference from pages F-11 through F-36 of our Annual Report to Stockholders for the fiscal year ended December 31, 2011, as provided in Item 8 hereof:*

Report of Independent Registered Public Accounting Firm .....	F-11
Consolidated Balance Sheets .....	F-13
Consolidated Statements of Operations .....	F-14
Consolidated Statements of Stockholders' Equity and Comprehensive Income .....	F-15
Consolidated Statements of Cash Flows .....	F-16
Notes to Consolidated Financial Statements .....	F-17

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

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

<u>Exhibit Number</u>	<u>Description</u>	<u>Location</u>
1.0	Underwriting Agreement, by and between Universal Biosensors, Inc. and Wilson HTM Corporate Finance Limited dated November 9, 2007.	Incorporated by reference to our Current Report on Form 8-K filed on November 16, 2007 as Exhibit 1.1.
3.1	Amended and restated articles of incorporation dated December 5, 2006.	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 3.1.
3.2	Amended and restated by-laws dated December 5, 2006.	Incorporated by reference to our Amendment No. 5 to Form 10 filed on April 29, 2008 as Exhibit 3.2.
10.1	License Agreement between LifeScan and Universal Biosensors, Inc effective April 1, 2002, as amended on October 25, 2007, December 5, 2005	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.1. October 2007 amendment incorporated by reference to our Form 10-Q filed on November 14, 2007 as Exhibit 10.2.
10.2	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.
10.3	Development and Research Agreement by and between Universal Biosensors, Inc and LifeScan, Inc dated April 1, 2002 as amended on October 29, 2007, June 1, 2007, December 7, 2005, December 21, 2004 and March 31, 2004	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.2. June 2007 amendment incorporated by reference to our Amendment No. 2 to Form 10 filed on June 12, 2007 as Exhibit 10.2. October 2007 amendment incorporated by reference to our Form 10-Q filed on November 14, 2007 as Exhibit 10.3.

- 10.4 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.
- 10.5 Form of indemnity agreement entered into with directors of us, our chief financial officer and company secretary Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.3.
- 10.6 Lease of premises 1 Corporate Avenue, Rowville Victoria Australia by and between Universal Biosensors Pty Ltd and Heyram Properties Pty Ltd. Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.5.
- 10.7 AusIndustry, R&D Start Program Agreement, effective February 25, 2005 (particular and general conditions) Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.6.
- 10.8 Employee Option Plan Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.7
- 10.9 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
- 10.10 Employment agreement between Universal Biosensors Pty Ltd and Mr. Garry Chambers effective April 1, 2006 Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.9
- 10.11 Employment agreement between Universal Biosensors Pty Ltd and Dr Ronald Chatelier dated April 1, 2006 Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.10
- 10.12 Employment agreement between Universal Biosensors Pty Ltd and Dr Alastair Hodges effective April 1, 2006 Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.11
- 10.13 Employment agreement between Universal Biosensors Pty Ltd and Mr. Adrian Oates dated August 15, 2007 Incorporated by reference to our Form 10-K filed on March 16, 2010 as Exhibit 10.12
- 10.14 Master Services and Supply Agreement by and between Universal Biosensors Pty Ltd, Universal Biosensors, Inc. and LifeScan, Inc. dated October 29, 2007 Incorporated by reference to our Quarterly Report on Form 10-Q filed on November 14, 2007 as Exhibit 10.1. Confidentiality treatment has been granted for portions of this exhibit. These confidential portions have been omitted and were filed separately with the SEC.
- 10.15 First Amendment to the Master services and Supply Agreement dated December 11, 2008 (which amends the Master Services and Supply Agreement by and between Universal Biosensors Pty Ltd, Universal Biosensors, Inc. and LifeScan, Inc. dated October 29, 2007 and filed on November 14, 2007 as Exhibit 10.1 to our Quarterly Report on Form 10-Q) Incorporated by reference to our Annual Report on Form 10-K filed on March 30, 2009 as Exhibit 10.14

- 10.16 Second Services Addendum — manufacturing Process Support (which amends the Master Services and Supply Agreement by and between Universal Biosensors Pty Ltd, Universal Biosensors, Inc. and LifeScan, Inc. dated October 29, 2007 incorporated by reference to our Quarterly Report on Form 10-Q filed on November 14, 2007 as Exhibit 10.1.) Incorporated by reference to our Annual Report on Form 10-K filed on March 30, 2009 as Exhibit 10.15
- 10.17 Advanced Care Enhanced Product Agreement (which is an addendum to the Amended and Restated Master Services and Supply Agreement filed on August 7, 2009 as Exhibit 10.3 to our Quarterly Report on Form 10-Q) Incorporated by reference to our Quarterly Report on Form 10-Q filed on August 7, 2009 as Exhibit 10.1. Confidentiality treatment has been granted for portions of this exhibit. These confidential portions have been omitted and were filed separately with the SEC.
- 10.18 Fifth Amendment to Development and Research Agreement (which amends the Development and Research Agreement by and between Universal Biosensors, Inc. and LifeScan, Inc. dated April 1, 2002 and filed on April 30, 2007 as Exhibit 10.2 to our Form 10, the Amendment to the Development and Research Agreement filed on June 12 as Exhibit 10.2 to Amendment No. 2 to our Form 10 and the Amendment to Development and Research Agreement filed on November 14, 2007 as Exhibit 10.3 to our Quarterly Report on Form 10-Q) Incorporated by reference to our Quarterly Report on Form 10-Q filed on August 7, 2009 as Exhibit 10.2.
- 10.19 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.
- 10.20 Manufacturing Initiation Payment Addendum to Master Services and Supply Agreement (which is an addendum to the Amended and Restated Master Services and Supply Agreement filed on August 7, 2009 as Exhibit 10.3 to our Quarterly Report on Form 10-Q) Incorporated by reference to our Quarterly Report on Form 10-Q filed on August 7, 2009 as Exhibit 10.4. Confidentiality treatment has been granted for portions of this exhibit. These confidential portions have been omitted and were filed separately with the SEC.

10.21	Employment agreement between Universal Biosensors Pty Ltd and Mr. Andrew Denver dated September 9, 2010	Incorporated by reference to our Current Report on Form 8-K/A filed on December 22, 2010 as Exhibit 10.1.
10.22	Collaboration Agreement between Universal Biosensors Pty Ltd and Siemens Healthcare Diagnostics Inc. dated September 9, 2011.	Incorporated by reference to our Quarterly Report on Form 10-Q filed on November 3, 2011 as Exhibit 10.20. Confidentiality treatment has been granted for portions of this exhibit. These confidential portions have been omitted and were filed separately with the SEC.
10.23	Statement of Work for MAP Feasibility Project between Universal Biosensors Pty Ltd, LifeScan, Inc. and Cilag GmbH International dated October 11, 2011.	Incorporated by reference to our Quarterly Report on Form 10-Q filed on November 3, 2011 as Exhibit 10.21. Confidentiality treatment has been granted for portions of this exhibit. These confidential portions have been omitted and were filed separately with the SEC.
10.24	Novation Agreement and First Amendment to the Amended and Restated Master Services and Supply Agreement between Universal Biosensors, Inc., Universal Biosensors Pty Ltd, LifeScan, Inc. and Cilag GmbH International dated October 11, 2011.	Incorporated by reference to our Quarterly Report on Form 10-Q filed on November 3, 2011 as Exhibit 10.22.
10.25	Second Amendment to the Amended and Restated Master Services and Supply Agreement between Universal Biosensors, Inc., Universal Biosensors Pty Ltd, LifeScan, Inc. and Cilag GmbH International dated October 11, 2011.	Incorporated by reference to our Quarterly Report on Form 10-Q filed on November 3, 2011 as Exhibit 10.23. Confidentiality treatment has been granted for portions of this exhibit. These confidential portions have been omitted and were filed separately with the SEC.
10.26	Employment agreement between Universal Biosensors Pty Ltd and Mr. Paul Wright effective March 1, 2011	Incorporated by reference to our Current Report on Form 8-K filed on February 25, 2011 as Exhibit 10.1.
10.27	Employment agreement between Universal Biosensors Pty Ltd and Mr. Fred Davis effective November 2, 2011	Filed herewith
13.0	Annual Report	Filed herewith
14.0	Code of Ethics	Incorporated by reference to our Annual Report on Form 10-K filed on March 28, 2008 as Exhibit 14.0
21.0	List of Subsidiaries	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 21.0
24.0	Power of Attorney	Included on signature page
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act	Filed herewith
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act	Filed herewith
32.0	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act	Filed herewith

- 101 The following materials from the Universal Biosensors, Inc. Annual Report on Form 10-K for the financial year ended December 31, 2011 formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Condensed Balance Sheets, (ii) the Consolidated Condensed Statements of Operations, (iii) the Consolidated Condensed Statements of Changes in Stockholder's Equity and Comprehensive Income, (iv) the Consolidated Condensed Statements of Cash Flows and (v) the Notes to Consolidated Condensed Financial Statements tagged as blocks of text
- 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

**SIGNATURES**

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

Universal Biosensors, Inc.  
(Registrant)

By: /s/ Paul Wright  
Paul Wright  
Principal Executive Officer

Date: March 13, 2012

**POWER OF ATTORNEY**

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

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Paul Wright</u> Paul Wright	Chief Executive Officer (Principal Executive Officer)	March 13, 2012
<u>/s/ Salesh Balak</u> Salesh Balak	Chief Financial Officer (Principal Financial Officer)	March 13, 2012
<u>/s/ Andrew Denver</u> Andrew Denver	Director and Chairman	March 13, 2012
<u>/s/ Denis Hanley</u> Denis Hanley	Director	March 13, 2012
<u>/s/ Andrew Jane</u> Andrew Jane	Director	March 13, 2012
<u>/s/ Elizabeth Wilson</u> Elizabeth Wilson	Director	March 13, 2012
<u>/s/ Colin Adam</u> Colin Adam	Director	March 13, 2012
<u>/s/ Marshall Heinberg</u> Marshall Heinberg	Director	March 13, 2012

**Universal Biosensors, Inc.**

**2011 Annual Report**

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

### Universal Biosensors, Inc.

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

#### Our Business

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

We were incorporated in the State of Delaware on September 14, 2001 and our shares of common stock in the form of CHESS Depository Interests ("CDIs") have been quoted on the Australian Securities Exchange ("ASX") since December 13, 2006. Our securities are not currently traded on any other public market. Our wholly owned subsidiary and primary operating vehicle, Universal Biosensors Pty Ltd ("UBS") was incorporated as a proprietary limited company in Australia on September 21, 2001. UBS conducts our research, development and manufacturing activities in Melbourne, Australia.

We have rights to an extensive patent portfolio, with certain patents owned by UBS and a number licensed to UBS under a license agreement between LifeScan, Inc. ("LifeScan") and UBS ("License Agreement"). Unless otherwise noted, references to "LifeScan" in this document are references collectively or individually to LifeScan, Inc., and/or LifeScan Europe, a division of Cilag GmbH International, both affiliates of Johnson and Johnson.

We are using our electrochemical cell technology platform to develop tests for a number of different markets. Our current focus is as set out below:

- *Blood glucose* — UBS provides services and acts as a non-exclusive manufacturer of test strips for LifeScan's "OneTouch® Verio™", pursuant to a Master Services and Supply Agreement with LifeScan ("Master Services and Supply Agreement"). LifeScan continues its global rollout of the OneTouch Verio product which is currently available in North America, major European markets and Australia. We also undertake research and development work for LifeScan pursuant to a development and research agreement ("Development and Research Agreement").
- *Coagulation testing market* — UBS is working with Siemens Healthcare Diagnostics, Inc. ("Siemens") to develop a range of test strips and reader products for the point-of-care coagulation market, pursuant to a collaboration agreement ("Collaboration Agreement").
- *Other electrochemical-cell based tests* — we are working on proving the broader applicability of our technology platform for other immunoassay and molecular diagnostic point-of-care tests. We may seek to enter into collaborative arrangements or strategic alliances with respect to any tests arising from this work.

#### Results of Operations

##### Revenue from Products

OneTouch® Verio™ was first launched in the Netherlands in January 2010 and has subsequently been launched in Australia, in major European markets and North America. The manufacturing results of the blood glucose test strips during the respective periods are as follows:

	Years Ended December 31,		
	2011	2010	2009
	A\$	A\$	A\$
Revenue from products .....	12,063,582	11,760,009	132,733
Cost of goods sold .....	(12,310,302)	(10,801,062)	(458,162)
	<u>(246,720)</u>	<u>958,947</u>	<u>(325,429)</u>

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

### Universal Biosensors, Inc.

Pursuant to the agreement we have with LifeScan, one of two pricing methodologies will apply depending on whether we are manufacturing above or below a specified quantity of blood glucose test strips in a quarter. If less than the specified quantity of test strips is produced within a quarter, we are considered to be in the "interim costing period". In the interim costing period, the Company is not expected to generate any profit from the manufacture of test strips, but is expected to recover most of its glucose manufacturing costs. If manufactured volumes increase beyond the specified quantity of blood glucose test strips per quarter, the interim costing period will cease to apply and a different pricing methodology will apply, at which time we expect our blood glucose manufacturing operations to be profitable. We commenced commercial production in 2009 and operated under the interim costing period regime during that year. During 2010 and 2011, we ceased to be in the interim costing period during the fourth quarter of each of 2010 and 2011 at which time we generated profits from our blood glucose manufacturing operations. Our quarterly results from our blood glucose manufacturing operations for the 2011 and 2010 financial year reflect this.

	2011 Quarter Ended			
	December 31	September 30	June 30	March 31
	A\$	A\$	A\$	A\$
Revenue from products . . . . .	4,322,897	2,153,518	2,267,766	3,319,401
Cost of goods sold . . . . .	(3,809,376)	(2,314,082)	(2,694,792)	(3,492,052)
	513,521	(160,564)	(427,026)	(172,651)
	2010 Quarter Ended			
	December 31	September 30	June 30	March 31
	A\$	A\$	A\$	A\$
Revenue from products . . . . .	5,672,739	3,202,873	1,359,584	1,524,813
Cost of goods sold . . . . .	(4,189,520)	(3,136,390)	(1,936,716)	(1,538,436)
	1,483,219	66,483	(577,132)	(13,623)

During 2009, LifeScan chose not to proceed with the registration of the then current product but to proceed with an enhanced product, called One-Touch Verio, and acknowledged that there would be a delay as a result. As a result of this change, LifeScan agreed to pay us an additional amount per strip manufactured by us up to a certain volume in 2010. In 2011, as long as we remained in the interim costing period, LifeScan agreed to pay us an additional amount per strip equivalent to 50% of the amount agreed with LifeScan in 2010. These additional payments ceased during the third quarter of 2011 resulting in the higher margin in the last quarter of 2010 when compared to the same period in 2011 and the small profit in the third quarter of 2010.

#### **Revenue from Services**

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

- *Contract research and development* — we undertake contract research and development on behalf of our customers and partners. Contract research and development revenue up to the 2009 financial year has been recorded under the caption "Research and development income". As we commenced commercial production in 2010, the research and development was seen more as a service we provide which meant presenting it within "Revenue from Services";
- *Product enhancement* — a service fee based on the number of strips sold by our customers and partners is payable to us as an ongoing reward for our services and efforts to enhance the product;
- *Other services* — ad-hoc services provided on an agreed basis based on our customers and partners requirements.

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

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

	Years Ended December 31,		
	2011	2010	2009
	A\$	A\$	A\$
Revenue from services . . . . .	2,632,870	6,420,027	2,850,071
Cost of services . . . . .	<u>(708,149)</u>	<u>(1,481,674)</u>	<u>(169,241)</u>
	1,924,721	4,938,353	2,680,830
Income — Research and development income . . . . .	—	—	1,337,125

Contract research and development makes up the major portion of revenue from services. The nature and scope of contract research and development is determined by our customers and partners based upon their requirements hence our revenues and margins tend to fluctuate. This is reflected in our past three years results wherein the margin during the 2011 financial year has decreased by 61% compared to the 2010 financial year while the margin during the 2010 financial year has increased by 23% compared to the 2009 financial year. In September 2011, we commenced a new research and development project for LifeScan to determine the feasibility of an innovative blood glucose product. The feasibility project is expected to take 12 months. Revenue is recognized for the feasibility project when services have been performed, the amount of the payment can be reliably measured and collectability is reasonably assured. We recognize revenue for accounting purposes ratably over the feasibility period.

We received a non-refundable payment of US\$3 million in September 2011 upon entering into a collaboration agreement with Siemens. This deliverable is not a separate unit of accounting and has been recorded as deferred revenue and will be recognized as revenue across the deliverables in the arrangement with Siemens.

***Milestone Payment***

We received a milestone payment of A\$17,722,641 in 2009 triggered by the first grant to LifeScan of regulatory clearance to sell the blood glucose test.

***Research and Development Expenses***

Research and development expenses are related to developing electrochemical cell platform technologies. Research and development expenses consist of costs associated with research activities, as well as costs associated with our product development efforts, including pilot manufacturing costs. Research and development expenses include:

- consultant and employee related expenses, which include consulting fees, salary and benefits;
- materials and consumables acquired for the research and development activities;
- external research and development expenses incurred under agreements with third party organizations and universities; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation of leasehold improvements and equipment and laboratory and other supplies.

Our principal research and development activities can be described as follows:

***(a) Blood coagulation***

Since 2005, we have undertaken development work on a prothrombin time test for monitoring the therapeutic range of the anticoagulant, warfarin, based on measuring activity of the enzyme thrombin. In

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

**Universal Biosensors, Inc.**

September 2011 we entered into a collaboration agreement with Siemens pursuant to which will develop a range of test strips and reader products for the point-of-care coagulation market. The first test to be developed will be a modified version of a Prothrombin Time International Normalized Ratio ("PT-INR") test developed by UBS, followed by other tests in the point-of-care coagulation market.

*(b) Immunoassay*

We are continuing to develop our immunoassay platform. We are developing a D-dimer test for the detection and monitoring of several conditions associated with thrombotic disease, particularly deep venous thrombosis (clots in the leg) and pulmonary embolism (clots in the lung). Development work on this project has been undertaken since early 2008.

This work will allow the electrochemical cell platform technology to be expanded to a range of immunoassay tests.

*(c) DNA/RNA*

We have undertaken some early stage feasibility work assessing the possibility of using DNA binding chemistries to build a strip test for DNA, RNA and as a possible alternative method for improving the sensitivity of protein assays. This concept work is at an early stage and may not yield any positive results. We have recently entered into a license to access certain molecular diagnostic technology.

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

	<u>Years Ended December 31,</u>		
	<u>2011</u>	<u>2010</u>	<u>2009</u>
	A\$	A\$	A\$
Research and development expenses .....	<u>9,812,396</u>	<u>6,482,150</u>	<u>14,898,072</u>

Depending on the number of research and development activities we undertake and the development phase of the research and development, our research and development expenditure will fluctuate. Research and development expenditure increased by 51% during 2011 compared to 2010 and decreased by 56% during 2010 compared to 2009. Research and development expenses for 2009 reflect the conclusion of the development phase for the blood glucose product, wherein a significant amount of the work was carried out. All costs pertaining to this project after January 2010 are now captured in cost of goods sold as opposed to being treated as a research and development expenditure as they were prior to January 2010. During 2010 and 2011, our research and development activities were primarily focussed around the blood coagulation platform. Whilst we had established feasibility of the first product on this platform, the prothrombin time test, in 2010, we were at an advanced stage in 2011. During 2011 we had entered the formal development and validation stage of the prothrombin time test. An increased volume of work is required during this development phase of a research and development. During the latter half of 2011, we also commenced work on a range of other test strips and reader products for the point-of-care coagulation market pursuant to our agreement with Siemens.

While we have a degree of control as to how much we spend on research and development activities in the future, we cannot predict what it will cost to complete our individual research and development programs successfully or when or if they will be commercialized. The timing and cost of any program is dependent upon achieving technical objectives, which are inherently uncertain.

In addition, our business strategy contemplates that we may enter into collaborative arrangements with third parties for one or more of our non-blood glucose programs. In the event that we are successful in securing such third party collaborative arrangements, the third party will direct the research and development activities which will influence our research and development expenditure and these parties may contribute towards all or part of the cost of these activities.

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

### Universal Biosensors, Inc.

#### *General and Administrative Expenses*

General and administrative expenses currently consist principally of salaries and related costs, including stock option expense, for personnel in executive, business development, finance, accounting, information technology and human resources functions. Other general and administrative expenses include depreciation, repairs and maintenance, insurance, facility costs not otherwise included in research and development expenses, consultancy fees and professional fees for legal, audit and accounting services.

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

	Years Ended December 31,		
	2011	2010	2009
	A\$	A\$	A\$
General and administrative expenses .....	<u>7,271,488</u>	<u>7,185,550</u>	<u>5,635,569</u>

General and administrative expenses increased by 1% during 2011 compared to 2010 and increased by 28% during 2010 compared to 2009. This increase in expenses, particularly during 2010, reflects efforts put into business development to establish collaborative partnerships in the fields outside the area of glucose and diabetes. 2010 was also the first financial year wherein our auditors had to undertake internal controls work in order to furnish an attestation report regarding internal controls over financial reporting as required under the Sarbanes Oxley Act. This resulted in us incurring additional expenditure.

#### *Interest Income*

Interest income decreased to A\$683,323 in 2011 from A\$1,192,889 in 2010. The decrease in interest income is attributable to the lower amounts of funds available for investment. Interest income increased to A\$1,192,889 in 2010 from A\$809,459 in 2009. The increase in interest income is attributable to increased returns on the funds invested and the higher amounts of funds available for investment.

#### **Critical Accounting Estimates and Judgments**

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

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

##### *(a) Revenue Recognition*

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

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

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

### Universal Biosensors, Inc.

vendor-specific objective evidence or third-party evidence of selling price involves management's judgment. The Company's process considers multiple factors that may vary depending upon the unique facts and circumstances related to each deliverable.

#### *(b) Stock-Based Compensation*

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

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

#### *Share Price at Valuation Date*

The value of the options granted in 2010 and 2011 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 value of the options granted in 2009 have been determined using the average closing price of the Company's common stock on the ASX on the five days on which the Company's common stock has traded prior to the approval of grant. The ASX is the only exchange upon which our securities are quoted.

#### *Volatility*

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

#### *Time to Expiry*

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

#### *Risk Free Rate*

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

#### *(c) Income Taxes*

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

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

#### *(d) Impairment of Long-Lived Assets*

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

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

**Universal Biosensors, Inc.**

**Financial Condition, Liquidity and Capital Resources**

*Net Financial Assets*

Our net financial assets position is shown below:

	Years Ended December 31,		
	2011	2010	2009
	A\$	A\$	A\$
Financial assets:			
Cash and cash equivalents . . . . .	15,089,209	23,271,766	31,291,011
Accounts receivables . . . . .	4,889,783	3,588,798	415,397
Financial instruments . . . . .	83,339	—	—
Total financial assets . . . . .	<u>20,062,331</u>	<u>26,860,564</u>	<u>31,706,408</u>
Debt:			
Short and long term debt/borrowings . . . . .	—	—	—
Financial instruments . . . . .	—	—	47,412
Total debt . . . . .	—	—	47,412
Net financial assets . . . . .	<u>20,062,331</u>	<u>26,860,564</u>	<u>31,658,996</u>

We rely largely on our existing cash and cash equivalents and funds from our operations 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.

*Measures of Liquidity and Capital Resources*

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

	Years Ended December 31,		
	2011	2010	2009
	A\$	A\$	A\$
Cash and cash equivalents . . . . .	15,089,209	23,271,766	31,291,011
Working capital . . . . .	17,584,523	25,940,899	32,118,842
Ratio of current assets to current liabilities . . . . .	3.51 : 1	6.82 : 1	13.05 : 1
Shareholders' equity per common share . . . . .	0.22	0.30	0.33

The movement in cash and cash equivalents and working capital in each of the years was primarily due to the timing of cash receipts, payments, sales and accruals in the ordinary course of business. 2009 was also impacted by the receipt of a milestone payment of A\$17,722,641. We have not identified any collection issues with respect to receivables.

*Summary of Cash Flows*

	Years Ended December 31,		
	2011	2010	2009
	A\$	A\$	A\$
Cash provided by/(used in):			
Operating activities . . . . .	(7,159,118)	(6,414,248)	5,867,156
Investing activities . . . . .	(1,102,943)	(2,320,293)	(2,990,007)
Financing activities . . . . .	79,504	715,296	78,998
Net increase/(decrease) in cash and cash equivalents . . . . .	<u>(8,182,557)</u>	<u>(8,019,245)</u>	<u>2,956,147</u>

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

### Universal Biosensors, Inc.

Our net cash used in operating activities in 2011 and 2010 was primarily for our research and development projects including efforts involved in establishing our manufacturing. The outflows during these two years have been partially offset by receipts from our customers and partners. The positive operating activity result in 2009 is predominantly as a result of the receipt of the milestone payment of A\$17,722,641 in December 2009.

Our net cash used in investing activities for all years is primarily for the purchase of various plant and equipment and fit out of our facilities based on our needs.

Our net cash provided by financing activities is primarily proceeds received from employees exercising their options.

#### Off-Balance Sheet Arrangement

The future minimum lease payments under non-cancellable operating leases (with initial or remaining lease terms in excess of one year) as of December 31, 2011 are:

	A\$
Less than 1 year .....	556,082
1 — 3 years .....	714,244
3 — 5 years .....	—
More than 5 years .....	—
Total minimum lease payments .....	1,270,326

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

#### Contractual Obligations

Our future contractual obligations at December 31, 2011 were as follows:

	Payments Due By Period				
	Total	Less than 1	1 – 3 years	3 – 5 years	More than 5
	A\$	A\$	A\$	A\$	A\$
Asset Retirement Obligations(1) .....	2,166,691	—	—	2,166,691	—
Operating Lease Obligations(2) .....	1,270,326	556,082	714,244	—	—
Purchase Obligations(3) .....	3,173,761	1,773,761	1,400,000	—	—
Other Long-Term Liabilities on Balance Sheet(4) .....	181,367	—	119,237	55,860	6,270
Total .....	6,792,145	2,329,843	2,233,481	2,222,551	6,270

- (1) Represents legal obligations associated with the retirement and removal of long-lived assets.
- (2) Our operating lease obligations relate primarily to the lease of our premises.
- (3) Represents outstanding purchase orders and contractual obligations that are payable on the achievement of certain milestones
- (4) Represents long service leave owing to the employees.

#### Segments

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

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

### Universal Biosensors, Inc.

#### Recent Accounting Pronouncements

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

#### Financial Risk Management

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

##### *Foreign Currency Market Risk*

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

The following table sets out the notional amounts and weighted average exchange rates by expected (contractual) maturity dates. These notional amounts generally are used to calculate the contractual payments to be exchanged under the contract.

	<u>2012 (*)</u>	<u>Fair Value</u>
<b><i>Anticipated Transactions and Related Derivatives</i></b>		
AUD Functional Currency:		
Forward exchange agreements (Sell USD/Buy AUD)		
Contract amount . . . . .	US\$4,000,000	A\$4,114,179
Average contractual exchange rate . . . . .	0.9923	

\* Expected maturity or transaction date

##### *Interest Rate Risk*

Since the majority of our investments are in cash and cash equivalents in AUD, our exposure to interest income is affected by changes in the general level of 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.



## Report of Independent Registered Public Accounting Firm

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, consolidated statements of stockholders' equity and comprehensive income and consolidated statements of cash flows present fairly, in all material respects, the financial position of Universal Biosensors, Inc. and its subsidiaries at December 31, 2011 and December 31, 2010, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2011 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the appendix under Item 15(a)(2) present fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements and financial statement schedule, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements, on the financial statement schedule, and on the Company's internal control over financial reporting based on our audits (which were integrated audits in 2011 and 2010). We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) 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 directors of the company; and (iii) 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.

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

/s/ PricewaterhouseCoopers

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PricewaterhouseCoopers

Sydney  
March 13, 2012

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**Universal Biosensors, Inc.**  
**Consolidated Balance Sheets**

	<u>December 31,</u> <u>2011</u>	<u>December 31,</u> <u>2010</u>
	<u>A\$</u>	<u>A\$</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	15,089,209	23,271,766
Inventories, net .....	3,619,400	3,191,093
Accounts receivable .....	4,889,783	3,588,798
Prepayments .....	92,048	303,181
Financial instruments .....	83,339	—
Other current assets .....	827,508	46,196
Total current assets .....	<u>24,601,287</u>	<u>30,401,034</u>
Non-current assets:		
Property, plant and equipment .....	33,151,027	32,713,280
Less accumulated depreciation .....	(12,855,847)	(9,586,365)
Property, plant and equipment — net .....	<u>20,295,180</u>	<u>23,126,915</u>
Other non-current assets .....	320,000	310,000
Total non-current assets .....	<u>20,615,180</u>	<u>23,436,915</u>
Total assets .....	<u><u>45,216,467</u></u>	<u><u>53,837,949</u></u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable .....	620,682	1,764,364
Accrued expenses .....	2,061,528	2,099,477
Deferred revenue .....	3,509,721	—
Employee entitlements provision .....	824,833	596,294
Total current liabilities .....	<u>7,016,764</u>	<u>4,460,135</u>
Non-current liabilities:		
Asset retirement obligations .....	2,166,691	1,998,060
Employee entitlements provision .....	181,367	160,675
Deferred revenue .....	829,039	—
Total non-current liabilities .....	<u>3,177,097</u>	<u>2,158,735</u>
Total liabilities .....	<u><u>10,193,861</u></u>	<u><u>6,618,870</u></u>
Commitments and contingencies (Note 3) .....	<u>—</u>	<u>—</u>
Stockholders' equity:		
Preferred stock, \$0.01 par value. Authorized 1,000,000 shares; issued and outstanding nil in 2011 (2010: nil)		
Common stock, \$0.0001 par value. Authorized 300,000,000 shares; issued and outstanding 159,139,965 shares in 2011 (2010: 158,871,495) .....	15,914	15,887
Additional paid-in capital .....	79,446,995	77,034,717
Accumulated deficit .....	(29,533,213)	(22,922,688)
Current year loss .....	(14,692,117)	(6,610,525)
Accumulated other comprehensive income .....	(214,973)	(298,312)
Total stockholders' equity .....	<u>35,022,606</u>	<u>47,219,079</u>
Total liabilities and stockholders' equity .....	<u><u>45,216,467</u></u>	<u><u>53,837,949</u></u>

See accompanying notes to the financial statements

**Universal Biosensors, Inc.**  
**Consolidated Statements of Operations**

	Years Ended December 31,		
	2011 A\$	2010 A\$	2009 A\$
<b>Revenue</b>			
Revenue from products .....	\$ 12,063,582	\$ 11,760,009	\$ 132,733
Revenue from services .....	2,632,870	6,420,027	2,850,071
Research and development income .....	—	—	1,337,125
Milestone payment .....	—	—	17,722,641
Total revenue .....	<u>14,696,452</u>	<u>18,180,036</u>	<u>22,042,570</u>
<b>Operating costs &amp; expenses</b>			
Cost of goods sold .....	12,310,302	10,801,062	458,162
Cost of services .....	708,149	1,481,674	169,241
Research and development .....	9,812,396	6,482,150	14,898,072
General and administrative .....	<u>7,271,488</u>	<u>7,185,550</u>	<u>5,635,569</u>
Total operating costs & expenses .....	<u>30,102,335</u>	<u>25,950,436</u>	<u>21,161,044</u>
Profit/(loss) from operations .....	(15,405,883)	(7,770,400)	881,526
<b>Other income/(expense)</b>			
Interest income .....	683,323	1,192,889	809,459
Interest expense .....	—	—	(9,636)
Other .....	<u>30,443</u>	<u>(33,014)</u>	<u>(250,886)</u>
Total other income/(expense) .....	713,766	1,159,875	548,937
Net profit/(loss) before tax .....	(14,692,117)	(6,610,525)	1,430,463
Income tax benefit/(expense) .....	—	—	—
Net profit/(loss) .....	<u>\$ (14,692,117)</u>	<u>\$ (6,610,525)</u>	<u>\$ 1,430,463</u>
Basic net profit/(loss) per share .....	\$ (0.09)	\$ (0.04)	\$ 0.01
Average weighted number of shares — basic .....	159,017,777	157,584,044	157,013,578
Diluted net profit/(loss) per share .....	\$ (0.09)	\$ (0.04)	\$ 0.01
Average weighted number of shares — diluted .....	159,017,777	157,584,044	161,354,802

See accompanying notes to the financial statements.

**Universal Biosensors, Inc.**  
**Consolidated Statements of Stockholders' Equity and Comprehensive Income**

	Ordinary shares		Additional Paid-in Capital	Accumulated Deficit	Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount A\$				
<b>Balances at January 1, 2009</b> .....	156,976,936	15,698	73,338,995	(24,353,151)	(298,312)	48,703,230
Comprehensive Income						
Unrealised loss on derivatives and hedges .....	—	—	—	—	(47,412)	(47,412)
Net profit .....	—	—	—	1,430,463	—	1,430,463
Total Comprehensive income ...						1,383,051
Exercise of stock options issued to employees .....	138,327	14	78,984	—	—	78,998
Shares issued to employees .....	40,670	4	69,948	—	—	69,952
Stock option expense .....	—	—	1,078,771	—	—	1,078,771
<b>Balances at December 31, 2009</b> .....	157,155,933	15,716	74,566,698	(22,922,688)	(345,724)	51,314,002
Comprehensive income						
Unrealised gain on derivatives and hedges .....	—	—	—	—	47,412	47,412
Net loss .....	—	—	—	(6,610,525)	—	(6,610,525)
Total Comprehensive income ...						(6,563,113)
Exercise of stock options issued to employees .....	1,667,581	167	715,129	—	—	715,296
Shares issued to employees .....	47,981	4	75,887	—	—	75,891
Stock option expense .....	—	—	1,677,003	—	—	1,677,003
<b>Balances at December 31, 2010</b> .....	158,871,495	15,887	77,034,717	(29,533,213)	(298,312)	47,219,079
Comprehensive income						
Unrealised gain on derivatives and hedges .....	—	—	—	—	83,339	83,339
Net loss .....	—	—	—	(14,692,117)	—	(14,692,117)
Total Comprehensive income ...						(14,608,778)
Exercise of stock options issued to employees .....	181,999	18	79,486	—	—	79,504
Shares issued to employees .....	86,471	9	76,950	—	—	76,959
Stock option expense .....	—	—	2,255,842	—	—	2,255,842
<b>Balances at December 31, 2011</b> .....	159,139,965	15,914	79,446,995	(44,225,330)	(214,973)	35,022,606

See accompanying notes to the financial statements.

**Universal Biosensors, Inc.**  
**Consolidated Statements of Cash Flows**

	Years Ended December 31,		
	2011	2010	2009
	A\$	A\$	A\$
<b>Cash flows from operating activities provided by/(used in):</b>			
Net profit/(loss) .....	(14,692,117)	(6,610,525)	1,430,463
Adjustments to reconcile net profit/(loss) to net cash provided by/ (used in) operating activities:			
Depreciation and amortization .....	3,298,541	2,990,858	2,851,285
Share based payments expense .....	2,255,842	1,677,003	1,078,771
Loss on fixed assets disposal .....	17,715	2,618	60,658
Change in assets and liabilities:			
Inventory .....	(428,307)	(2,885,969)	(305,124)
Accounts receivables .....	(1,300,985)	(3,733,332)	(114,713)
Prepaid expenses and other current assets .....	(725,797)	(6,079)	141,331
Deferred revenue .....	4,492,426	118,305	290,904
Employee entitlements .....	249,231	73,493	50,192
Accounts payable and accrued expenses .....	(325,667)	1,959,380	383,389
Net cash provided by/(used in) operating activities .....	<u>(7,159,118)</u>	<u>(6,414,248)</u>	<u>5,867,156</u>
<b>Cash flows from investing activities:</b>			
Instalment payments to acquire plant and equipment .....	—	(988,334)	(2,145,808)
Purchases of property, plant and equipment .....	(1,102,943)	(1,331,959)	(844,199)
Net cash used in investing activities .....	<u>(1,102,943)</u>	<u>(2,320,293)</u>	<u>(2,990,007)</u>
<b>Cash flows from financing activities:</b>			
Proceeds from borrowings .....	—	—	479,673
Repayment of borrowings .....	—	—	(479,673)
Proceeds from stock options exercised .....	79,504	715,296	78,998
Net cash provided by financing activities .....	<u>79,504</u>	<u>715,296</u>	<u>78,998</u>
Net increase/(decrease) in cash and cash equivalents .....	(8,182,557)	(8,019,245)	2,956,147
Cash and cash equivalent at beginning of period .....	23,271,766	31,291,011	28,334,864
<b>Cash and cash equivalents at end of period .....</b>	<b><u>15,089,209</u></b>	<b><u>23,271,766</u></b>	<b><u>31,291,011</u></b>

See accompanying notes to the financial statement

**Universal Biosensors, Inc.**  
**Notes to Consolidated Financial Statements**  
**(for the years ended December 31, 2009, 2010 and 2011)**

**(1) Basis of Presentation**

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

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

During 2010, the Group (consisting of Universal Biosensors, Inc. and its wholly owned subsidiary, Universal Biosensors Pty Ltd) ceased to be a development stage enterprise as it has established its commercial scale manufacturing and is generating revenue from its manufacturing operations.

**(2) Summary of Significant Accounting Policies**

*Principles of Consolidation*

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

*Use of Estimates*

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

*Reclassification*

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

*Cash & Cash Equivalents*

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.

*Short-Term Investments (Held-to-maturity)*

Short-term investments constitute all highly liquid investments with term to maturity from three months to twelve months. The carrying amount of short-term investments is equivalent to its fair value.

*Concentration of Credit Risk and Other Risks and Uncertainties*

Cash and cash equivalents and accounts receivables consists of financial instruments that potentially subject the Company to concentration of credit risk to the extent of the amount recorded on the balance sheet. The Company's cash and cash equivalents are invested with two of Australia's four largest banks. The Company is exposed to credit risk in the event of default by the banks holding the cash or cash equivalents to the extent of the

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

***Derivative Instruments and Hedging Activities***

*Derivative financial instruments*

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

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

*Cash flow hedges*

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

Where a derivative financial instrument is designated as a hedge of the variability in cash flows of a recognized asset or liability, or a highly probable forecast transaction, the effective part of any unrealised gain or loss on the derivative financial instrument is recognized directly in equity. When the forecast transaction subsequently results in the recognition of a non-financial asset or non-financial liability, the associated cumulative gain or loss is removed from equity and included in the initial cost or other carrying amount of the non-financial asset or liability.

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

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

***Inventory***

Inventories are stated at the lower of cost or net realizable value. Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and estimated costs necessary to dispose. Inventories are principally determined under the average cost method which approximates cost. Cost comprises direct materials, direct labour and an appropriate portion of variable and fixed overhead expenditure, the latter being allocated on the basis of normal operating capacity. Cost also includes the transfer from equity of

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any gains/losses on qualifying cash flow hedges relating to purchases of raw material. Costs of purchased inventory are determined after deducting rebates and discounts.

	Years Ended December 31,		
	2011	2010	2009
	A\$	A\$	A\$
Raw materials .....	3,254,675	2,798,045	289,069
Work in progress .....	102,239	188,629	16,055
Finished goods .....	262,486	204,419	—
	3,619,400	3,191,093	305,124

***Receivables***

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

	Years Ended December 31,		
	2011	2010	2009
	A\$	A\$	A\$
Accounts receivable .....	4,889,783	3,588,798	415,397
Allowance for doubtful debts .....	—	—	—
	4,889,783	3,588,798	415,397

***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 3 to 10 years. Leasehold improvements are amortized on the straight-line method over the shorter of the remaining lease term or estimated useful life of the asset. Maintenance and repairs are charged to operations as incurred and include normal services and does not include items of a capital nature.

The Company receives Victorian government grant monies under grant agreements to support our development activities, including in connection with the purchase of plant and equipment. Plant and equipment is presented net of the government grant. The grant monies are recognized against the acquisition costs of the related plant and equipment as and when the related assets are purchased.

***Research and Development***

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

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Research and development expenses for years ended December 31, 2011, 2010 and 2009 are as follows:

	Years Ended December 31,		
	2011	2010	2009
	A\$	A\$	A\$
Research and development expenses .....	9,812,396	6,482,150	14,898,072

***Income Taxes***

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

Where it is more likely than not that some portion or all of the deferred tax assets will not be realized the deferred tax assets are reduced by a valuation allowance. The valuation allowance is sufficient to reduce the deferred tax assets to the amount that is more likely than not to be realized. A reconciliation of the valuation and qualifying accounts is attached as Schedule ii.

We are subject to income taxes in the United States and Australia. U.S. federal income tax returns up to the 2010 financial year have been filed. Internationally, consolidated income tax returns up to the 2010 financial year have been filed.

***Asset Retirement Obligations***

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

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

Our overall ARO changed as follows:

	Years Ended December 31,	
	2011	2010
	A\$	A\$
Opening balance at January 1 .....	1,998,060	1,842,547
Accretion expense .....	168,631	155,513
Ending balance at December 31 .....	2,166,691	1,998,060

***Fair Value of Financial Instruments***

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

- *Market approach* — based on market prices and other information from market transactions involving identical or comparable assets or liabilities.

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

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

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

***Impairment of Long-Lived Assets***

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

***Australian Goods and Services Tax (GST)***

Revenues, expenses and assets are recognized net of the amount of associated GST, unless the GST incurred is not recoverable from the taxation authority. In this case it is recognized as part of the cost of acquisition of the asset or as part of the expense. Receivables and payables are stated inclusive of the amount of GST receivable or payable. The net amount of GST recoverable from, or payable to, the taxation authority is included with other receivables or payables in the balance sheet.

***Revenue Recognition***

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

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

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

Revenue from services are recognized when a persuasive evidence of an arrangement exists, services have been rendered, the price is fixed or determinable, and collectability is reasonably assured. Revenue recognition principles are assessed for each new contractual arrangement and the appropriate accounting is determined for each service.

Where our agreements contain multiple elements, or deliverables, such as the manufacture and sale of products, provision of services or research and development activities, they are assessed to determine whether separate delivery of the individual elements of such arrangements comprises more than one unit of accounting. Where an arrangement can be divided into separate units of accounting (each unit constituting a separate earnings process), the arrangement consideration is allocated amongst those varying units based on the relative selling

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price of the separate units of accounting and the applicable revenue recognition criteria applied to the separate units. Selling prices are determined using fair value, either vendor specific objective evidence or third party evidence of the selling price, when available, or the Company's best estimate of selling price when fair value is not available for a given unit of accounting.

Under ASC 605-25, which the Company adopted on January 1, 2009, the delivered item(s) are separate units of accounting, provided (i) the delivered item(s) have value to a customer on a stand-alone basis, and (ii) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in our control. Where the arrangement cannot be divided into separate units, the individual deliverables are combined as a single unit of accounting and the total arrangement consideration is recognized across other deliverables in the arrangement or over the estimated collaboration period. Payments under these arrangements typically include one or more of the following: non-refundable, upfront payments; funding of research and/or development efforts; and milestone payments.

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

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

*Product and Service Agreements*

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

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

In October 2011, the Company entered into a Statement of Work agreement with LifeScan to provide services for a feasibility study for an innovative blood glucose product. The services relating to this agreement are expected to take 12 months to complete which commenced in September 2011.

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*Research and Development Agreement*

On September 9, 2011 the Company entered into a new collaboration agreement with Siemens to develop coagulation related products for hospital point-of-care and ambulatory care coagulation markets. In addition to an up-front, non-refundable payment of US\$3 million; the Company may receive up to six payments from Siemens upon the achievement of certain defined milestones relating to feasibility, regulatory submissions and the launch of the products to be developed. The Company has concluded that the up-front payment is not a separate unit of accounting and recorded the amount as deferred revenue to be recognized as revenue across other deliverables in the arrangement with Siemens based upon the Company's best estimate of selling price. The deliverables related to each milestone are considered substantive and are not priced at a significant incremental discount to the other deliverables. As the achievement of the milestones is contingent upon a future event, the revenue for each deliverable will be recognized as the contingencies are met and the consideration becomes fixed and determinable.

*Interest income*

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

*Foreign Currency*

*Functional and reporting currency*

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates ("the functional currency"). The functional currency of the Company and UBS is AUD or A\$ for all years presented.

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

*Transactions and balances*

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

The Company has recorded foreign currency transaction losses of A\$4,442, A\$512,474 and A\$250,886 in each of the years ended December 31, 2011, 2010 and 2009, respectively.

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

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

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

*Commitments and Contingencies*

Liabilities for loss contingencies, arising from claims, assessments, litigation, fines, and penalties and other sources are recorded when it is probable that a liability has been incurred and the amount of the assessment can be reasonably estimated. These were nil as at December 31, 2011 (2010: nil).

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***Patent and License Costs***

Legal fees incurred for patent application costs have been charged to expense and reported in research and development expense. Legal fees incurred for patents relating to commercialized products are capitalized and amortized over the life of the patents.

***Clinical Trial Expenses***

Clinical trial costs are a component of research and development expenses. These expenses include fees paid to participating hospitals and other service providers, which conduct certain testing activities on behalf of the Company. Depending on the timing of payments to the service providers and the level of service provided, the Company records prepaid or accrued expenses relating to these costs.

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

***Leased Assets***

All of the Company's leases for the years ended December 31, 2011, 2010 and 2009 are considered operating leases. The costs of operating leases are charged to the statement of operations on a straight-line basis over the lease term.

***Stock-based Compensation***

We measure stock-based compensation at grant date, based on the estimated fair value of the award, and recognize the cost as an expense on a straight-line basis over the vesting period of the award. We estimate the fair value of stock options using the Trinomial Lattice model. We also grant our employees Restricted Stock Units ("RSUs") and Zero Priced Employee Options ("ZEPOs"). RSUs are stock awards granted to employees that entitle the holder to shares of common stock as the award vests. ZEPOs are stock options granted to employees that entitle the holder to shares of common stock as the award vests. The value of RSUs and ZEPOs are determined and fixed on the grant date based on the Company's stock price. See note 5 for further details.

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

***Employee Benefit Costs***

The Company contributes to standard defined contribution superannuation funds on behalf of all employees at nine percent of each such employee's salary. Superannuation is a compulsory savings program whereby employers are required to pay a portion of an employee's remuneration to an approved superannuation fund that the employee is typically not able to access until they are retired. The Company permits employees to choose an approved and registered superannuation fund into which the contributions are paid. Contributions are charged to the statement of operations as they become payable.

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

Basic and diluted net profit/(loss) per share is presented in conformity with ASC 260 – Earnings per Share. Basic and diluted net profit/(loss) per share has been computed using the weighted-average number of common shares outstanding during the period. Other than in a profit making year, the potentially dilutive options issued under the Universal Biosensors Employee Option Plan were not considered in the computation of diluted net profit/(loss) per share because they would be anti-dilutive given the Company's loss making position.

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***Total Comprehensive Income***

The Company follows ASC 220 – Comprehensive Income. Comprehensive income 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 and cumulative translation adjustments.

***Recent Accounting Pronouncements***

In December 2011, the FASB issued ASU 2011-11 which amended the disclosure requirements regarding offsetting assets and liabilities of derivatives, sale and repurchase agreements, reverse sale and repurchase agreements, and securities borrowing and securities lending arrangements. The enhanced disclosures will require entities to provide both net and gross information for these assets and liabilities. The amendment is effective for fiscal years beginning on or after January 1, 2013. The Company does not anticipate that this amendment will have a material impact on its financial statements.

In June 2011, the FASB issued ASU No. 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income. The new guidance allows an entity to present components of net income and other comprehensive income in one continuous statement, referred to as the statement of comprehensive income, or in two separate, but consecutive statements. The guidance eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. While the new guidance changes the presentation of comprehensive income, there are no changes to the components that are recognized in net income or other comprehensive income under current accounting guidance. This new guidance is effective for fiscal years and interim periods beginning after December 15, 2011. This guidance will result in a change in the way we present Other Comprehensive Income and its components, but will not have an impact on our financial position, results of operations or cash flows.

In May 2011, the FASB issued ASU No. 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. generally accepted accounting principles (GAAP) and International Financial Reporting Standards (IFRS). This ASU is intended to result in convergence between U.S. GAAP and IFRS requirements for measurement of and disclosures about fair value. The guidance amends current fair value measurement and disclosure guidance to include increased transparency around valuation inputs and investment categorization. This new guidance is effective for fiscal years and interim periods beginning after December 15, 2011. We do not believe the adoption of the new guidance will have a significant impact on the company's consolidated financial statements.

**(3) Commitments and Contingent Liabilities**

***Operating Leases***

UBS entered into a lease with respect to premises at 1 Corporate Avenue, Rowville Victoria which commenced on November 1, 2006 for an initial period of seven years and five months, with two options to renew the lease for successive five-year periods. The Company's primary bank has issued a bank guarantee of A\$250,000 in relation to a rental bond to secure the payments under the lease. This bank guarantee is secured by a security deposit held at the bank and has been recorded as "Other Assets" in Consolidated Balance Sheets.

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

The Company has also entered into a lease with respect to certain office equipment. The lease is for a period of 60 months which commenced in December 2007.

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Future minimum lease payments under non-cancelable operating leases (with initial or remaining lease terms in excess of one year) as of December 31, 2011 are:

	A\$
2012 .....	556,082
2013 .....	567,932
2014 .....	146,312
2015 and thereafter .....	—
Total minimum lease payments .....	1,270,326

Rent expense was A\$576,301, A\$556,584 and A\$533,749 for the fiscal years ended December 31, 2011, 2010 and 2009, respectively.

***Government research grants***

On October 28, 2006, Universal Biosensors Pty Ltd was awarded a grant by the State of Victoria to support the establishment of a medical diagnostic manufacturing facility in Victoria, Australia for the manufacture of new technologies for disease monitoring and to increase support of local and export markets. These payments are subject to the achievement of milestones which include capital expenditure by Universal Biosensors Pty Ltd of predetermined minimum amounts. The State of Victoria may require Universal Biosensors Pty Ltd to refund any amounts paid under the grant together with interest should Universal Biosensors Pty Ltd commit a breach of its obligations under the grant agreement. The State of Victoria may also withhold, suspend, cancel or terminate any payment or payments upon a failure to comply with obligations or if Universal Biosensors Pty Ltd chooses not to proceed with these initiatives or it becomes insolvent. The total amount received under the Victorian State Government Grant during 2011 was A\$55,346 (2010: A\$39,875, 2009: A\$130,000). This grant has been recognized against the acquisition cost of the related plant and equipment.

On October 1, 2010, Universal Biosensors Pty Ltd was awarded a grant of A\$250,000 by the State of Victoria to assist in the upgrade of the current manufacturing facility to ultimately support the production of strips for a new point of care test. These payments are subject to the achievement of milestones which include capital expenditure by Universal Biosensors Pty Ltd of predetermined minimum amounts. The State of Victoria may require Universal Biosensors Pty Ltd to refund any amounts paid under the grant together with interest should Universal Biosensors Pty Ltd fail to complete the upgrade within a stipulated timeframe or fails to fulfill its commitments towards the upgrade. The State of Victoria may also withhold, suspend, cancel or terminate any payment or payments upon a failure to comply with obligations or if Universal Biosensors Pty Ltd chooses not to proceed with these initiatives or it becomes insolvent. The total amount received under the Victorian State Government Grant during 2011 was A\$175,000 (2010: Nil). This grant has been recognized against the acquisition cost of the related plant and equipment.

***Guarantees***

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

**(4) Income Taxes**

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

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A reconciliation of the (benefit)/provision for income taxes with the amount computed by applying the Australian statutory company tax rate of 30% to the profit/(loss) before income taxes is as follows:

	Years ended December 31,					
	2011		2010		2009	
	A\$	%	A\$	%	A\$	%
Profit/(loss) before income taxes	(14,692,117)		(6,610,525)		1,430,463	
Computed by applying income tax rate of home jurisdiction	(4,407,635)	30	(1,983,157)	30	429,139	30
Research & development incentive	(635,470)	4	(421,341)	6	(3,524,333)	(246)
Disallowed expenses/(income):						
Share based payment	676,753	(4)	503,100	(7)	323,631	22
Other	8,849	—	4,730	—	(226,924)	(16)
Change in valuation allowance	<u>4,357,503</u>	<u>(30)</u>	<u>1,896,668</u>	<u>(29)</u>	<u>2,998,487</u>	<u>210</u>
Income tax expense/(benefit)	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>

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

	As of December 31,	
	2011 A\$	2010 A\$
Deferred tax assets:		
Operating loss carry forwards	16,794,322	12,923,654
Unamortized capital raising cost	1,000	104,850
Depreciation and amortization	(378,385)	(663,990)
Asset retirement obligations	650,007	599,418
Employee entitlements	301,860	227,090
Other	<u>987,644</u>	<u>807,923</u>
Total deferred tax assets	18,356,448	13,998,945
Valuation allowance for deferred tax assets	<u>(18,356,448)</u>	<u>(13,998,945)</u>
Net deferred tax asset	<u>—</u>	<u>—</u>

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

At December 31, 2011 the Company has A\$55,981,074 (A\$43,078,848 at December 31, 2010) 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.

**(5) Employee Incentive Schemes**

**(a) Stock Option Plan**

In 2004, the Company adopted an employee option plan ("Plan"). Options may be granted pursuant to the Plan to any person considered by the board to be employed by the Group on a permanent basis (whether full time, part time or on a long term casual basis). Each option gives the holder the right to subscribe for one share of common stock. The total number of options that may be issued under the Plan is such maximum amount permitted by law and the Listing Rules of the Australian Securities Exchange ("ASX"). The exercise price and

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any exercise conditions are determined by the board at the time of grant of the options. Any exercise conditions must be satisfied before the options vest and become capable of exercise. The options lapse on such date determined by the board at the time of grant or earlier in accordance with the Plan. Options granted to date have had a term up to 10 years and generally vest in equal tranches over three years.

An option holder is not permitted to participate in a bonus issue or new issue of securities in respect of an option held prior to the issue of shares to the option holder pursuant to the exercise of an option. If Universal Biosensors changes the number of issued shares through or as a result of any consolidation, subdivision, or similar reconstruction of the issued capital of the Company, the total number of options and the exercise price of the options (as applicable) will likewise be adjusted. Options granted in 2009, 2010 and 2011 were 4,164,200, 914,500 and 3,555,500 respectively.

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

	Grant Date												
	Nov-11	Nov-11	Sep-11	Mar-11	Feb-11	Nov-10	Nov-10	Feb-10	Nov-09	Jun-09	Jun-09	May-09	Feb-09
Exercise Price (A\$) . . . . .	Nil	0.89	1.00	1.37	1.38	Nil	1.58	1.6	1.72	Nil	0.94	Nil	0.5
Share Price at Grant Date (A\$) . . . .	0.89	0.89	1.00	1.37	1.38	1.58	1.58	1.6	1.73	0.95	0.95	1.18	0.43
Volatility . . . . .	68%	68%	69%	70%	71%	72%	72%	77%	78%	80%	80%	81%	77%
Expected Life (years) . . . . .	7	7	7	7	7	7	7	7	10	10	10	10	10
Risk Free Interest Rate . . . . .	3.72%	3.72%	3.89%	5.36%	5.45%	5.27%	5.27%	5.34%	5.63%	5.49%	5.49%	4.87%	4.26%
Fair Value of Option (A\$) . . . . .	0.89	0.52	0.59	0.83	0.83	1.58	0.96	0.99	1.13	0.95	0.62	1.04	0.28

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

*Share price at valuation date*

The value of the options granted in 2010 and 2011 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 value of the options granted in 2009 have been determined using the average closing price of the Company's common stock on the ASX on the five days on which the Company's common stock has traded prior to the approval of grant. The ASX is the only exchange upon which our securities are quoted.

*Volatility*

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

*Time to Expiry*

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

*Risk free rate*

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

**Universal Biosensors, Inc.**  
**Notes to Consolidated Financial Statements**  
**(for the years ended December 31, 2009, 2010 and 2011)**

Stock option activity during the current period is as follows:

	<u>Number of shares</u>	<u>Weighted average exercise price</u> A\$
Balance at December 31, 2010 .....	8,539,704	0.93
Granted .....	3,355,500	1.25
Exercised .....	(181,999)	0.46
Lapsed .....	(295,669)	1.33
Balance at December 31, 2011 .....	<u>11,417,536</u>	<u>1.02</u>

At December 31, 2011, the number of options exercisable was 8,011,691 (2010: 5,908,214 and 2009: 5,808,324). At December 31, 2011, total stock compensation expense recognized in income statement was A\$2,255,842 (2010: A\$1,677,003 and 2009: A\$1,078,771).

The following table represents information relating to stock options outstanding under the plans as of December 31, 2011:

<u>Exercise Price</u> A\$	<u>Options Outstanding</u>		<u>Options Exercisable Shares</u>
	<u>Shares</u>	<u>Weighted average remaining life in years</u>	
\$0.30 .....	1,516,770	2.00	1,516,770
\$0.35 .....	443,099	4.00	443,099
\$1.18 .....	623,000	5.20	623,000
\$1.20 .....	590,000	5.70	590,000
\$1.13 .....	—	—	—
\$0.89 .....	824,000	6.20	824,000
\$0.70 .....	224,667	6.60	224,667
\$0.50 .....	81,333	7.10	81,333
Nil .....	58,334	7.40	58,334
\$0.94 .....	1,201,000	7.50	1,201,000
Nil .....	410,000	7.50	116,663
\$1.72 .....	1,568,333	7.90	1,053,345
\$1.60 .....	50,000	5.10	33,332
\$1.58 .....	383,500	5.90	127,819
Nil .....	100,000	5.90	33,333
\$1.37 .....	355,000	6.20	118,330
\$1.38 .....	2,300,000	6.10	966,666
\$1.00 .....	86,000	6.70	—
\$0.89 .....	502,500	6.90	—
Nil .....	100,000	6.90	—
	<u>11,417,536</u>		<u>8,011,691</u>

**Universal Biosensors, Inc.**  
**Notes to Consolidated Financial Statements**  
**(for the years ended December 31, 2009, 2010 and 2011)**

The table below sets forth the number of employee stock options exercised and the number of shares issued in the period from December 31, 2009. We issued these shares in reliance upon exemptions from registration under Regulation S under the Securities Act of 1933, as amended.

<u>Period Ending</u>	<u>Number of Options Exercised and Corresponding Number of Shares Issued</u>	<u>Weighted Average Exercise Price</u>	<u>Proceeds Received</u>
		A\$	A\$
2009 .....	138,327	0.60	78,998
2010 .....	1,667,581	0.49	715,296
2011 .....	<u>181,999</u>	0.46	<u>79,504</u>
Total .....	<u>1,987,907</u>		<u>873,798</u>

As of December 31, 2011, there was A\$1,673,079 of unrecognized compensation expense related to unvested share-based compensation arrangements under the Employee Option Plan. This expense is expected to be recognized as follows:

<u>Fiscal Year</u>	<u>A\$</u>
2012 .....	1,208,797
2013 .....	412,575
2014 .....	<u>51,707</u>
	<u>1,673,079</u>

The aggregate intrinsic value for all options outstanding as at December 31, 2011 was zero.

**(b) Restricted Share Plan**

Our Employee Share Plan was adopted by the Board of Directors in 2009. The Employee Share Plan permits our Board to grant shares of our common stock to our employees and directors. 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 Plan. The Company currently proposes to continue to issue A\$1,000 worth of restricted shares of common stock to employees of the Company on a recurring basis, but no more frequently than annually. The restricted shares have the same terms of issue as our existing shares of common stock but are not able to be traded until the earlier of three years from the date on which the shares are issued or the date the relevant employee ceases to be an employee of the Company or any of its associated group of companies.

The table below sets forth the restricted shares issued by the Company:

	<u>Number of Restricted Shares Issued</u>	<u>Market Value of Restricted Shares Issued</u>
November, 2009 .....	40,670	A\$69,952
May, 2010 .....	581	A\$ 999
November, 2010 .....	47,400	A\$74,892
November, 2011 .....	86,471	A\$76,959

**Universal Biosensors, Inc.**  
**Notes to Consolidated Financial Statements**  
**(for the years ended December 31, 2009, 2010 and 2011)**

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

	<u>Number of shares</u>	<u>Weighted average issue price</u> A\$
Balance at December 31, 2010 .....	82,841	1.64
Granted .....	86,471	0.89
Release of restricted shares .....	(11,549)	1.64
Balance at December 31, 2011 .....	<u>157,763</u>	<u>1.23</u>

**(6) Related Party Transactions**

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

In September 2011, we entered into a license agreement with SpeeDx Pty Ltd (“SpeeDx”) pursuant to which SpeeDx granted us a license in the field of molecular diagnostics. Under the agreement we make milestone payments totaling A\$500,000 if certain specified targets are achieved and payments ranging from 5% to 15% of our sales and licensing revenues to SpeeDx. Messrs Denver and Jane are directors of the Company and SpeeDx Pty Ltd. Certain of our substantial shareholders also hold substantial shareholdings in SpeeDx. CM Capital Pty Ltd, which holds approximately 11% of our shares and of which Mr Jane is a director, holds approximately 34% of the issued shares in SpeeDx. PFM Cornerstone Limited, which holds approximately 8% of our shares and of which Messrs Denver and Hanley and Dr Adam are directors, holds approximately 34% of the issued shares in SpeeDx. Johnson & Johnson Development Corporation has a beneficial interest in approximately 9% of our shares. An affiliate of Johnson & Johnson, Johnson and Johnson Research Pty Ltd owns approximately 13% of issued shares in SpeeDx.

Based on the latest Amendment to Schedule 13G filed on January 25, 2012, Johnson and Johnson Development Corporation (a venture capital wholly owned subsidiary of Johnson & Johnson) beneficially held 14,915,400 shares in the Company as at December 31, 2011 which represents approximately 9.4% of the Company’s shares.

The following transactions occurred with LifeScan:

	<u>As of December, 31</u>		
	<u>2011</u>	<u>2010</u>	<u>2009</u>
	A\$	A\$	A\$
<i>Current Receivables — Owing by LifeScan</i>			
Sale of goods .....	1,999,764	3,588,798	
Sale of services .....	2,890,019	—	
	<u>4,889,783</u>	<u>3,588,798</u>	
<i>Current Liabilities — Owing to LifeScan</i>			
Purchase of goods .....	<u>786,708</u>	—	
<i>Revenue from LifeScan</i>			
Revenue from products .....	12,063,582	11,760,009	132,733
Revenue from services .....	2,632,870	6,420,027	2,850,071
Research and development income .....	—	—	1,337,125
Milestone payment .....	—	—	17,722,641
	<u>14,696,452</u>	<u>18,180,036</u>	<u>22,042,570</u>

**Universal Biosensors, Inc.**  
**Notes to Consolidated Financial Statements**  
**(for the years ended December 31, 2009, 2010 and 2011)**

**(7) Financial Instruments**

*Financial Assets*

	Years Ended December 31,		
	2011	2010	2009
	A\$	A\$	A\$
Financial assets:			
Cash and cash equivalents . . . . .	15,089,209	23,271,766	31,291,011
Accounts receivables . . . . .	4,889,783	3,588,798	415,397
Financial instruments . . . . .	83,339	—	—
Total financial assets . . . . .	<u>20,062,331</u>	<u>26,860,564</u>	<u>31,706,408</u>
Debt:			
Short and long term debt/borrowings . . . . .	—	—	—
Financial instruments . . . . .	—	—	47,412
Total debt . . . . .	<u>—</u>	<u>—</u>	<u>47,412</u>
Net financial assets . . . . .	<u>20,062,331</u>	<u>26,860,564</u>	<u>31,658,996</u>

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

We regularly review all our financial assets for impairment. There were no impairments recognized in 2011, 2010 and 2009.

*Derivative Instruments and Hedging Activities*

In determining fair value, we utilize valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as consider our own and counterparty credit risk. At December 31, 2011 and 2010 we did not have any assets or liabilities that utilize Level 3 inputs. The valuation of our foreign exchange derivatives are based on the market approach using observable market inputs, such as forward rates and incorporate non-performance risk (the credit standing of the counterparty when the derivative is in a net asset position, and the credit standing of the Company when the derivative is in a net liability position). Our derivative assets are categorized as Level 2.

At December 31, 2011 (2010: nil) we had outstanding contracts with a notional amount of US\$4.0 million. The fair value of these contracts at December 31, 2011 (2010: nil) was an asset of A\$83,339 recorded as 'Financial Instruments' in consolidated balance sheet. As of December 31, 2011, substantially all of the derivative gain recognized in accumulated other comprehensive income (AOCI) will be recognized in earnings within the next 12 months. No amount of ineffectiveness was recorded in earnings for these designated cash flow hedges for the year ended December 31, 2011 (2010: nil). For further details, see Notes to Consolidated Financial Statements — *Note 2. Summary of Significant Accounting Policies.*

**Universal Biosensors, Inc.**  
**Notes to Consolidated Financial Statements**  
**(for the years ended December 31, 2009, 2010 and 2011)**

**(8) Property, Plant and Equipment**

	As of December, 31	
	2011	2010
	A\$	A\$
Plant and equipment . . . . .	18,893,890	15,110,554
Leasehold improvements . . . . .	8,722,639	8,810,036
Capital work in process . . . . .	5,534,498	8,792,690
	33,151,027	32,713,280
Accumulated depreciation . . . . .	(12,855,847)	(9,586,365)
Property, plant & equipment, net . . . . .	20,295,180	23,126,915

Capital work in process relates to assets under construction and comprises primarily of specialized manufacturing equipment. Legal right to the assets under construction rests with the Company. The amounts capitalized for capital work in process represents the percentage of expenditure that has been completed, and once the assets are placed into service the Company begins depreciating the respective assets. The accumulated amortisation of capitalised leasehold improvements for the fiscal years ended December 31, 2011, 2010 and 2009 was A\$5,376,432, A\$4,090,724 and A\$2,770,434, respectively.

The Company receives Victorian government grants under certain research agreements to purchase plant and equipment. Plant and equipment is presented net of the government grant of A\$680,221 for the year ended December 31, 2011 (2010: A\$449,875). The grants are recognized against the acquisition costs of the related plant and equipment as and when the related assets are purchased. Grants received in advance of the relevant expenditure are treated as deferred income and included in Current Liabilities on the balance sheet as the Company does not control the monies until the relevant expenditure has been incurred. Grants due to the Company under research agreements are recorded as Currents Assets on the consolidated balance sheets.

Depreciation expense was A\$3,298,541, A\$2,990,858 and A\$2,851,285 for the fiscal years ended December 31, 2011, 2010 and 2009, respectively.

**(9) Accrued Expenses**

Accrued expenses consist of the following:

	As of December, 31	
	2011	2010
	A\$	A\$
Legal, tax and accounting fees . . . . .	511,121	591,184
Salary and related costs . . . . .	706,053	587,695
Research and development materials . . . . .	35,050	120,000
Production materials . . . . .	786,708	657,142
Other . . . . .	22,596	143,456
	2,061,528	2,099,477

**(10) Stockholders' Equity — Common Stock**

Holders of common stock are generally entitled to one vote per share held on all matters submitted to a vote of the holders of common stock. At any meeting of the shareholders, the presence, in person or by proxy, of the

**Universal Biosensors, Inc.**  
**Notes to Consolidated Financial Statements**  
**(for the years ended December 31, 2009, 2010 and 2011)**

majority of the outstanding stock entitled to vote shall constitute a quorum. Except where a greater percentage is required by the Company's Amended and Restated Certificate of Incorporation or By-laws, the affirmative vote of the holders of a majority of the shares of common stock then represented at the meeting and entitled to vote at the meeting shall be sufficient to pass a resolution. Holders of common stock are not entitled to cumulative voting rights with respect to the election of directors, and the common stock does not have pre-emptive rights.

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

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

**(11) Retirement Benefits**

Universal Biosensors Pty Ltd contributes to standard defined contributions superannuation funds on behalf of all employees at an amount up to nine per cent of employee salary. The Company permits employees to choose the superannuation fund into which the contributions are paid, provided the fund is appropriately registered.

Universal Biosensors Pty Ltd contributed A\$806,158, A\$714,123 and A\$698,919 for the fiscal years ended December 31, 2011, 2010 and 2009, respectively.

**(12) Net Profit/(Loss) per Share**

Basic net profit/(loss) per ordinary share was computed by dividing the net profit/(loss) applicable to common stock by the weighted-average number of common stock outstanding during the period. Options granted to employees under the Universal Biosensors Employee Option Plan are considered to be potential ordinary shares for the purpose of calculating diluted net profit/(loss) per share. However, all these were not included in the calculation of diluted net profit/(loss) per share in the year when the Group made a net loss as the effect of including them is anti-dilutive.

	<u>Years Ended December 31,</u>		
	<u>2011</u>	<u>2010</u>	<u>2009</u>
Weighted average shares used as denominator in calculating:			
Basic net profit/(loss) per share . . . . .	<u>159,017,777</u>	<u>157,584,044</u>	<u>157,013,578</u>
Diluted net profit/(loss) per share . . . . .	<u>159,017,777</u>	<u>157,584,044</u>	<u>161,354,802</u>

**(13) Guarantees and Indemnifications**

The certificate of incorporation and amended and restated by-laws 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.

**Universal Biosensors, Inc.**  
**Notes to Consolidated Financial Statements**  
**(for the years ended December 31, 2009, 2010 and 2011)**

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

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

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

No liability has arisen under these indemnities as at December 31, 2011.

**(14) Segments**

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

The Company operates predominantly in one geographical area, being Australia.

**(15) Deed of Cross Guarantee**

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

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

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

Universal Biosensors, Inc.

**Schedule ii — Valuation and Qualifying Accounts**  
**(for the years ended December 31, 2009, 2010 and 2011)**

	Balance at Beginning of Period	Additions		Deductions	Balance at end of Period
		Charged to Costs and Expenses	Charged to Other Accounts		
	A\$	A\$	A\$	A\$	A\$
<b><i>Year ended December 31, 2009</i></b>					
Deferred income tax valuation allowance . . . . .	10,601,120	2,998,487	—	(1,899,796)	11,699,811
<b><i>Year ended December 31, 2010</i></b>					
Deferred income tax valuation allowance . . . . .	11,699,811	1,896,668	372,305	—	13,968,784
<b><i>Year ended December 31, 2011</i></b>					
Deferred income tax valuation allowance . . . . .	13,968,784	4,357,503	30,161	—	18,356,448

# ASX Additional Information

Additional information required by Australian Securities Exchange Ltd and not shown elsewhere in this report is as follows. The information is current as at March 1, 2012.

## (a) Distribution of equity securities

As at March 1, 2012 there were:-

- 158,991,999 fully paid shares of common stock held by CHESS Depository Nominees Pty Ltd on behalf of 1,405 individual holders of CDIs. All issued shares of common stock carry one vote per share and carry the rights to dividends.
- 154,214 unquoted fully paid restricted shares of common stock held by 77 individual employees of the Company. All issued shares of common stock carry one vote per share and carry the rights to dividends.
- 11,258,290 options over shares of common stock held by 87 individual option holders.

The Company's shares of common stock are traded on Australian Securities Exchange in the form of CHESS Depository Interests, or CDIs. CHESS Depository Nominees Pty Ltd, a wholly owned subsidiary of Australian Securities Exchange Ltd, holds legal title in the Company's shares of common stock on behalf of holders of CDIs. The following table sets out the beneficial interests in the underlying shares of common stock rather than legal title.

Holding ranges	Beneficial interests in shares of common stock traded as CDIs	Beneficial interests in restricted employee shares of common stock	Options over shares of common stock
1 – 1,000	163	–	–
1,001 – 5,000	312	77	–
5,001 – 10,000	249	–	–
10,001 – 100,000	582	–	66
100,001 – and over	99	–	21
	1,405	77	87

There are 88 holders of CDIs with a less than marketable parcel.

## (b) Holders of CDIs holding greater than 5%

Name	Beneficial interests in shares of common stock	
	Number	Percentage
The Principals Cornerstone Fund Pty Limited*	18,651,074	11.731
CM Capital Investments Pty Ltd	17,794,384	11.192
HSBC Custody Nominees (Australia) Limited	15,004,946	9.438
PFM Cornerstone Limited	11,883,018	7.474
Cogent Nominees Pty Limited	8,500,000	5.346

\* Shares held on trust for Messrs Denver, Hanley, and Dr Adam.

**(c) Twenty largest holders of quoted equity securities**

Name	Beneficial interests in shares of common stock	
	Number	Percentage
1 The Principals Cornerstone Fund Pty Limited*	18,651,074	11.719
2 CM Capital Investments Pty Ltd	17,794,384	11.181
3 HSBC Custody Nominees (Australia) Limited	15,004,946	9.428
4 PFM Cornerstone Limited	11,883,018	7.467
5 Cogent Nominees Pty Limited	8,500,000	5.341
6 Aust Executor Trustees SA Ltd (Tea Custodians Limited)	7,943,933	4.992
7 Kaasim Pty Ltd	7,782,636	4.890
8 National Nominees Limited	6,127,163	3.850
9 JP Morgan Nominees Australia Limited	4,228,243	2.657
10 Equity Trustees Limited	2,903,930	1.825
11 Citicorp Nominees Pty Limited	2,892,988	1.818
12 Mr Denis Michael Hanley	2,313,230	1.454
13 Dr Alastair McIndoe Hodges	2,059,085	1.294
14 Garry Chambers	1,761,424	1.107
15 Mr Thomas William Beck & Mrs Lynne Carol Beck	1,738,387	1.092
16 Warragai Investments Pty Ltd	1,500,000	0.943
17 Ronald Chatelier	1,279,421	0.804
18 Mr Andrew Denver & Mrs Linda Denver	1,181,812	0.743
19 Mr Christopher J La Croix & Mrs Kathleen M La Croix	1,166,718	0.733
20 Equity Trustees Limited	1,154,795	0.726
	110,644,075	74.062
	159,146,213	

\* Shares held on trust for Messrs Denver, Hanley, and Dr Adam.

**(d) Restricted Securities**

As at March 1, 2012, there are 154,214 fully paid restricted shares of common stock issued to 77 Company employees pursuant to the terms and conditions of the Universal Biosensor, Inc. employee share plan. The restricted shares are not able to be traded until the earlier of the following: (i) three years from the date on which the shares are issued; or (ii) the date on which an employee ceases to be an employee of Universal Biosensors, Inc. and its associated group of companies.

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# Corporate Directory

## **Board of Directors**

Mr Paul Wright (CEO)  
Mr Andrew Denver (Chairman)  
Dr Colin Adam  
Mr Denis Hanley  
Mr Marshall Heinberg  
Mr Andrew Jane  
Dr Elizabeth (Jane) Wilson

## **Registered Office in Australia**

1 Corporate Avenue  
Rowville Victoria 3178  
Australia  
Telephone: +61 3 9213 9000  
Facsimile: +61 3 9213 9099  
Email: [info@universalbiosensors.com](mailto:info@universalbiosensors.com)  
Website: [www.universalbiosensors.com](http://www.universalbiosensors.com)  
ASX code: UBI

## **Name and address of Universal Biosensors' registered agent in the United States**

Corporation Service Company  
2711 Centerville Road, Suite 400,  
Wilmington, County of New Castle  
Delaware, Unites States of America

## **Share Registry**

Boardroom Pty Limited  
Level 7, 207 Kent Street  
Sydney New South Wales 2000  
Australia  
Telephone: +61 2 9290 9600  
Facsimile: +61 2 9279 0664  
Email: [enquiries@boardroomlimited.com.au](mailto:enquiries@boardroomlimited.com.au)  
Website: [www.boardroomlimited.com.au](http://www.boardroomlimited.com.au)

## **Auditor**

PricewaterhouseCoopers LLP  
Darling Park Tower 2  
201 Sussex Street  
Sydney New South Wales 2000  
Australia

## **Australian Legal Adviser**

PFM Legal Pty Ltd  
Level 12  
117 York Street  
Sydney New South Wales 2000  
Australia

## **US Legal Adviser**

Venable LLP  
575, 7th Street, NW  
Washington DC 20004  
United States of America



**Universal Biosensors**