

UNITED STATES SECURITIES AND EXCHANGE CO
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, 2010

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)

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

98-0424072
(I.R.S. Employer Identification Number)

Not Applicable
(Zip Code)

SEC Mail Processing Section

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Washington, DC 110

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

<u>Title of Each Class</u>	<u>Name of Each Exchange on Which Registered</u>
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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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\$120,242,780 (equivalent to US\$102,482,921) as of June 30, 2010.

The number of shares outstanding of each of the registrant's classes of common stock as of March 2, 2011:

<u>Title of Class</u>	<u>Number of Shares</u>
Common Stock, US\$.0001 par value	158,968,161

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-1 through F-38 of our Annual Report to Stockholders for the fiscal year ended December 31, 2010 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 with respect to our tests in development, including revenues expected from such collaborations;
- 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 sales of products we develop and the quantities of such products to be manufactured by us;
- our expectations with respect to regulatory submissions, approvals and market launches of products we develop or are involved in developing;
- our expectations with respect to our research and development programs 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 were incorporated as a corporation in the State of Delaware pursuant to the Delaware General Corporation Law on September 14, 2001. Our wholly owned subsidiary and primary operating vehicle, Universal Biosensors Pty Ltd ACN 098 234 309, was incorporated as a proprietary limited company in Australia under the Corporations Act 2001 (*Commonwealth of Australia*) on September 21, 2001. Our research and development and manufacturing activities are undertaken in Melbourne, Australia, by Universal Biosensors Pty Ltd. Our shares of common stock in the form of CHESD Depository Interests ("CDIs") were quoted on the Australian Securities Exchange ("ASX") on December 13, 2006 and continue to be quoted on that exchange. Our securities are not currently traded on any other public market.

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.universalsensors.com. The information contained in, or that can be accessed through, our web site is not part of this Form 10-K.

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. The blood test devices we are developing comprise a novel disposable test strip and a reusable meter. These simple to use portable test devices require a finger prick of blood and are designed to be used by the patient (at the "point-of-care") to provide accurate and quick results to enable new treatment or an existing treatment to be immediately reviewed.

We have rights to an extensive patent portfolio comprising patent applications owned by our wholly owned Australian subsidiary, Universal Biosensors Pty Ltd, and a large number of patents and patent applications licensed to us by LifeScan, Inc. ("LifeScan US"), an affiliate of Johnson & Johnson. LifeScan US 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 US pursuant to a license agreement with us ("License Agreement"). We are also parties to a Development and Research Agreement with LifeScan US pursuant to which we undertake contract research and development for LifeScan US in the area of diabetes management and the development of a blood glucose test for diabetics ("Development and Research Agreement"). We are also parties to a Master Services and Supply Agreement with LifeScan US which contains the terms pursuant to which Universal Biosensors Pty Ltd provides certain services in the field of blood glucose monitoring and acts as a non-exclusive manufacturer of the blood glucose test strips we developed. Unless otherwise noted, references to "LifeScan" are either references to LifeScan US or its affiliates collectively or either of them individually as the context requires.

We use our technology base to develop a range of electrochemical-cell based tests.

We have developed a blood glucose test (used in the management of diabetes) with LifeScan. We commenced manufacture of the blood glucose test strips for this test in our facility in Corporate Avenue, Rowville, Melbourne, in December 2009. This test was launched by LifeScan in the Netherlands in January 2010 and in Australia in September 2010 under the trade name "One Touch Verio®". We act as a non-

exclusive manufacturer of the blood glucose test strips. In the future, we expect that LifeScan will manufacture all or a large proportion of its own requirements. Subject to mutually agreed terms, we intend to develop other tests for LifeScan in the field of diabetes and blood glucose management.

We are working on a prothrombin time test for monitoring the therapeutic range of the anticoagulant warfarin based on measuring activity of the enzyme thrombin. We are developing a D-dimer test on our immunoassay platform 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). We are also developing a C-reactive protein test on our immunoassay platform to assist in the diagnosis and management of inflammatory conditions. We do not currently intend to establish our own sales and marketing force to commercialize any of the non-blood glucose products which we develop. Rather, our efforts are focused on establishing collaborative partnerships for the tests derived from the platform. In the second half of 2009 we commenced business development efforts to establish partnerships for our tests outside the fields of blood glucose and diabetes. To date we have not secured a partnership outside of blood glucose and diabetes and cannot predict with any certainty when or whether our efforts may be successful. We use third party contractors to assist us in securing partners.

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:

- 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 our non-blood glucose tests;
- manufacturing test strips for our customers and partners as required;
- extending the electrochemical cell technology by developing new tests;
- undertaking contract research and development work on behalf of our customers and partners;
- providing post market support services to our customers and partners.

Plan of Operations for the Remainder of the Fiscal Year Ending December 2011

Our plan of operations over the remainder of the fiscal year ending December 2011 is to:

- seek to identify and then negotiate collaborative arrangements or strategic alliances with third parties with respect to one or more of our non-blood glucose programs;
- manufacture test strips to satisfy our customers and partners demand requirements;
- provide the necessary post-market support for our customers and partners;
- continue to undertake contract research and development work on behalf of our customers and partners;
- seek to develop additional products;
- advance our research and development activities with respect to our prothrombin time test, C-reactive protein test and D-dimer test up to a point where they provide credible evidence of the value for potential partners.

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, 2010, 2009 and 2008, 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. The range of blood test devices we are developing comprise a novel disposable test strip and a reusable meter. These simple to use pocket portable devices require a finger prick of blood and are designed to be used at the point-of-care to provide accurate and quick results to enable potential or existing treatments to be immediately reviewed. The electrical signals generated when a sample of blood reacts with the chemistry contained within the cell are then recorded by the meter and converted into a reading which is displayed on the meter. The first test we have developed with LifeScan is a test for the self-monitoring of blood glucose, which comprises the largest point-of-care biosensor market. We are also developing a test for blood coagulation (“prothrombin time”), which comprises the second largest point-of-care biosensor market. Our other efforts are directed towards the measurement of blood borne biomarkers using ligand binding (“immunoassay”), the measurement of enzyme activity, and other techniques.

Novel technologies

Electrochemical cells used in point-of-care blood tests have electrodes positioned within the electrochemical cell in a traditional side-by-side or “co-planar” layout. The electrodes in the electrochemical cell in the test strips which we have developed and are developing have a parallel, opposing and much more closely spaced configuration. This novel configuration of the electrodes in the electrochemical cell is designed to allow for greater accuracy while retaining other critical features including the ability to obtain results quickly using only a small finger prick sample of blood. Data is produced almost immediately and can be reviewed at the point-of-care allowing new treatment to be instigated or existing treatment to be reviewed and modified if necessary. The configuration of the electrodes has allowed for increased miniaturization of the electrochemical cell and is designed to enable our test strips to be manufactured in a continuous and considerably simplified process.

Industry background

We operate in the high growth, point-of-care segment of the global in vitro diagnostics (IVD) industry. Historically biological testing has been performed by trained scientists running sophisticated analyzers in a dedicated test site. These dedicated or centralized testing sites include 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 further segmented into consumer testing, such as the blood glucose self-monitoring performed by diabetics, or testing of patients by one of a variety of medical or laboratory professionals (professional point-of-care) 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 can be a suitable platform for adapting relevant central laboratory tests to a point-of-care format.

The key objective of point-of-care testing is to generate an accurate and quick result so that appropriate treatment can be implemented immediately or an existing treatment reviewed and modified, leading to an improved clinical and/or economic outcome. Our tests in development are designed for use by patients and healthcare professionals in a number of point-of-care settings including doctors’ offices, emergency rooms, and health clinics or, in some cases, at a patient’s home.

Point-of-care tests in development and partnering strategy

Our initial focus was on the development of blood glucose tests, by virtue of our business relationship with LifeScan. Our strategy is to apply the electrochemical cell technology to other biomarkers and then to enter into collaborative arrangements or strategic alliances with third parties to complete the development and commercialization of those products.

The following table summarizes the non-blood glucose point-of-care tests we are currently developing and the applicable development stage of the applicable test. All time periods set forth in the table below refer to calendar years and anticipated milestone dates are estimates only.

<u>Point-of-Care Test</u>	<u>Development Stage</u>	<u>Next Anticipated Milestones</u>
Prothrombin time test	<ul style="list-style-type: none">• Development work undertaken since early 2005• Working prototype developed• Test feasibility established and ready to enter formal development/validation• Strip manufacturing equipment undergoing commissioning	<ul style="list-style-type: none">• Test targeted to be ready to submit for approval during the first quarter of 2012• Continue efforts to enter into collaborative arrangements or strategic alliances with a third party
D-dimer test	<ul style="list-style-type: none">• Development work undertaken since early 2008• A minimum of two additional years of development/ product validation work required	<ul style="list-style-type: none">• Develop working prototype• Commence product validation in 2012• Establish manufacturing process• Continue efforts to enter into collaborative arrangements or strategic alliances with a third party
Immunoassay C-reactive protein test	<ul style="list-style-type: none">• Development work undertaken since 2004• Working prototype developed• Optimization and improvement work continuing on this project	<ul style="list-style-type: none">• Exploration of new design formats• Continue efforts to enter into collaborative arrangements or strategic alliances with third parties

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 been at the facilities at 1 Corporate Avenue since August 2007. 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. We completed upgrading and fitting out this facility in 2008.

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.

Distribution

Our partner is responsible for the commercialization and distribution of the blood glucose product.

Regulatory clearances

In all major territories of the world, regulatory clearances are required prior to marketing diagnostic tests. The regulatory clearance requirements vary from country to country and product to product, however, regulatory clearances typically require a satisfactory “technical 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 partner, would be required to submit for clearance to sell in each of the major jurisdictions in which the relevant 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.

The blood glucose test has received regulatory clearance to sell in Europe and Australia. LifeScan is responsible for determining the location and timing of any future submissions for regulatory clearance to sell the blood glucose product.

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 certain patents within an extensive portfolio of patents and patent applications as well as know-how. We patent the technology, inventions and improvements that we consider important to the development of our business. Pursuant to the License Agreement, we have an exclusive license to a suite of patents, patent applications and know-how in all fields of use excluding the fields of diabetes and blood glucose management generally, the rights to which are retained by LifeScan. The exclusive license is subject to LifeScan having retained the right to make, have made, use, and sell under and exploit in any way the licensed patents, patent applications and know-how.

Pursuant to the Development and Research Agreement, we have a limited license to the patents, patent applications and know-how that are the subject of the License Agreement, in the field of diabetes and blood glucose management generally but only for the purpose of carrying out our obligations for LifeScan. Likewise, pursuant to the Master Services and Supply Agreement, we have a limited license to intellectual property of LifeScan but only for the purpose of performing our obligations under the Master Services and Supply Agreement.

We rely on the owned patent applications and the patents and patent applications licensed to us by LifeScan in the manufacturing and commercialization of the point-of-care diagnostic tests being developed by us.

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 2
<i>Electrochemical Cells</i> (this patent family relates to an electrochemical cell which enables levels of analytes such as glucose to be measured whilst using a small volume of sample)	2015
<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)	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>Biosensor Apparatus and Methods of Use</i>	Refer Note 1

- (1) The patent application is either pending, allowed, or published
(2) This patent family is due for national stage entry in October 2011

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 the License Agreement, LifeScan has responsibility for prosecution of the patent applications licensed to us by them and the fees for the licensed patent applications and patents. 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 partners may seek approval to sell point-of-care tests that we have developed, or license our intellectual property, 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 of the blood glucose test strips in our facility in Corporate Avenue, Rowville, Melbourne, in December 2009. We satisfy our contractual obligations with respect to inventory and the supply of test strips as agreed in the Master Services and Supply Agreement.

Dependence on single customer.

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

	<u>2010</u>	<u>2009</u>	<u>2008</u>
	A\$	A\$	A\$
Revenue from products	11,760,009	132,733	—
Revenue from services	6,420,027	2,850,071	3,121,754
Research and development income	—	1,337,125	1,170,190
Milestone payment	—	17,722,641	—
Interest income	1,192,889	809,459	2,542,060
Fee income	—	—	1,131,222
Total income	<u>19,372,925</u>	<u>22,852,029</u>	<u>7,965,226</u>
Income from LifeScan as a % of total income	94%	96%	68%

Our dependence on LifeScan for a significant proportion of our revenue is likely to continue until we enter into collaborative arrangements or strategic alliances with third parties in connection with our non-glucose products and those products are launched into the market.

Competitive conditions of our business

Our revenue is currently highly dependent on the success of the blood glucose product we have developed with LifeScan. LifeScan launched the blood glucose product, named “One Touch Verio®”, in the Netherlands in January 2010 and in Australia in September 2010. 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. We do not yet know when LifeScan will launch the product in other jurisdictions, if the product will be successful, whether customers will prefer it over competitive offerings, nor the rate at which it might be adopted. During 2011 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.

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.

We will face competition from approved and marketed products as well as products in development, from both point-of-care and central laboratory testing. We expect our prothrombin time test to compete with existing point-of-care technologies from competitors such as Roche Diagnostics, Alere Inc. and Abbott Point of Care. We will also have to compete with the tests that run on automated analyzers. Companies providing systems into the central laboratory which run reagents that will compete with us include 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. To compete, we intend to establish collaborative arrangements or strategic alliances with other life sciences companies and will need to show that our prothrombin time test is effective and is a time and cost saving alternative. Even if we can show competitive product advantages, customers may be resistant to changing their supplier.

We are continuing to develop an immunoassay diagnostic for the detection of important biomarkers, and we have chosen C-reactive protein and D-dimer to illustrate the platform potential in the first instance. We continue to explore ways to improve the sensitivity of our immunodiagnostics to develop a powerful and robust platform with broad applicability. We will proceed with partnering efforts for these programs when technical risk is further reduced. Should our partnering efforts be successful and the products brought to market, they will face competition from approved and marketed products in both the point-of-care and central laboratory market places.

We expect that any D-dimer test developed on our platform and brought to market will have to compete with testing for D-dimer in pathology laboratories from competitors such as Siemens AG, Roche Holding Ltd, Instrumentation Laboratory, Diagnostica Stago and Biomerieux, and with existing point-of-care technologies from competitors such as Biosite Diagnostics (now part of Alere Inc.). Similarly, a C-reactive protein test will face competition from established competitors in point-of-care including Cholestech Corporation (now part of Alere Inc.), Orion Corporation and Axis Shield plc. In addition, companies providing central laboratory tests will represent sources of competition. All of these companies have well established brand recognition, sales and marketing forces, and have significant resources available to support their product. To compete, we will need to show potential partners that our immunodiagnostic tests can be effective in a time and cost efficient manner. Even if we can show competitive product advantages, customers may be resistant to changing their supplier.

Employees

At March 2, 2011, we had 95 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.

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 developed by us 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. In addition, market acceptance depends on the effectiveness of marketing strategies employed by our partners or us to sell the products.

Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, more convenient, less expensive, or reach markets sooner than products developed by us. The global diabetes market place is intensely competitive and dominated by multinationals such as LifeScan, Roche, Abbott and Bayer. The blood glucose product we developed with LifeScan was first launched in January 2010. While initial market acceptance for the blood glucose product has been positive, there is no guarantee that our product will receive a positive acceptance in future countries in which the product will be launched or that market acceptance will be maintained or will secure adequate market share.

Further, we cannot be sure that any future products developed by us will be successful in the marketplace or in securing a significant market share. Our ability to be or maintain profitability in the future will be adversely affected if any of the products developed by us 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 have a material adverse effect on our business and financial position.

We are 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 derived from LifeScan and our business is therefore currently 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. Any changes in LifeScan's requirements will directly affect our business. To date, we have funded our operations primarily through the issue of shares, from payments received under the Development and Research Agreement with LifeScan, various payments received under the Master Services and Supply Agreement with LifeScan and from Australian state and federal grants received by Universal Biosensors Pty Ltd. We do not currently have, and may never have, any other products or services that generate revenues or substantial revenues.

We act as a non-exclusive manufacturer of the blood glucose test strips we developed with LifeScan, and in the future we expect that LifeScan is likely to manufacture a large proportion or all of its own requirements. If our manufacturing capacity is not fully utilized or not utilized at all, our revenues will decline. Additionally, we would cease to have the potential to receive revenues from the sale of blood glucose strips 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. If this occurred, our business would be adversely affected. LifeScan also has the ability to buy out our service fee revenue by paying us a lump sum amount after certain conditions are met. 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 the option to buy out the service fee revenue is exercised by LifeScan, 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.

LifeScan may choose to utilize less of our research and development services and as a result our operating results may suffer. We receive income from contract research and development activities undertaken for LifeScan pursuant to a Development and Research Agreement and Master Services and Supply Agreement. If this development and research work 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.

Limitations in our business strategy.

Our business strategy is limited in that we have little control over decisions relating to the blood glucose products. LifeScan has the sole rights to commercialize the blood glucose products and makes the key decisions on product manufacture, product choice and product launch. Decisions made by LifeScan with respect to the manufacture and commercialization of the blood glucose products we develop with them will affect the extent and timing of revenues to us. We generally act as a non-exclusive manufacturer of the blood glucose test strips we developed with LifeScan, and in the future LifeScan is likely to manufacture all or a large proportion of its own requirements thus not utilizing our manufacturing capacity. LifeScan may choose not to launch new blood glucose products we develop, may choose to launch the products in a limited number of jurisdictions, may delay the launch of products or its sales and marketing efforts to commercialize the products may not be successful, all of which would have a material adverse effect on our business and financial position. To the extent we are successful in securing other partnerships, we may face the same limitations in control with respect to the commercialization of other products we develop.

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

Our margins may be decreased 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 for LifeScan may decrease our margins or cause us to suffer a loss on the manufacture of blood glucose test strips for LifeScan. The Master Services and Supply Agreement contains a cap on the amount we may charge per strip manufactured. If our costs of manufacture per strip were to exceed the cap we would suffer a loss on the sale of those strips.

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. This may adversely affect our business position. 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 short term 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 unhedged currency fluctuations, which could be significant.

If the above factors cause decreased margins it would have a material adverse effect on our business and financial position.

Our business strategy 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 demonstrating that our electrochemical cell technology can be extended to create other platforms and then to seek to enter into collaborative arrangements, licensing agreements or strategic alliances with other life sciences companies or other industry participants for these platforms, or for the products we have developed as proof of principle on those platforms. 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 alliances on acceptable terms, if at all. An inability to enter a collaborative arrangement or partnership would be detrimental to our business and financial position.

Our ability to enter into partnership arrangements will suffer if the performance of the point-of-care tests developed by us is not perceived as being comparable or superior to established laboratory methods. For example, while the use of the C-reactive protein as a marker for inflammatory conditions is generally widely accepted, it is predominantly a test performed in centralized laboratories. We cannot be sure that the market will accept the use of a point-of-care C-reactive protein test for the management of inflammatory conditions in the manner we anticipate. Clinical data may not provide sufficient support, nor may the health economic benefits sufficiently support the introduction of point-of-care C-reactive protein 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. These factors may inhibit or eliminate our ability to attract a partner.

There may also be obstacles to our ability to enter into a partnership arrangements for a prothrombin time test. A number of new therapies are entering the market which may eliminate or significantly reduce the need for prothrombin time testing. However it is not known how widespread the acceptance of these new medications will be, nor whether they will be successfully reimbursed for long term use.

If we are unable to enter collaborative arrangements with respect to our products, 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, significant monies and management time invested may be rendered unproductive and worthless. Because we have not established any internal sales and marketing capacity, to achieve commercial success we must enter into and maintain successful arrangements with others to sell, market and distribute our products. 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. These arrangements may result in us receiving less revenue than if we sold such products directly, may place the development, sales and marketing of our products outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us. Collaborative arrangements, licensing agreements or strategic alliances will subject us to a number of risks, including the risk that:

- we may not be able to control the amount and timing of resources that our strategic partner/ collaborators may devote to our products;
- our strategic partner/collaborators 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 collaborator'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.

New product design and development is costly, labor intensive and uncertain.

The design and development of our prothrombin time test, D-dimer test (and immunoassay platform generally), C-reactive protein test, and any new diagnostic tests including new blood glucose tests will take a

number of years to complete, will be costly to develop and the outcomes of design and development activities are uncertain.

Some of our tests still have a significant degree of technical risk, and design and development work and product validation may be unsuccessful or not warrant product commercialization. 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 our not being profitable, or trigger dissolution of partnerships. The outcome of clinical trials may not be predictive of the success of later clinical trials. Considerable investments in time and money may be 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 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.

Manufacture of allegedly defective test strips could potentially expose us to substantial costs, write-offs and reputational damage.

Manufacture of allegedly defective test strips may cause substantial costs, write-offs and potential delays in our shipment of product to customers, and expose us to product liability claims and product recalls, which would have a material adverse effect on our business and financial results.

There are many elements to manufacturing each lot of blood glucose test strips that can cause variability beyond acceptable limits. We may be required to discard defective test strips after we have incurred significant material and labor costs, resulting in manufacturing delays and delayed shipment of tests strips to LifeScan. 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 tests strips to LifeScan.

Manufacture of allegedly defective test strips exposes us to the risk of product liability claims and product recalls, resulting in 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. While we have obtained product liability and recall liability insurance in accordance with the Master Services and Supply Agreement, 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 our performance under the Master Services and Supply Agreement. Any claim for damages under the Master Services and Supply Agreement or other claim against us could be substantial.

Risks associated with regulatory clearance and changes to regulation.

Our products are medical devices and therefore subject to extensive regulation in all major markets. The process of obtaining regulatory clearance is costly and time consuming and there can be no assurance that the required regulatory clearances will be obtained. Products cannot be commercially sold without regulatory clearance. We are aware that LifeScan has obtained regulatory clearances for the initial blood glucose product in certain jurisdictions but will still require approval in other jurisdictions. However, with respect to any new tests we develop, if we or our partners are 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 manufacturers, applicable regulatory bodies would 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 are subject to continual review and periodic inspections. Potentially costly responses may be required 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 commercial partners 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.

In 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. Additionally, we do not currently have long term contractual arrangements with certain of our suppliers so may not be able to guarantee the supply of certain of our materials. 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. LifeScan is likewise subject to supply risks which may delay their ability to supply customers with the blood glucose product and have a consequential adverse effect on our business and results of operations.

We anticipate that we will outsource the manufacture of the meters for our non-blood glucose tests. In circumstances where we seek to outsource the manufacture of certain meters or other components, 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 we are at 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 and other problems that could seriously harm our business. Any blood glucose meter shortages or manufacturing delays could result in the reduction in sales of the blood glucose product and consequent delays or reduction in our revenues, which would have an adverse effect on us.

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 development 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.

The market for in vitro diagnostics is intensely competitive, price sensitive and subject to rapid change. We and any partner may be unable to accurately anticipate changes in the markets and the direction of technological innovation and the demands of our customers, 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 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 would force us 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 have only manufactured limited commercial quantities of blood glucose tests strips and therefore have limited experience as a manufacturer.

We have only recently commenced manufacturing commercial quantities of the blood glucose test strips for LifeScan. There are technical challenges establishing commercial manufacturing for our other products and to increasing our manufacturing capacity in a significant manner, 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. Continued turbulence in the US and international markets and economies may adversely affect our ability to enter into collaborative

arrangements and the spending patterns of users of test strips we are developing and the financial condition of our current and any future partners. This may adversely impact demand for products developed and services provided 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.

In addition, as a result of these conditions, our ability to raise capital and the availability of credit, if required in the future, may be adversely affected. 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 calibre 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.

All of our operations are conducted at a single location. Any disruption at our facility could adversely affect our operations and increase our expenses.

All of our 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 insurance. However, a natural disaster, such as a fire, flood or earthquake, 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 2, 2011, 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\$1.37 on March 2, 2011. 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.

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 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 12% 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 Messrs Denver, Hanley and Dr. Adam, of which Messrs Denver and Hanley and Dr. Adam are directors. 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 8% of our shares. Mr. Andrew Jane is one of our directors and a director of CM Capital Investments Pty Ltd which holds approximately 11% 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 February 10, 2011, Johnson & Johnson and Johnson and Johnson Development Corporation, beneficially owned 11.45% shares of the Company. 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 the blood glucose test strips using custom manufacturing equipment and we intend to manufacture the disposable test strips for each of our future point-of-care tests using our own 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. Likewise, if we are successful in securing a partner for one of our other tests and the development of that test is successful, and if our existing facilities and equipment continue to be utilized for the manufacture of blood glucose test strips, we will likewise need to secure additional or alternative facilities and establish additional large scale equipment sufficient to satisfy manufacturing requirements for the new product.

ITEM 3. LEGAL PROCEEDINGS.

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

ITEM 4. [REMOVED AND RESERVED]

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.

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 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
Fiscal Year 2009		
First Quarter	A\$0.41	A\$0.66
Second Quarter	A\$0.56	A\$1.20
Third Quarter	A\$0.83	A\$1.40
Fourth Quarter	A\$1.30	A\$1.98

Security details

As of March 2, 2011, there were 158,968,161 shares of our common stock issued and outstanding and 8,409,702 employee options that are exercisable for an equivalent number of shares of common stock (5,811,548 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 2, 2011	1,628	10

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, 2010.

Equity Compensation Plan Information			
<u>Plan Category</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	8,539,704	0.93	(1)
Equity compensation plans not approved by security holders(2)	<u>—</u>	<u>—</u>	(1)
Total	<u>8,539,704</u>	<u>0.93</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.
- (2) On February 24, 2011 our Board of Directors approved the appointment of Mr. Paul Wright as a director and the Chief Executive Officer of the Company effective as of March 1, 2011. At the time of the Board's approval of his appointment, the Board also approved a long term incentive to Mr. Paul Wright in the form of a grant of 2,300,000 market price employee options under the Company's Employee Option Plan, subject to stockholder approval in relation to the proposed grant. The 2,300,000 employee options are proposed to be granted for no cash consideration and with an exercise price of A\$1.38.

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, 2008 to December 31, 2010. 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>
2008			
May, 2008	18,124	A\$0.35	5,047
2009			
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>
2010			
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>

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

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

There were no repurchases of equity securities in 2010.

ITEM 6. SELECTED FINANCIAL DATA.

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

	<u>Years Ended December 31,</u>				
	<u>2010</u>	<u>2009</u>	<u>2008</u>	<u>2007</u>	<u>2006</u>
	<u>A\$</u>	<u>A\$</u>	<u>A\$</u>	<u>A\$</u>	<u>A\$</u>
Revenue					
Revenue from products	\$ 11,760,009	\$ 132,733	\$ —	\$ —	\$ —
Revenue from services	6,420,027	2,850,071	3,121,754	—	—
Research and development income	—	1,337,125	1,170,190	1,192,015	2,654,280
Milestone payment	—	17,722,641	—	—	—
Total revenue	<u>18,180,036</u>	<u>22,042,570</u>	<u>4,291,944</u>	<u>1,192,015</u>	<u>2,654,280</u>
Operating costs & expenses					
Cost of goods sold(1)	10,801,062	458,162	—	—	—
Cost of services	1,481,674	169,241	3,121,754	—	—
Research and development (2 and 3)	6,482,150	14,898,072	11,585,258	7,157,216	3,466,604
General and administrative(4)	7,185,550	5,635,569	5,510,127	4,226,757	2,511,182
Total operating costs & expenses	<u>25,950,436</u>	<u>21,161,044</u>	<u>20,217,139</u>	<u>11,383,973</u>	<u>5,977,786</u>
Profit/(loss) from operations	(7,770,400)	881,526	(15,925,195)	(10,191,958)	(3,323,506)
Other income/(expense)					
Interest income	1,192,889	809,459	2,542,060	1,440,102	443,769
Interest expense	—	(9,636)	(9,489)	—	—
Fee income	—	—	1,131,222	—	—
Other	(33,014)	(250,886)	265,310	(210,382)	87,076
Total other income/(expense)	1,159,875	548,937	3,929,103	1,229,720	530,845
Net profit/(loss) before tax	(6,610,525)	1,430,463	(11,996,092)	(8,962,238)	(2,792,661)
Income tax benefit/(expense)	—	—	206	145,000	(163,000)
Net profit/(loss)	<u>\$ (6,610,525)</u>	<u>\$ 1,430,463</u>	<u>\$ (11,995,886)</u>	<u>\$ (8,817,238)</u>	<u>\$ (2,955,661)</u>

	Years Ended December 31,				
	2010	2009	2008	2007	2006
	A\$	A\$	A\$	A\$	A\$
Basic net profit/(loss) per share	\$ (0.04)	\$ 0.01	\$ (0.08)	\$ (0.07)	\$ (0.06)
Average weighted number of shares used as denominator in calculating basic net profit/(loss) per share	157,584,044	157,013,578	156,970,679	129,637,286	49,408,822
Diluted net profit/(loss) per share	\$ (0.04)	\$ 0.01	\$ (0.08)	\$ (0.07)	\$ (0.06)
Average weighted number of shares used as denominator in calculating diluted net profit/(loss) per share	157,584,044	161,354,802	156,970,679	129,637,286	49,408,822

Notes:

1 Includes non-cash compensation expense (cost of goods sold)	\$168,512	\$ 21,207	\$ —	\$ —	\$ —
2 Net of research grant income in these amounts	\$ —	\$ —	\$300,613	\$872,513	\$578,653
3 Includes non-cash compensation expense (research and development)	\$859,551	\$653,474	\$661,497	\$339,882	\$147,373
4 Includes non-cash compensation expense (general and administrative)	\$648,940	\$404,090	\$299,611	\$277,833	\$273,694

	Years Ended December 31,				
	2010	2009	2008	2007	2006
	A\$	A\$	A\$	A\$	A\$
Balance Sheet Data:					
Cash and cash equivalents	23,271,766	31,291,011	28,334,864	41,958,285	30,184,756
Total assets	53,837,949	56,083,468	52,505,321	63,512,160	37,879,601
Long-term debt	—	—	—	—	—
Convertible preference shares(1)	—	—	—	—	—
Total stockholders' (deficit) equity	47,219,079	51,314,002	48,703,230	59,749,624	35,281,927

(1) Convertible preference shares were converted to shares of common stock immediately prior to the issue of shares in our initial public offering in Australian and concurrent US private placement in December 2006.

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 2010 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 2010 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-38, 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, 2010, 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, 2010			
	Quarter Ended	Quarter Ended	Quarter Ended	Quarter Ended
	March 31	June 30	September 30	December 31
	A\$	A\$	A\$	A\$
Revenue				
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	<u>3,417,946</u>	<u>2,763,363</u>	<u>4,988,204</u>	<u>7,010,523</u>
Operating costs & expenses				
Cost of goods sold(1)	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 (2 and 3)	1,554,227	1,799,551	1,543,482	1,584,890
General and administrative(4)	1,469,609	1,788,984	1,675,868	2,251,089
Total operating costs & expenses	<u>4,808,336</u>	<u>5,772,441</u>	<u>6,732,138</u>	<u>8,637,521</u>
Profit/(loss) from operations	(1,390,390)	(3,009,078)	(1,743,934)	(1,626,998)
Other income/(expense)				
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
Notes:				
1 Includes non-cash compensation expense (cost of goods sold)	\$ 40,688	\$ 45,051	\$ 28,489	\$ 54,284
2 Net of research grant income in these amounts	\$ —	\$ —	\$ —	\$ —
3 Includes non-cash compensation expense (research and development)	\$ 245,968	\$ 272,343	\$ 172,215	\$ 169,025
4 Includes non-cash compensation expense (general and administrative)	\$ 172,130	\$ 219,029	\$ 129,969	\$ 127,812

	Year Ended December 31, 2009			
	Quarter Ended	Quarter Ended	Quarter Ended	Quarter Ended
	March 31	June 30	September 30	December 31
	A\$	A\$	A\$	A\$
Revenue				
Revenue from products	\$ —	\$ —	\$ —	\$ 132,733
Revenue from services	1,467,464	312,590	819,181	250,836
Research and development income	388,319	349,848	310,945	288,013
Milestone payment	—	—	—	17,722,641
Total revenue	1,855,783	662,438	1,130,126	18,394,223
Operating costs & expenses				
Cost of goods sold(1)	—	—	—	458,162
Cost of services	14,835	47,285	80,136	26,985
Research and development(2)	3,233,635	4,104,205	3,681,701	3,878,531
General and administrative(3)	1,190,592	1,395,286	1,543,305	1,506,386
Total operating costs & expenses	4,439,062	5,546,776	5,305,142	5,870,064
Profit/(loss) from operations	(2,583,279)	(4,884,338)	(4,175,016)	12,524,159
Other income/(expense)				
Interest income	267,074	193,184	161,041	188,160
Interest expense	(3,613)	(3,614)	(2,409)	—
Fee income	—	—	—	—
Other	(33,778)	52,265	5,368	(274,741)
Total other income/(expense)	229,683	241,835	164,000	(86,581)
Net profit/(loss) before tax	(2,353,596)	(4,642,503)	(4,011,016)	12,437,578
Income tax benefit/(expense)	—	—	—	—
Net profit/(loss)	<u>\$ (2,353,596)</u>	<u>\$ (4,642,503)</u>	<u>\$ (4,011,016)</u>	<u>\$ 12,437,578</u>
Basic net profit/(loss) per share	\$ (0.01)	\$ (0.03)	\$ (0.03)	\$ 0.08
Average weighted number of shares used as denominator in calculating basic net profit/(loss) per share	156,976,936	156,976,936	157,004,871	157,094,376
Diluted net profit/(loss) per share	\$ (0.01)	\$ (0.03)	\$ (0.03)	\$ 0.08
Average weighted number of shares used as denominator in calculating diluted net profit/(loss) per share	156,976,936	156,976,936	157,004,871	161,828,109
Notes:				
1 Includes non-cash compensation expense (cost of goods sold)	\$ —	\$ —	\$ —	\$ 21,207
2 Includes non-cash compensation expense (research and development)	\$ 95,997	\$ 81,024	\$ 229,637	\$ 246,816
3 Includes non-cash compensation expense (general and administrative)	\$ 44,451	\$ 35,506	\$ 172,253	\$ 151,880

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. Andrew Denver, Chairman and Interim Chief Executive Officer, and Sales Balak, Chief Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Messrs. Denver 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, 2010, 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, 2010. 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, 2010, our internal control over financial reporting was effective.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2010 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/ Andrew Denver
Andrew Denver
Principal Executive Officer

/s/ Salesh Balak
Salesh Balak
Principal Financial Officer

March 10, 2011

**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, 2010, 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 2011 (the "2011 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 2011 Proxy Statement under the caption "Other Matters — Beneficial Ownership Reporting Compliance."

We have adopted our Code of Ethics for Senior Financial Officers, a code of ethics that applies to our Principal Executive Officer and Principal Financial Officer. This code of ethics may be accessed and reviewed through our website at www.universalbiosensors.com. We intend to satisfy any disclosure 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.universalbiosensors.com

The information required by this item regarding any material changes to the procedures by which security holders may recommend nominees to our Board of Directors is incorporated by reference to the 2011 Proxy Statement under the caption "Management of the Company — Board Committees — Remuneration and Nomination Committee."

The information required by this item regarding our Audit Committee is incorporated by reference to the 2011 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 2011 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 2011 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 2011 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 2011 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 2011 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 2011 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-38 of our Annual Report to Stockholders for the fiscal year ended December 31, 2010, 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.

<u>Exhibit Number</u>	<u>Description</u>	<u>Location</u>
10.2	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.
10.3	Form of indemnity agreement entered into with directors of us, our chief financial officer and company secretary	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.3.
10.4	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.
10.5	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.
10.6	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
10.7	Employment agreement between Universal Biosensors Pty Ltd and Mr. Saresh 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
10.8	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
10.9	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
10.10	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
10.11	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
10.12	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.

<u>Exhibit Number</u>	<u>Description</u>	<u>Location</u>
10.13	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
10.14	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
10.15	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.
10.16	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.

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10.17	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.
10.18	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.
10.19	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.
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

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/ Andrew Denver

Andrew Denver
Principal Executive Officer

Date: March 10, 2011

POWER OF ATTORNEY

Each person whose signature appears below hereby constitutes and appoints Andrew Denver 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/ Andrew Denver</u> Andrew Denver	Interim Chief Executive Officer and Chairman (Principal Executive Officer)	March 10, 2011
<u>/s/ Salesh Balak</u> Salesh Balak	Chief Financial Officer (Principal Financial Officer)	March 10, 2011
<u>/s/ Denis Hanley</u> Denis Hanley	Director	March 10, 2011
<u>/s/ Andrew Jane</u> Andrew Jane	Director	March 10, 2011
<u>/s/ Elizabeth Wilson</u> Elizabeth Wilson	Director	March 10, 2011
<u>/s/ Colin Adam</u> Colin Adam	Director	March 10, 2011
<u>/s/ Marshall Heinberg</u> Marshall Heinberg	Director	March 10, 2011
<u>/s/ Paul Wright</u> Paul Wright	Director	March 10, 2011

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Universal Biosensors, Inc.

2010 Annual Report

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Form 10-K of Universal Biosensors, Inc. enclosed herewith is incorporated herein.

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. The blood test devices we are developing comprise a novel disposable test strip and a reusable meter. These simple to use portable test devices require a finger prick of blood and are designed to be used by the patient (at the "point-of-care") to provide accurate and quick results to enable new treatment or an existing treatment to be immediately reviewed.

We use our technology base to develop electrochemical-cell based tests.

We have developed a blood glucose test (used in the management of diabetes) with LifeScan, Inc. ("LifeScan US"), an affiliate of Johnson & Johnson. We commenced manufacture of the blood glucose test strips for this test in our facility in Corporate Avenue, Rowville, Melbourne, in December 2009. This test was launched by LifeScan US in the Netherlands in January 2010 and in Australia in September 2010, under the trade name "One Touch Verio®". We act as a non-exclusive manufacturer of the blood glucose test strips. LifeScan US and its affiliates (collectively referred to as "LifeScan") will establish their own manufacturing capability and, in the future, is likely to manufacture all or a large proportion of its own requirements. Subject to mutually agreed terms, we intend to develop other tests for LifeScan in the field of diabetes and blood glucose management.

We are working on a prothrombin time test for monitoring the therapeutic range of the anticoagulant warfarin based on measuring activity of the enzyme thrombin. We are developing a D-dimer test on our immunoassay platform 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). We are developing a C-reactive protein test on our immunoassay platform to assist in the diagnosis and management of inflammatory conditions. We are also developing other tests using the electrochemical cell technology. We do not currently intend to establish our own sales and marketing force to commercialize any of the non-blood glucose products which we develop. Rather, our efforts are focused on establishing collaborative partnerships for the tests derived from the platform. In the second half of 2009 we commenced business development efforts to establish partnerships in fields outside the area of blood glucose and diabetes. To date we have not secured a partnership and cannot predict with any certainty if or when our efforts might be successful.

Results of Operations

Manufacture of Products

In November 2009, LifeScan received initial regulatory clearance to sell their blood glucose product which we developed with them. We commenced manufacture of the blood glucose test strips required for this product in our facility in Rowville, Melbourne, in December 2009. This test was launched by LifeScan in the

Netherlands in January 2010 and in Australia in September 2010, under the trade name “One Touch Verio®”. The manufacturing results of the blood glucose test strips during the respective periods are as follows:

	Years Ended December 31,		
	2010	2009	2008
	A\$	A\$	A\$
Revenue	11,760,009	132,733	—
Cost of goods sold	(10,801,062)	(458,162)	—
	<u>958,947</u>	<u>(325,429)</u>	<u>—</u>

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 tests 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. As 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 ceased to be in the interim costing period during the second half of 2010 at which time we generated profits from our blood glucose manufacturing operations. Our quarterly results from our blood glucose manufacturing operations for the 2010 financial year reflect this.

	Quarters Ended			
	December 31	September 30	June 30	March 31
	A\$	A\$	A\$	A\$
Revenue	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)
	<u>1,483,219</u>	<u>66,483</u>	<u>(577,132)</u>	<u>(13,623)</u>

Services Performed

We provide various services to LifeScan. The revenue is grouped into the following categories:

- *Contract research and development* — we undertake contract research and development in the area of diabetes management for LifeScan. 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 to LifeScan which meant presenting it within “Revenue from Services”;
- *Product enhancement* — a service fee based on the number of strips sold by LifeScan 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 LifeScan’s requirements.

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

	Years Ended December 31,		
	2010	2009	2008
	A\$	A\$	A\$
Revenue from services	6,420,027	2,850,071	3,121,754
Cost of services	(1,481,674)	(169,241)	(3,121,754)
	4,938,353	2,680,830	—
Income — Research and development income	—	1,337,125	1,170,190

The contribution during the 2010 financial year has increased by 23% compared to the 2009 financial year and reflects increase in the scope of the services we performed for LifeScan. During the 2008 financial year, we provided certain services under an arrangement where no margin was earned as the costs of providing the services was equal to the revenue recognized.

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 research and development activities can be described as follows:

(a) Blood glucose

In 2009, we completed the research and development efforts relating to the first blood glucose test which we undertook for LifeScan. We currently undertake some minor research and development activities relating to this product.

There are other blood glucose research and development activities undertaken by us from time to time on behalf of LifeScan. These are recorded under the caption "Cost of Services" as these are specifically funded by LifeScan, the revenue for which is recorded under "Revenue from Services".

(b) 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. A working prototype has been developed. We expect product validation for this test in 2011.

(c) Immunoassay

We are developing a C-reactive protein test on our immunoassay platform to assist in the diagnosis and management of inflammatory conditions. Development work on this project has been undertaken since 2004. A prototype on this test has been developed.

We are also developing a D-dimer test on our immunoassay platform 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.

These tests illustrate the ability for the electrochemical cell platform technology to be expanded to a range of immunoassay tests.

(d) 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. In the event the feasibility shows promise, we would need to negotiate suitable licence terms to access the technology.

We do not currently intend to establish our own sales and marketing force to commercialize any of the non-blood glucose products which we develop. Rather, our strategy is focused on establishing collaborative partnerships for our platform with major multinationals whose ambition is to lead in key clinical and market segments. We have commenced business development efforts to establish partnerships in fields outside the area of blood glucose and diabetes.

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

	Years Ended December 31,		
	2010	2009	2008
	A\$	A\$	A\$
Research and development expenses	6,482,150	14,898,072	11,885,871
Research grants received recognized against related research and development expenses	—	—	(300,613)
Research and development expenses as reported	<u>6,482,150</u>	<u>14,898,072</u>	<u>11,585,258</u>

Research and development expenditure decreased by 56% during 2010 compared to the previous financial year and reflects the conclusion of the development phase for the blood glucose product, wherein the major body of the work was carried out in 2008 and 2009 and the blood glucose product was launched in January 2010. 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.

While it is entirely within our 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

General and Administrative Expenses

General and administrative expenses currently consist principally of salaries and related costs, including stock option expense, for personnel in executive, 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,		
	2010	2009	2008
	A\$	A\$	A\$
General and administrative expenses	<u>7,185,550</u>	<u>5,635,569</u>	<u>5,510,127</u>

General and administrative expenses increased by 28% during 2010 compared to the previous financial year. This increase in expenses reflects growth in the size and complexity of our operations and also efforts put into business development to establish partnerships in the field outside the area of glucose and diabetes.

There are also incremental costs associated with our shares trading in the form of CHES Depository Interests (“CDIs”) quoted on the Australian Securities Exchange (“ASX”) and compliance costs associated with being a United States issuer subject to Securities and Exchange Commission (“SEC”) reporting requirements. In relation to the latter, 2010 is the first financial year wherein we have to furnish an attestation report of our registered public accounting firm regarding internal controls over financial reporting.

Interest Income

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 invested. Interest income decreased to A\$809,459 in 2009 from A\$2,542,060 in 2008. The decrease in interest income is attributable to lower returns and the lower amounts of funds invested for most of the year.

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 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 2008 and 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 value of the options granted in 2010 has been determined using the closing price of our common stock trading in the form of CDIs on ASX at the time of grant of the options. The ASX is the only exchange upon which our securities are quoted.

Volatility

With respect to the options granted in 2008, 2009 and 2010, we applied an annual volatility determined partially by reference to the annual volatilities of a number of ASX listed companies of a similar size and with similar operations but also having regard to the volatility on the trading data 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) Research and Development Expenditure

We receive grant funding under state and government research grant agreements to undertake work on the applicable grant programs. In order to receive the grant funding, our existing grant agreements require us to incur specified eligible expenditure in the conduct of the applicable grant program. There are circumstances where grant funding may not be payable and there are certain limited circumstances, such as when we fail to use our best endeavors to commercialize the program within a reasonable time of completion of the program or upon termination of a grant due to our breach of the agreement or our insolvency, where we may be required to repay some or all of the research grants. To date we have not been required to repay any of our grant monies. The grants are recognized against the related research and development expenses as and when the relevant research expenditure is incurred.

(d) Income Taxes

We apply ASC 740 — Income Taxes (formerly Statement of Financial Accounting Standards No. 109 — Accounting for 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.

(e) 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.

Financial Condition, Liquidity and Capital Resources

Net Financial Assets/(Liabilities)

Our net financial assets/(liabilities) position is shown below:

	Years Ended December 31,		
	2010	2009	2008
	A\$	A\$	A\$
Financial assets:			
Cash and cash equivalents	23,271,766	31,291,011	28,334,864
Accounts receivables	3,588,798	415,397	31,657
Total financial assets	<u>26,860,564</u>	<u>31,706,408</u>	<u>28,366,521</u>
Debt:			
Short and long term debt/borrowings	—	—	—
Total debt	<u>—</u>	<u>—</u>	<u>—</u>
Net financial assets	<u>26,860,564</u>	<u>31,706,408</u>	<u>28,366,521</u>

We rely largely on our existing cash and cash equivalents 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 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.

Measures of Liquidity and Capital Resources

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

	Years Ended December 31,		
	2010	2009	2008
	A\$	A\$	A\$
Cash and cash equivalents	23,271,766	31,291,011	28,334,864
Working capital	26,250,899	32,118,842	30,845,011
Ratio of current assets to current liabilities	6.89 : 1	13.05 : 1	17.19 : 1
Shareholders' equity per common share	0.30	0.33	0.31

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 collectability issues with respect to receivables.

Summary of Cash Flows

	Years Ended December 31,		
	2010	2009	2008
	A\$	A\$	A\$
Cash provided by/(used in):			
Operating activities	(6,414,248)	5,867,156	(7,140,386)
Investing activities	(2,320,293)	(2,990,007)	(6,471,419)
Financing activities	715,296	78,998	(11,616)
Net increase/(decrease) in cash and cash equivalents	<u>(8,019,245)</u>	<u>2,956,147</u>	<u>(13,623,421)</u>

Our net cash used in operating activities in 2008 was primarily for our research and development projects with no significant funding at all. The increase in operating activities from 2008 to 2009 is predominantly as a result of the receipt of the milestone payment of A\$17,722,641 in December 2009. The increase has been offset by our payments for our ongoing operations. Our net cash used in operating activities in 2010 was primarily for our ongoing research and development efforts and efforts involved in establishing our commercial scale manufacturing.

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. Our net cash used in investing activities was high in the early years including in 2008 as we were involved in establishing our commercial scale manufacturing which required substantial investment including fitting out our new facilities and purchase of manufacturing plant and equipment.

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-cancelable operating leases (with initial or remaining lease terms in excess of one year) as of December 31, 2010 are:

	<u>A\$</u>
Less than 1 year	537,526
1 — 3 years	1,124,013
3 — 5 years	146,312
More than 5 years	<u>—</u>
Total minimum lease payments	<u><u>1,807,851</u></u>

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, 2010 were as follows:

	<u>Payments Due by Period</u>				
	<u>Total</u>	<u>Less Than</u>	<u>1-3 Years</u>	<u>3-5 Years</u>	<u>More Than</u>
	<u>A\$</u>	<u>1 Year</u>	<u>A\$</u>	<u>A\$</u>	<u>5 Years</u>
		<u>A\$</u>			<u>A\$</u>
Long-Term Debt Obligations	—	—	—	—	—
Asset Retirement Obligations(1)	1,998,060	—	—	1,998,060	—
Operating Lease Obligations(2)	1,807,851	537,526	1,124,013	146,312	—
Purchase Obligations(3)	5,402,250	5,402,250	—	—	—
Other Long-Term Liabilities on					
Balance Sheet under GAAP(4)	<u>160,675</u>	<u>—</u>	<u>100,509</u>	<u>58,235</u>	<u>1,931</u>
Total	<u><u>9,368,836</u></u>	<u><u>5,939,776</u></u>	<u><u>1,224,522</u></u>	<u><u>2,202,607</u></u>	<u><u>1,931</u></u>

(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

(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.

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.

As at balance sheet date, there were no open derivatives.

Interest Rate Risk

Our exposure to interest income sensitivity, which is affected by changes in the general level of Australian interest rates because the majority of our investments are in AUD in cash and cash equivalents. 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.



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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, 2010 and December 31, 2009, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2010 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, 2010, 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 was an integrated audit in 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.

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

PricewaterhouseCoopers

Sydney
March 10, 2011

Universal Biosensors, Inc.
Consolidated Balance Sheets

	<u>December 31,</u> <u>2010</u>	<u>December 31,</u> <u>2009</u>
	A\$	A\$
ASSETS		
Current assets:		
Cash and cash equivalents	23,271,766	31,291,011
Inventories, net	3,191,093	305,124
Accrued income	—	118,305
Accounts receivable	3,588,798	415,397
Prepayments	303,181	2,289,149
Other current assets	<u>356,196</u>	<u>364,339</u>
Total current assets	30,711,034	34,783,325
Property, plant and equipment	32,713,280	27,898,099
Less accumulated depreciation	<u>(9,586,365)</u>	<u>(6,597,956)</u>
Property, plant and equipment — net	<u>23,126,915</u>	<u>21,300,143</u>
Total assets	<u><u>53,837,949</u></u>	<u><u>56,083,468</u></u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	1,764,364	434,207
Accrued expenses	2,099,477	1,201,893
Financial instruments	—	47,412
Deferred income	—	559,931
Employee entitlements provision	<u>596,294</u>	<u>421,040</u>
Total current liabilities	4,460,135	2,664,483
Non-current liabilities:		
Asset retirement obligations	1,998,060	1,842,547
Employee entitlements provision	<u>160,675</u>	<u>262,436</u>
Total non-current liabilities	<u>2,158,735</u>	<u>2,104,983</u>
Total liabilities	<u><u>6,618,870</u></u>	<u><u>4,769,466</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 2010 (2009: nil)		
Common stock, \$0.0001 par value. Authorized 300,000,000 shares; issued and outstanding 158,871,495 shares in 2010 (2009: 157,155,933)	15,887	15,716
Additional paid-in capital	77,034,717	74,566,698
Accumulated deficit	(22,922,688)	(24,353,151)
Current year earnings/(loss)	(6,610,525)	1,430,463
Accumulated other comprehensive income	<u>(298,312)</u>	<u>(345,724)</u>
Total stockholders' equity	<u>47,219,079</u>	<u>51,314,002</u>
Total liabilities and stockholders' equity	<u><u>53,837,949</u></u>	<u><u>56,083,468</u></u>

See accompanying notes to the financial statements

Universal Biosensors, Inc.
Consolidated Statements of Operations

	Years Ended December 31,		
	2010	2009	2008
	A\$	A\$	A\$
Revenue			
Revenue from products	\$ 11,760,009	\$ 132,733	\$ —
Revenue from services	6,420,027	2,850,071	3,121,754
Research and development income	—	1,337,125	1,170,190
Milestone payment	—	17,722,641	—
Total revenue	18,180,036	22,042,570	4,291,944
Operating costs & expenses			
Cost of goods sold(1)	10,801,062	458,162	—
Cost of services	1,481,674	169,241	3,121,754
Research and development (2 and 3)	6,482,150	14,898,072	11,585,258
General and administrative(4)	7,185,550	5,635,569	5,510,127
Total operating costs & expenses	25,950,436	21,161,044	20,217,139
Profit/(loss) from operations	(7,770,400)	881,526	(15,925,195)
Other income/(expense)			
Interest income	1,192,889	809,459	2,542,060
Interest expense	—	(9,636)	(9,489)
Fee income	—	—	1,131,222
Other	(33,014)	(250,886)	265,310
Total other income/(expense)	1,159,875	548,937	3,929,103
Net profit/(loss) before tax	(6,610,525)	1,430,463	(11,996,092)
Income tax benefit/(expense)	—	—	206
Net profit/(loss)	\$ (6,610,525)	\$ 1,430,463	\$ (11,995,886)
Basic net profit/(loss) per share	\$ (0.04)	\$ 0.01	\$ (0.08)
Average weighted number of shares used as denominator in calculating basic net profit/(loss) per share	157,584,044	157,013,578	156,970,679
Diluted net profit/(loss) per share	\$ (0.04)	\$ 0.01	\$ (0.08)
Average weighted number of shares used as denominator in calculating diluted net profit/(loss) per share	157,584,044	161,354,802	156,970,679
Notes:			
1 Includes non-cash compensation expense (cost of goods sold)	\$ 168,512	\$ 21,207	\$ —
2 Net of research grant income in these amounts	\$ —	\$ —	\$ 300,613
3 Includes non-cash compensation expense (research and development)	\$ 859,551	\$ 653,474	\$ 661,497
4 Includes non-cash compensation expense (general and administrative)	\$ 648,940	\$ 404,090	\$ 299,611

See accompanying notes to the financial statements.

Universal Biosensors, Inc.

Consolidated Statement of Changes in Stockholders' Equity and Comprehensive Income

	Ordinary Shares		Additional Paid-in Capital	Accumulated Deficit	Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount A\$				
Balances at January 1, 2008	156,958,812	15,696	72,389,505	(12,357,265)	(298,312)	59,749,624
Transaction costs on shares issued . .	—	—	(16,663)	—	—	(16,663)
Comprehensive income						
Net loss	—	—	—	(11,995,886)	—	(11,995,886)
Total Comprehensive income . .						(11,995,886)
Exercise of stock options issued to employees	18,124	2	5,045	—	—	5,047
Stock option expense	—	—	961,108	—	—	961,108
Balances at December 31, 2008 . . .	156,976,936	15,698	73,338,995	(24,353,151)	(298,312)	48,703,230
Comprehensive Income						
Loss on derivatives and hedges, net of tax	—	—	—	—	(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
Balances at December 31, 2009 . . .	157,155,933	15,716	74,566,698	(22,922,688)	(345,724)	51,314,002
Comprehensive income						
Gain on derivatives and hedges, net of tax	—	—	—	—	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
Balances at December 31, 2010 . . .	158,871,495	15,887	77,034,717	(29,533,213)	(298,312)	47,219,079

See accompanying notes to the financial statements.

Universal Biosensors, Inc.
Consolidated Statements of Cash Flows

	Years Ended December 31,		
	2010	2009	2008
	A\$	A\$	A\$
Cash flows from operating activities provided by/(used in):			
Net profit/(loss)	(6,610,525)	1,430,463	(11,995,886)
Adjustments to reconcile net profit/(loss) to net cash provided by/(used in) operating activities:			
Depreciation and impairment of plant and equipment	2,990,858	2,851,285	2,266,847
Share based payments expense	1,677,003	1,078,771	961,108
Loss on fixed assets disposal	2,618	60,658	34,207
Change in assets and liabilities:			
Inventory	(2,885,969)	(305,124)	486,633
Accounts receivables	(3,733,332)	(114,713)	439,691
Prepaid expenses and other current assets	(6,079)	141,331	191,728
Accrued income	118,305	—	(38,494)
Income tax payable	—	—	(18,000)
Deferred revenue	—	290,904	—
Employee entitlements	73,493	50,192	264,286
Accounts payable and accrued expenses	<u>1,959,380</u>	<u>383,389</u>	<u>267,494</u>
Net cash provided by/(used in) operating activities	<u>(6,414,248)</u>	<u>5,867,156</u>	<u>(7,140,386)</u>
Cash flows from investing activities:			
Proceeds/(purchases) from sale of investment securities	—	—	3,123,501
Instalment payments to acquire plant and equipment	(988,334)	(2,145,808)	(3,616,235)
Purchases of property, plant and equipment	<u>(1,331,959)</u>	<u>(844,199)</u>	<u>(5,978,685)</u>
Net cash used in investing activities	<u>(2,320,293)</u>	<u>(2,990,007)</u>	<u>(6,471,419)</u>
Cash flows from financing activities:			
Transaction costs on share issue	—	—	(16,663)
Proceeds from borrowings	—	479,673	—
Repayment of borrowings	—	(479,673)	—
Proceeds from stock options exercised	<u>715,296</u>	<u>78,998</u>	<u>5,047</u>
Net cash provided by/(used in) financing activities	<u>715,296</u>	<u>78,998</u>	<u>(11,616)</u>
Net increase/(decrease) in cash and cash equivalents	(8,019,245)	2,956,147	(13,623,421)
Cash and cash equivalent at beginning of period	31,291,011	28,334,864	41,958,285
Effect of exchange rate fluctuations on the balances of cash held in foreign currencies	<u>—</u>	<u>—</u>	<u>—</u>
Cash and cash equivalents at end of period	<u>23,271,766</u>	<u>31,291,011</u>	<u>28,334,864</u>

See accompanying notes to the financial statement

Universal Biosensors, Inc.
Notes to Consolidated Financial Statements
(for the years ended December 31, 2008, 2009 and 2010)

(1) Basis of Presentation

These 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 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 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 Universal Biosensors Pty Ltd (collectively referred to as "Universal Biosensors" or "the Group"). 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.

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 amount recorded on the balance sheets. The Company has not experienced any losses on its

Universal Biosensors, Inc.

Notes to Consolidated Financial Statements — (Continued)

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 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. If a hedge of a forecast transaction subsequently results in the recognition of a financial asset or a financial liability, then the associated gains and losses that were recognized directly in equity are reclassified into the income statement in the same period or periods during which the asset acquired or liability assumed affects the income statement.

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 income statement in the same period or periods during which the hedged forecast transaction affects the income statement and on the same line item as that hedged forecast transaction. The ineffective part of any gain or loss is recognized immediately in the income statement.

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 income statement.

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 make the sale. 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

Universal Biosensors, Inc.

Notes to Consolidated Financial Statements — (Continued)

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

	Years Ended December 31,		
	2010	2009	2008
	A\$	A\$	A\$
Raw materials — at cost	2,798,045	289,069	—
Work in progress — at cost	188,629	16,055	—
Finished goods — at cost	204,419	—	—
	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.

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 minor corrections and 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. Grant monies 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 the grant agreement are recorded as “Currents Assets” on the balance sheet.

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.

The Group receives Australian Commonwealth government grant funding under an R&D Start Grant Agreement as compensation for expenses incurred in respect of certain research activities into dry chemistry immunosensors. Such grants reduce the related research and development expenses as and when the relevant research expenses are incurred. Grants received in advance of incurring the relevant expenditure are treated as

Universal Biosensors, Inc.

Notes to Consolidated Financial Statements — (Continued)

deferred research grants and included in “Current Liabilities” on the balance sheet as the Group has not earned these amounts until the relevant expenditure has been incurred. Grants due to the Group under research agreements are included in “Current Assets” as accrued income on the balance sheet.

Research and development expenses for years ended December 31, 2010, 2009 and 2008 are as follows:

	Years Ended December 31,		
	2010	2009	2008
	A\$	A\$	A\$
Research and development expenses	6,482,150	14,898,072	11,885,871
Research grants received recognized against related research and development expenses	—	—	(300,613)
Research and development expenses as reported	6,482,150	14,898,072	11,585,258

Income Taxes

The Company applies ASC 740 — Income Taxes (formerly Statement of Financial Accounting Standards No. 109 — Accounting for 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 2009 financial year have been filed. Internationally, consolidated income tax returns up to the 2009 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 (formerly SFAS No. 143 — Accounting for Asset Retirement 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.

Universal Biosensors, Inc.

Notes to Consolidated Financial Statements — (Continued)

Our overall ARO changed as follows:

	Years Ended December 31,	
	2010	2009
	A\$	A\$
Opening balance at January 1	1,842,547	1,699,133
Accretion expense	155,513	143,414
Ending balance at December 31	1,998,060	1,842,547

Fair Value of Financial Instruments

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

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

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

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

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. Cash flows are presented on a gross basis.

Borrowings

In March 2009, Universal Biosensors Pty Ltd entered into an arrangement with Pacific Premium Funding Pty Limited to fund the Group's insurance premium. The total amount financed was A\$479,673 at inception.

Universal Biosensors, Inc.

Notes to Consolidated Financial Statements — (Continued)

Interest was charged at a rate of 2% per annum and the short-term borrowing was repayable over an eight month period. The short-term borrowing was secured by the insurance premium refund. The borrowing was fully repaid in August 2009.

Revenue Recognition

Revenue from products and services and milestone payment

The revenue from products and the milestone payment are part of an arrangement with multiple deliverables. Universal Biosensors and LifeScan are parties to a Master Services and Supply Agreement which was originally entered into in October 29, 2007 and which contains the terms pursuant to which Universal Biosensors Pty Ltd would provide certain services in the field of blood glucose monitoring to LifeScan and would generally act as a non-exclusive manufacturer of blood glucose test strips. On May 15, 2009, the agreement was amended and restated.

The Master Services and Supply Agreement may be terminated as a result of a party defaulting on its material obligations, a party becoming insolvent, at LifeScan's option after paying a lump sum service fee, or as a result of other factors detailed in the Master Services and Supply Agreement.

Revenue received under the Master Services and Supply Agreement was recognised in accordance with ASC 605-25 which was issued by the FASB in October 2009 and is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption and retrospective application are also permitted. The Company elected to early adopt the provisions of ASC 605-25 as of January 1, 2009 as there was a material modification to the Master Services and Supply Agreement in May 2009. Since there were no amounts recognized in the financial statements relating to the deliverables under the arrangement for the previous three quarters in 2009, there was no impact on previously filed financial statements during that year.

Revenue is earned under the arrangement described above as follows:

- *milestone payment.* The Company received a milestone payment of A\$17,722,641 in December 2009 triggered by the first grant to LifeScan of regulatory clearance to sell the blood glucose product;
- *contract manufacturing.* One of two pricing methodologies will apply depending on whether we are manufacturing above or below a specified quantity of blood glucose tests 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 manufacturing profit, but is expected to recover most of its glucose manufacturing costs. As 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 ceased to be in the interim costing period during the second half of 2010 at which time we generated profits from our blood glucose manufacturing operations; and
- *product enhancement.* A service fee based on the number of strips sold by LifeScan is payable to us as an ongoing reward for our services and efforts to enhance the product.

The milestone payment is considered a separate unit of accounting as it has stand-alone value to LifeScan on the basis that subsequent to receiving regulatory approval to market this product, LifeScan can manufacture and sell the product on an ongoing basis without involving us. There are no other activities related to this deliverable and consideration is contingent upon regulatory approval. The best estimate of selling price is commensurate with the efforts expended over a number of years plus a reasonable margin to assist LifeScan to achieve the agreed deliverable.

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Notes to Consolidated Financial Statements — (Continued)

Contract manufacturing of the strip by us is considered a separate unit of accounting as it has stand-alone value to LifeScan as these will be on-sold by LifeScan to its customers. We generally act only as a non-exclusive manufacturer of the blood glucose test strips we developed for LifeScan. There are no general rights of return of the delivered item. There are no other activities related to this deliverable. Consideration is contingent upon receiving firm purchase orders from LifeScan. The best estimate of selling price for contract manufacturing and ongoing efforts to enhance the product has been based on expected costs plus a reasonable margin at normalized volumes.

The ongoing efforts to enhance the product is considered a separate unit of accounting as it has stand-alone value to LifeScan as it increases the marketability of the product. There are no general rights of return of the delivered item. There are no other activities related to this deliverable. Consideration is contingent upon the sale of the strips by LifeScan. The best estimate of selling price for this deliverable is based on the expected efforts required to achieve this deliverable plus a reasonable margin.

All consideration within the contract is contingent. The remaining undelivered items are not priced at a significant incremental discount to the delivered items. Revenue for each deliverable will be recognized as each contingency is met and the consideration becomes fixed and determinable. The milestone payment in 2009 is considered to be a substantive payment and the entire amount has been recognized as revenue when the regulatory approval was received. Revenue for contract manufacturing is recognized in accordance with generally accepted accounting principles as outlined in ASC 605-10-S99, which requires that four basic criteria be met before revenue can be recognized: (i) persuasive evidence of an arrangement exists; (ii) the price is fixed or determinable; (iii) collectability is reasonably assured; and (iv) product delivery has occurred or services have been rendered. Revenue for ongoing efforts to enhance the product is also recognized in accordance with ASC 605-10-S99 when the final product is sold by LifeScan.

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 such as those specified under the Master Services and Supply Agreement including contract research work. 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 the income received from the milestone payment, contract manufacturing and the ongoing efforts to enhance the product indicative of its core operating activities or revenue producing goals of the Company, and as such have accounted for this income as "Net sales and gross revenues".

We perform other services for LifeScan from time to time based on their requirements. There are different arrangements for each service being provided. Revenue recognition principles are assessed for each new contractual arrangement and the appropriate accounting is determined for each service. Revenues received in advance of performing the services are treated as deferred income and included in liabilities on the balance sheet as the Group has not earned these amounts until the relevant services have been performed. We recognize revenue from these services, other than as already detailed above, on the following basis:

- (1) as we perform the services

Under the terms of our arrangement with LifeScan, we provide certain services relating to the blood glucose field. In accordance with ASC 605 — Revenue Recognition (formerly Emerging Issues Task Force ("EITF") Issue 99-19), revenue has been recognized on a gross basis as the Company has earned revenue from the provision of services. Other factors which management considered, which support the gross basis of revenue recognition are as follows:

- the Company was responsible for providing the service and was also the primary obligor with respect to purchasing goods and services from third party suppliers which in turn were used to provide services to LifeScan;

Universal Biosensors, Inc.

Notes to Consolidated Financial Statements — (Continued)

- the Company had unmitigated general inventory risk;
- the Company had credit risk; and
- pricing was not fixed but determined by the level of activity.

The principles of revenue recognition in ASC 605 have all been satisfied; services were performed by us which were supported by purchase orders issued by LifeScan on a regular basis, collection was assured, delivery of the services had occurred and the amount was objectively determined.

(2) on a proportional performance basis where revenues is related to costs incurred in providing the services required under the contract

The Company has provided services to LifeScan to enable LifeScan to establish its own manufacturing line for the blood glucose sensor strips. The proportional performance method has been used to recognize revenue. We believe this method is appropriate as the contract amount was determined prior to the commencement of the service, LifeScan receives value as the services are performed and LifeScan need not re-perform the services that it has already received from the Company should the service arrangement be terminated.

Research and development income

On April 1, 2002, the Company and LifeScan entered into a Development and Research Agreement pursuant to which the Company agreed to undertake contract research and development for LifeScan in the area of diabetes management to extend and develop the glucose sensor technology owned by LifeScan. The research and development activities are supervised by a steering committee comprised of representatives from both the Company and LifeScan. In consideration of us undertaking the research and development activities, LifeScan makes quarterly payments to the Company. The Development and Research Agreement automatically renews for successive one year periods on the same terms and conditions unless either LifeScan or the Company gives written notice of termination not less than nine months prior to the end of the relevant one year period (in which case the agreement terminates at the end of the relevant one year period), or the Development and Research Agreement is otherwise terminated in accordance with its terms. LifeScan owns all intellectual property developed by the Group under the Development and Research Agreement and the Group receives a license to such intellectual property outside of the LifeScan Field.

The income derived from the Development and Research Agreement is recognized over the period in which the agreed upon research services are completed. The Company recognizes income for accounting purposes ratably over the annual grant period. Under the Development and Research Agreement, the Company is not matching the income to a specific expenditure but instead to a specified period of research. The annual research and development income received from LifeScan is agreed upon with LifeScan from time to time and is subject to the Company continuing its research and development activities in the blood glucose area, the provision of quarterly reports and other obligations under the Development and Research Agreement. The Company has and continues to satisfy the requirements of the Development and Research Agreement.

Income recognized pursuant to the Development and Research Agreement has all been received in the financial years stated. No upfront payments have been received from LifeScan. There are no claw backs or repayment obligations relating to the Development and Research Agreement.

Fee Income

Pursuant to the agreement with LifeScan, consideration of A\$1,131,222 was paid in 2008 by LifeScan in consideration of the grant of rights by us. The grant of rights to LifeScan included a detailed written description of the Company's process for the manufacture of the initial blood glucose product, including all underlying know-how relevant to the process. Whilst the non-refundable fee is part of an arrangement with

Universal Biosensors, Inc.

Notes to Consolidated Financial Statements — (Continued)

multiple deliverables, this fee and the deliverable associated with it was considered a separate unit of accounting. There are no other activities related to this deliverable and there is objective and reliable evidence of the fair value of the undelivered items. The fair value of the rights as determined by management was based on estimated market value of labour hours consumed in writing up the documents relating to the rights. There are no general rights of return of the delivered items. These rights were internally generated and were carried at zero value within our financial statements. The rights were transferred and the consideration received in January 2008 at which time the service requirements (granting of the rights) had been fully satisfied.

The grant of these rights is considered to be a discrete earnings event as they are not linked in any way to the other deliverables in the arrangement and there is a risk that the other deliverables may not be achieved. The other deliverables in the arrangement are primarily related to manufacturing and the Company's ability to manufacture which can only occur once regulatory approval is received to market the product. Regulatory approval to market the product was only received in November 2009 and up until that date there was a risk that regulatory approval would not be obtained. Under the arrangement we have with LifeScan, they have the option of terminating the arrangement, which includes the rights for us to manufacture the product. There was no such risk involved in fulfilling our service requirements for the grant of rights as the service requirements were completed and fully satisfied when the consideration was received at which point the rights were transferred to LifeScan. These rights have value to LifeScan as they are able to use this information to build their own manufacturing capability.

Management has concluded that the core operations of the Company in the short term are expected to be research and development activities and the commercial manufacture of approved medical or testing devices and the provision of services such as those specified under the Master Services and Supply Agreement. The Company's ultimate goal is to utilize the underlying technology and skill base for the development of other marketable products that the Company will manufacture. The Company considers the income received for the grant of rights is not indicative of its core operating activities or revenue producing goals of the Company, and as such have accounted for this income as "non-operating income".

Interest revenue

Interest revenue 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 Universal Biosensors Pty Ltd is AUD for all years presented.

The consolidated financial statements are presented using a reporting currency of Australian dollars. Effective October 2008, the Company changed its reporting currency from U.S. Dollars (USD) to AUD. Prior to October 2008, the Company reported its consolidated balance sheet, statement of operations and stockholder's equity and cash flows in USD. The change in reporting currency is to better reflect the Company's performance and to improve investor's ability to compare the Company's financial results.

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 Statement of Operations.

Universal Biosensors, Inc.

Notes to Consolidated Financial Statements — (Continued)

The Company has recorded foreign currency transaction gains/(losses) of (A\$512,474), (A\$250,886) and A\$265,310 for each of the years ended December 31, 2010, 2009 and 2008, 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, 2010 (2009: nil).

Patent and License Costs

Legal fees incurred for patent application costs have been charged to expense and reported in research and development expense.

Clinical Trial Expenses

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

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

Leased Assets

All of the Company's leases for the years ended December 31, 2010, 2009 and 2008 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

As of January 1, 2006, the Company adopted ASC 718, using the modified prospective method, which requires measurement of compensation expense of all stock-based awards at fair value on the date of grant and amortization of the fair value over the vesting period of the award. The Company has elected to use the straight-line method of amortization. Under the modified prospective method, the provisions of ASC 718 apply to all awards granted or modified after the date of adoption. In addition, the unrecognized expense of awards not yet vested at the date of adoption, determined under the original provisions of ASC 718 shall be recognized in net income in the periods after adoption. The fair value of stock options is determined using the Trinomial Lattice model, which is consistent with valuation techniques previously utilized for options in

Universal Biosensors, Inc.

Notes to Consolidated Financial Statements — (Continued)

footnote disclosures required under ASC 718, as amended by ASC 718 (formerly SFAS No. 148 — Accounting for Stock-Based Compensation Transition and Disclosure). Such value is recognized as expense over the service period, net of estimated forfeitures, using the straight-line method under ASC 718. There were no transitional adjustments on adoption of ASC 718.

Pension 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 (formerly Statement of Financial Accounting Standards No. 128 — 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.

Total Comprehensive Income

The Company follows ASC 220 — Comprehensive Income (formerly SFAS No. 130 — Reporting Comprehensive Income (Loss)). 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 January 2010, the FASB issued ASU No. 2010-06 Fair Value Measurements and Disclosures Topic 820 "Improving Disclosures about Fair Value Measurements." This ASU requires certain new disclosures and clarifies existing disclosure requirements about fair value measurement as set forth in Codification Subtopic 820-10. The FASB's objective is to improve these disclosures and, thus, increase the transparency in financial reporting. This ASU is effective for fiscal years beginning on or after December 15, 2009, and interim periods within those fiscal years. The adoption of this ASU did not have a material impact on the Company's consolidated financial statements.

On February 25, 2010, the FASB issued ASU 2010-09 Subsequent Events Topic 855 "Amendments to Certain Recognition and Disclosure Requirements," effective immediately. The amendments in the ASU remove the requirement for an SEC filer to disclose a date through which subsequent events have been evaluated in both issued and revised financial statements. Revised financial statements include financial statements revised as a result of either correction of an error or retrospective application of U.S. GAAP. The FASB believes these amendments remove potential conflicts with the SEC's literature. The adoption of this ASU did not have a material impact on the Company's consolidated financial statements.

In April 2010, the FASB codified the consensus reached in Emerging Issues Task Force Issue No. 08-09, "Milestone Method of Revenue Recognition." FASB ASU No. 2010-17 "Revenue Recognition — Milestone Method (Topic 605)" provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research and development transactions. FASB ASU

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Notes to Consolidated Financial Statements — (Continued)

No. 2010 — 17 is effective for fiscal years beginning on or after June 15, 2010, and is effective on a prospective basis for milestones achieved after the adoption date. The Company does not expect this ASU will have a material impact on its financial position or results of operations when it adopts this update for the fiscal year beginning January 1, 2011.

In April 2010, the FASB issued ASU 2010-13, “Compensation — Stock Compensation (Topic 718): Effect of Denominating the Exercise Price of a Share-Based Payment Award in the Currency of the Market in Which the Underlying Equity Security Trades,” or ASU 2010-13. This ASU provides amendments to Topic 718 to clarify that an employee share-based payment award with an exercise price denominated in currency of a market in which a substantial portion of the entity’s equity securities trades should not be considered to contain a condition that is not a market, performance, or service condition. Therefore, an entity would not classify such an award as a liability if it otherwise qualifies as equity. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2010. The Company does not expect the adoption of ASU 2010-13 to have a significant impact on its consolidated financial statements.

(3) Commitments and Contingent Liabilities

Operating Leases

Universal Biosensors Pty Ltd 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.

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.

Future minimum lease payments under non-cancelable operating leases (with initial or remaining lease terms in excess of one year) as of December 31, 2010 are:

	A\$
2011	537,526
2012	556,082
2013	567,931
2014	146,312
2015 and thereafter	—
Total minimum lease payments	1,807,851

Rent expense was A\$556,584, A\$533,749 and A\$514,984 for the fiscal years ended December 31, 2010, 2009 and 2008, respectively.

Government research grants

Universal Biosensors Pty Ltd received a research grant from the Commonwealth of Australia under the Research and development START Program up to a maximum grant amount of A\$2,366,063 payable over the period from January 1, 2005 to September 30, 2007. The grant was previously set to expire on September 30, 2007. However, the term of the grant was extended to September 30, 2009. The Commonwealth of Australia

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Notes to Consolidated Financial Statements — (Continued)

may terminate the grant agreement for breach of the agreement by Universal Biosensors Pty Ltd, for failure to undertake the required research, if there is a change in control of Universal Biosensors Pty Ltd, or on the grounds of insolvency. In certain limited circumstances where Universal Biosensors Pty Ltd fails to use its best endeavors to commercialize the project within a reasonable time of completion or upon termination of the grant due to breach or insolvency, the Commonwealth of Australia may require Universal Biosensors Pty Ltd to repay some or the entire grant. The Company continues the development of the project funded by the R&D START Program.

The Company believes that the likelihood of being required to repay grant funding is remote because the Company continues to act in good faith with respect to the grant. A Research and development START grant advance of \$118,305 was received during 2010 (2009: nil, 2008: A\$262,119) and income of nil during 2010 (2009: nil, 2008: A\$300,613) was recognized. Accrued income at December 31, 2010 was nil (2009: A\$118,305, 2008: A\$118,305).

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 2010 was A\$39,875 (2009: A\$130,000, 2008: 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. No amounts have been received under this grant to date. This grant will be 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.

Universal Biosensors, Inc.

Notes to Consolidated Financial Statements — (Continued)

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,					
	2010		2009		2008	
	\$	%	\$	%	\$	%
Profit/(loss) before income taxes	(6,610,525)		1,430,463		(11,996,092)	
Computed by applying income tax rate of home jurisdiction	(1,983,157)	30	429,139	30	(3,598,828)	30
Research & development incentive	(421,341)	6	(3,524,333)	(246)	(702,124)	6
Disallowed expenses/(income):						
Share based payment	503,100	(7)	323,631	22	288,332	(3)
Other	4,730	—	(226,924)	(16)	2,600	—
Change in valuation allowance	1,896,668	(29)	2,998,487	210	4,010,020	(33)
Adjustment in respect of current income tax of prior years	—	—	—	—	(206)	—
Income tax expense/(benefit)	—	—	—	—	(206)	—

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

	As of December 31,	
	2010	2009
Deferred tax assets:		
Operating loss carry forwards	12,925,915	10,903,873
Unamortized capital raising cost	104,850	352,651
Depreciation and amortization	(143,647)	(392,582)
Asset retirement obligations	46,654	43,024
Employee entitlements	227,090	205,043
Other accruals	807,922	587,802
Total deferred tax assets	13,968,784	11,699,811
Valuation allowance for deferred tax assets	(13,968,784)	(11,699,811)
Net deferred tax asset	—	—

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, 2010 the Company has A\$43,086,384 (A\$36,346,242 at December 31, 2009) 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

Universal Biosensors, Inc.

Notes to Consolidated Financial Statements — (Continued)

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

An option holder is not permitted to participate in a bonus issue or new issue of securities in respect of an option held prior to the issue of shares to the option holder pursuant to the exercise of an option. If 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 2008, 2009 and 2010 were 1,553,000, 4,164,200 and 914,500 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-10	Nov-10	Feb-10	Nov-09	Jun-09	Jun-09	May-09	Feb-09	Aug-08	Mar-08
Exercise Price (A\$)	Nil	\$ 1.58	\$ 1.60	\$ 1.72	Nil	\$ 0.94	Nil	\$ 0.50	\$ 0.70	\$ 0.89
Share Price at Grant Date (A\$)	\$ 1.58	\$ 1.58	\$ 1.60	\$ 1.73	\$ 0.95	\$ 0.95	\$ 1.18	\$ 0.43	\$ 0.71	\$ 0.91
Volatility	72%	72%	77%	78%	80%	80%	81%	77%	71%	76%
Expected Life	7 years	7 years	7 years	10 years	10 years	10 years	10 years	10 years	10 years	10 years
Risk Free Interest Rate	5.27%	5.27%	5.34%	5.63%	5.49%	5.49%	4.87%	4.26%	5.85%	5.87%
Fair Value of Option (A\$)	\$ 1.58	\$ 0.96	\$ 0.99	\$ 1.13	\$ 0.95	\$ 0.62	\$ 1.04	\$ 0.28	\$ 0.45	\$ 0.59

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

Share price at valuation date

The value of the options granted in 2008 and 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 value of the options granted in 2010 has been determined using the closing price of our common stock trading in the form of CDIs on ASX at the time of grant of the options. The ASX is the only exchange upon which our securities are quoted.

Volatility

With respect to the options granted in 2008, 2009 and 2010, we applied an annual volatility determined partially by reference to the annual volatilities of a number of ASX listed companies of a similar size and with similar operations but also having regard to the volatility on the trading data 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 — (Continued)

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, 2009	<u>10,039,486</u>	<u>0.85</u>
Granted	914,500	1.12
Exercised	(1,667,581)	0.49
Lapsed	<u>(746,701)</u>	<u>1.12</u>
Balance at December 31, 2010	<u>8,539,704</u>	<u>0.93</u>

At December 31, 2010, the number of options exercisable was 5,908,214 (2009: 5,808,324 and 2008: 4,324,915).

The following table represents information relating to stock options outstanding under the plans as of December 31, 2010:

<u>Exercise Price</u> A\$	<u>Options Outstanding</u>		
	<u>Shares</u>	<u>Weighted Average Remaining Life in Years</u>	<u>Options Exercisable Shares</u>
2010 \$0.30	1,556,770	3.00	1,556,770
\$0.35	453,099	5.00	453,099
\$1.18	623,000	6.20	623,000
\$1.20	590,000	6.70	590,000
\$0.89	874,000	7.20	874,000
\$0.70	275,334	7.60	179,997
\$0.50	120,000	8.10	78,665
Nil	79,167	8.40	45,833
\$0.94	1,261,667	8.50	836,011
Nil	434,167	8.50	54,167
\$1.72	1,700,000	8.90	600,006
\$1.60	50,000	6.10	16,666
\$1.58	422,500	6.90	—
Nil	100,000	6.90	—

Universal Biosensors, Inc.

Notes to Consolidated Financial Statements — (Continued)

The table below sets forth the number of employee stock options exercised and the number of shares issued in the period from December 31, 2007. 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> A\$	<u>Proceeds Received</u> A\$
2008	18,124	0.35	5,047
2009	138,327	0.60	78,998
2010	<u>1,667,581</u>	0.49	<u>715,296</u>
Total	<u>1,824,032</u>		<u>799,341</u>

(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

(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:

Based on the latest Amendment to Schedule 13G filed on February 10, 2011, Johnson & Johnson and Johnson and Johnson Development Corporation beneficially owned approximately 11% of the Company's shares.

Universal Biosensors, Inc.

Notes to Consolidated Financial Statements — (Continued)

The following transactions occurred with LifeScan, a wholly owned subsidiary of Johnson & Johnson:

	As of December, 31	
	2010	2009
	A\$	A\$
<i>Current Receivables</i>		
Sale of goods	3,588,798	396,378
Sale of services	—	19,019
	3,588,798	415,397
<i>Revenue</i>		
Revenue from products	11,760,009	132,733
Revenue from services	6,420,027	2,850,071
Research and development income	—	1,337,125
Milestone payment	—	17,722,641
	18,180,036	22,042,570

(7) Financial Instruments

Financial Assets and Liabilities

	Years Ended December 31,		
	2010	2009	2008
	A\$	A\$	A\$
<i>Financial assets:</i>			
Cash and cash equivalents	23,271,766	31,291,011	28,334,864
Accounts receivables	3,588,798	415,397	31,657
Total financial assets	26,860,564	31,706,408	28,366,521
<i>Debt:</i>			
Short and long term debt/borrowings	—	—	—
Total debt	—	—	—
Net financial assets	26,860,564	31,706,408	28,366,521

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 2010, 2009 and 2008.

Derivative Instruments and Hedging Activities

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

Universal Biosensors, Inc.

Notes to Consolidated Financial Statements — (Continued)

(8) Property, Plant and Equipment

	As of December, 31	
	2010	2009
	A\$	A\$
Plant and equipment	15,110,554	13,271,715
Leasehold improvements	8,810,036	8,328,270
Capital work in process	8,792,690	6,298,114
	32,713,280	27,898,099
Accumulated depreciation	(9,586,365)	(6,597,956)
Property, plant & equipment, net	23,126,915	21,300,143

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, 2010, 2009 and 2008 was A\$4,090,724, A\$2,770,434 and A\$1,501,516, 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\$449,875 for the year ended December 31, 2010 (2009: A\$410,000). The grants are recognized against the acquisition costs of the related plant and equipment as and when the related assets are purchased. Grants received in advance of the relevant expenditure are treated as deferred income and included in Current Liabilities on the balance sheet as the Company does not control the monies until the relevant expenditure has been incurred. Grants due to the Company under research agreements are recorded as Currents Assets on the balance sheet.

Depreciation expense was A\$2,990,858, A\$2,851,285 and A\$2,266,847 for the fiscal years ended December 31, 2010, 2009 and 2008, respectively.

(9) Accrued Expenses

Accrued expenses consist of the following:

	As of December, 31	
	2010	2009
	A\$	A\$
Legal, tax and accounting fees	591,184	176,000
Salary and related on-costs	587,695	327,665
Research and development materials	120,000	698,228
Inventory	657,142	—
Other	143,456	—
	2,099,477	1,201,893

(10) Stockholders' Equity — Common Stock

Holder of common stock are generally entitled to one vote per share held on all matters submitted to a vote of the holders of common stock. At any meeting of the shareholders, the presence, in person or by proxy, of the majority of the outstanding stock entitled to vote shall constitute a quorum. Except where a greater

Universal Biosensors, Inc.

Notes to Consolidated Financial Statements — (Continued)

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\$714,123, A\$698,919 and A\$587,885 for the fiscal years ended December 31, 2010, 2009 and 2008, 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.

	Years Ended December 31,		
	2010	2009	2008
	A\$	A\$	A\$
Weighted average number of ordinary shares used as denominator in calculating:			
Basic net profit/(loss) per share	157,584,044	157,013,578	156,970,679
Diluted net profit/(loss) per share	157,584,044	161,354,802	156,970,679

(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 — (Continued)

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, 2010.

(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, 2008, 2009 and 2010)

	<u>Balance at Beginning of Period</u>	<u>Additions</u>		<u>Deductions</u>	<u>Balance at End of Period</u>
		<u>Charged to Costs and Expenses</u>	<u>Charged to Other Accounts</u>		
	A\$	A\$	A\$	A\$	A\$
<i>Year ended December 31, 2008</i>					
Deferred income tax valuation allowance	6,080,529	4,010,020	510,571	—	10,601,120
<i>Year ended December 31, 2009</i>					
Deferred income tax valuation allowance	10,601,120	2,998,487	—	(1,899,796)	11,699,811
<i>Year ended December 31, 2010</i>					
Deferred income tax valuation allowance	11,699,811	1,896,668	372,305	—	13,968,784

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 16, 2011.

(a) Distribution of equity securities

As at March 16, 2011 there were:-

- 158,930,172 fully paid shares of common stock held by CHESS Depository Nominees Pty Ltd on behalf of 1,616 individual holders of CDIs. All issued shares of common stock carry one vote per share and carry the rights to dividends.
- 77,989 unquoted fully paid restricted shares of common stock held by 71 individual employees of the Company. All issued shares of common stock carry one vote per share and carry the rights to dividends.
- 8,715,703 options over shares of common stock held by 97 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	Options over shares of common stock
1 – 1,000	203	0
1,001 – 5,000	461	1
5,001 – 10,000	274	0
10,001 – 100,000	635	78
100,001 – and over	114	18
	1,687	97

There are 37 holders of CDIs with a less than marketable parcel.

(b) Holders of CDIs holding greater than 5%

Name	Number	Percentage
The Principals Cornerstone Fund Pty Limited*	18,651,074	11.730
CM Capital Investments Pty Ltd	17,794,384	11.196
HSBC Custody Nominees (Australia) Limited	17,447,489	10.973
PFM Cornerstone Limited	11,654,679	7.330
Kaasim Pty Ltd	8,582,636	5.398

* 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	11.735
2. CM Capital Investments Pty Ltd	17,794,384	11.196
3. HSBC Custody Nominees (Australia) Limited	17,447,489	10.978
4. PFM Cornerstone Limited	11,654,679	7.333
5. Kaasim Pty Ltd	8,582,636	5.400
6. Cogent Nominees Pty Limited	7,855,068	4.942
7. Aust Executor Trustees NSW Ltd (Tea Custodians Limited)	5,550,110	3.492
8. Mr Alastair Hodges	3,057,962	1.924
9. Equity Trustees Limited	2,743,930	1.727
10. Mr Denis Michael Hanley	2,313,230	1.456
11. National Nominees Limited	1,974,001	1.242
12. Citicorp Nominees Pty Limited	1,903,740	1.198
13. Mr Garry Chambers	1,760,301	1.108
14. Mr Thomas William Beck and Mrs Lynne Carol Beck	1,690,768	1.064
15. Warragai Investments Pty Ltd	1,600,000	1.007
16. Mr Ronald Chatelier	1,288,298	0.811
17. Mr Andrew Denver & Mrs Linda Denver	1,181,812	0.744
18. Mr Christopher J La Croix & Mrs Kathleen M La Croix	1,166,718	0.734
19. Rojo Green Pty Ltd	1,110,807	0.699
20. Mr Andrew Denver	1,087,425	0.684
	110,414,432	69.474
	158,930,172	

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

(d) Restricted Securities

As at March 16, 2011, there are 77,989 fully paid restricted shares of common stock issued to 71 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.

Corporate Directory

Board of Directors

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

Registered Office in Australia

1 Corporate Avenue
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Telephone: +61 3 9213 9000
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Email: info@universalbiosensors.com
Website: www.universalbiosensors.com
ASX code: UBI

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

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Wilmington, County of New Castle
Delaware, Unites States of America

Share Registry

Registries Limited
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Australia
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Facsimile: +61 2 9279 0664
Email: registries@registries.com.au
Website: www.registries.com.au

Auditor

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Darling Park Tower 2
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Australia

Australian Legal Adviser

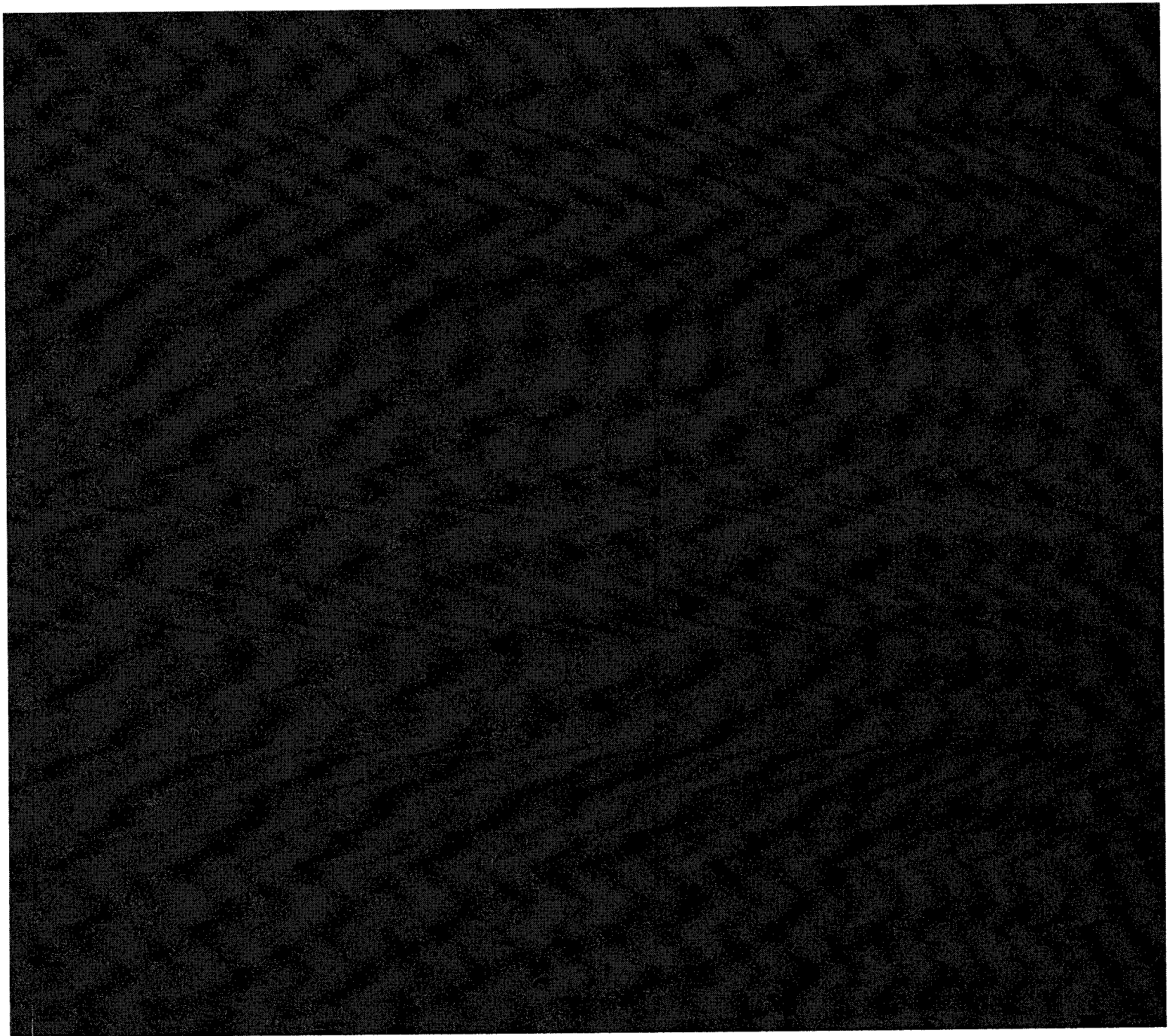
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Universal Biosensors





Universal Biosensors

Annual Report

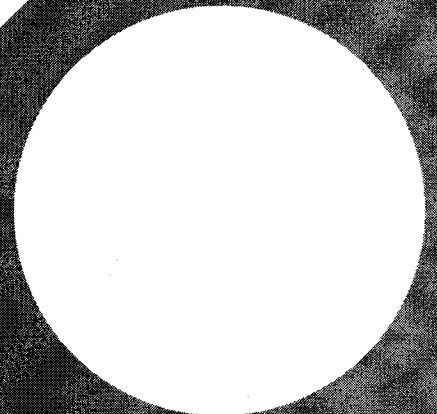
Universal Biosensors, Inc.

Annual Report for the Year Ended December 31, 2010

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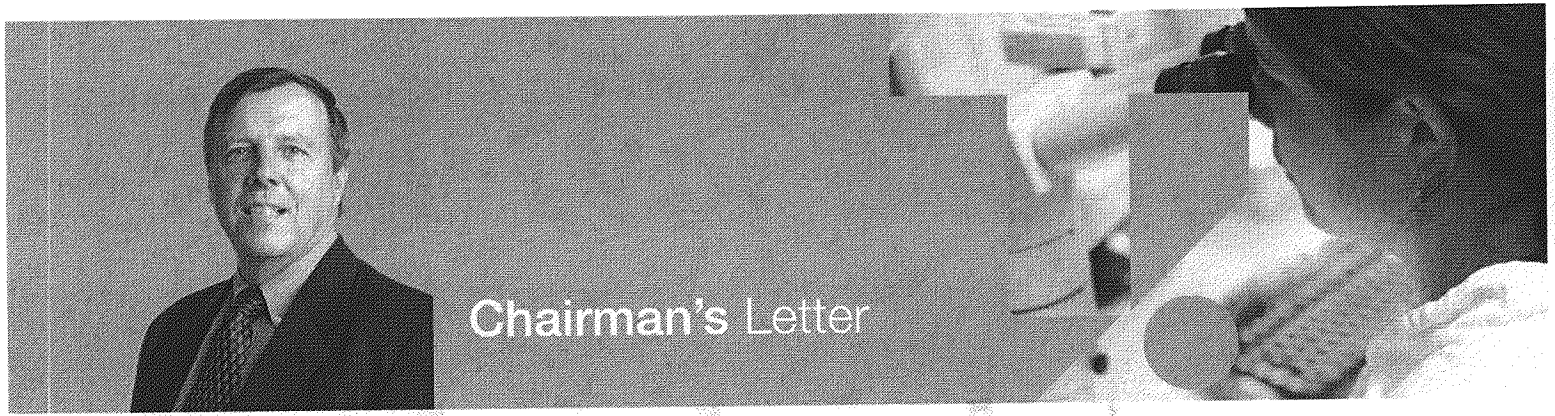
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Washington, DC 20549



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Chairman's Letter

At the beginning of the 2010 financial year, we highlighted three core strategies to create shareholder value. These were:

- creating a sustainable operating business;
- advancing our platform technologies; and
- capitalising on emerging market trends in point of care.

Our partnership with LifeScan, Inc., one of the world leaders in blood glucose point of care testing, has moved us closer to our goal of creating a sustainable operating business. With the OneTouch Verio® blood glucose product, we paired UBI's ability to develop world class technologies with LifeScan's commercial strengths. During 2010, the OneTouch Verio® product was launched by LifeScan in the Netherlands and Australia. More recently, the product has been launched in Italy and France. We achieved operating revenues of A\$18 million during 2010.

We continued our development of other point of care tests and during 2010 began the process of looking for partners who could provide access to the target market segments. This process resulted in our internal development efforts being focused on our PT/INR blood coagulation test to be our lead non-glucose product development for our next partnership. The worldwide market for point of care PT/INR testing has been valued in excess of US\$400 million and is forecast to reach over US\$1 billion by 2020. This form of testing is used to rapidly evaluate patients who are taking the anticoagulant ('blood thinner') warfarin enabling immediate dose adjustments. Warfarin is a mainstay of long-term anticoagulant therapy and is a common treatment for patients at risk of stroke and other coagulation ailments, including deep vein thrombosis. In the US alone, some 30 million warfarin prescriptions are filled every year and patient self testing has become the fastest growing segment within the point of care PT/INR market.

In November 2010, UBI released positive results in a US clinical study of UBI's PT/INR strip and meter system. The system prototype showed excellent correlation with the current market leader and bodes well for the next phase of the test's development, clinical testing and ultimately commercialization.

UBI's PT/INR test is based on its existing technology platform used to successfully produce blood glucose sensors. We believe UBI's PT/INR test will have substantial advantages relative to systems currently on market and will be attractive to a partner.

I am pleased with the success we have had in our lead developments, and believe our platform will be further leveraged into other growth segments such as:

1. point-of-care immunoassays (where we have developments underway with C-reactive protein and D-Dimer tests),
2. companion diagnostics, and
3. other segments where evidence based medicine is practiced and in the emerging area of personalized medicine.

Looking ahead, in blood glucose, we will continue to work in partnership with LifeScan who continues to roll out the OneTouch Verio® product.

As many of you know, after 5 years with UBI, Mr Mark Morrisson retired in September 2010 to pursue other interests. I would like to acknowledge Mark's contribution to the development of UBI and wish him success in his future endeavors. In February 2011, we announced the appointment of Mr Paul Wright to the role of CEO. Paul has experience as Chief Executive Officer with two global technology companies and extensive experience in international strategy consulting and commercial development with a focus on manufacturing industries. As UBI transitions to a substantial operating business, Paul's skills will greatly enhance our ability to achieve our goals.

Finally, I would like to acknowledge the Board and the entire UBI team for their efforts during the 2010 financial year and thank you, our shareholders for your continued support of our company.



Andrew Denver
Chairman

Form 10-K

