



Universal Biosensors

Annual Report

Universal Biosensors, Inc.

Annual Report for the Year Ended December 31, 2009



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Chairman's Letter



Dear Shareholder

2009 was an eventful year for your company with many successes and significant challenges having been overcome. The performance of the UBI team in meeting the requirements of one of the world's most respected healthcare companies, Johnson and Johnson, was outstanding.

November 2009 saw the clearance to sell being granted to LifeScan for the One Touch Verio product, the name under which the product we designed with LifeScan has been taken to market and resulting in UBI receiving a milestone payment of \$US16 million. The One Touch Verio product was launched in the Netherlands in January 2010 and early feedback confirms the value of its market leading attributes.

Early in the year the US regulatory agency the FDA increased its level of concern with certain types of products currently on the market that could not discriminate between certain types of sugars. UBI had been working on an improvement that would alleviate this issue so in early 2009, with LifeScan, we changed the product specifications and essentially embarked on a new product development. This new product was then approved for sale in Europe in November 2009, a development time less than 1 year!

We now have proven the robustness of the technical platform, we have met the requirements of an industry leader and we now wait for the commercial success of this first product in an ever demanding diabetes market.

UBI will focus on expanding the base of products in diabetes care as well as advancing the immunoassay products in a point-of-care setting through a corporate partner with the capability to support products in this environment.

On your behalf I congratulate the team of passionate and committed professionals at UBI for a year of intense effort and great success.

Yours faithfully

Andrew Denver
Chairman



CEO's Report

2009 was an extremely satisfying year for UBI with the receipt of first regulatory clearance to sell and subsequent commercial launch in January 2010 of LifeScan's One Touch 'Verio' product, the blood glucose test we developed with LifeScan. UBI finished the year with a strong cash balance and was profitable at year end.

UBI has worked with LifeScan over a number of years to develop better blood glucose monitoring systems to improve the lives of people with diabetes. In January 2010 we witnessed the launch of One Touch Verio in the Netherlands. The Netherlands is a particularly demanding 'high requirements' market, and one ideally suited to showcasing the market leading accuracy, which is one of the key attributes being exploited by LifeScan. This benefit for people with diabetes comes at a time when market regulators and medical experts are calling on industry to show performance gains in the accuracy of their monitoring systems.

The launch of One Touch Verio is satisfying from a number of perspectives. UBI now has both technical and market validation for the electrochemical cell technology platform it has been, and continues to develop.

UBI will manufacture blood glucose tests strips for LifeScan and receive manufacturing fees and quarterly service fees on the sale of the test strips. With market success, UBI expects that LifeScan will add its own manufacturing capacity to increase the number of strips that can be manufactured for consumers. I anticipate UBI will see the first of LifeScan's capacity additions from mid-2011 onwards. Regardless of whether the strips are manufactured by UBI or LifeScan, UBI will receive a quarterly service fee for each strip sold.

UBI will also continue to undertake further funded research and development work for LifeScan to develop further novel blood glucose products. UBI would also anticipate deriving income from manufacturing some of these future products. Once launched, sales of these products will also earn quarterly service fees for UBI.

At the time of writing, One Touch Verio had been in market for just several weeks. LifeScan has reported to us that the initial market response to the product appears to have been extremely positive with customers pleased by the product's strong attributes. UBI expects LifeScan will continue to roll out the product according to its plans. As a consequence we expect steady sales growth across 2010.

We have also made solid gains in the non-glucose arm of the UBI business. Coupled with the validation shown for the core technology by one of the world's leading suppliers, we have advanced our first products, the prothrombin time and C-reactive protein tests to the point where we can confidently and credibly show these strip and meter systems to potential partners. Use of prototypes in the hands of potential customers has also been well received. UBI's strategy with respect to these products is focused on establishing collaborative partnerships for its platform with major multinationals whose ambition is to lead in key clinical and market segments. UBI is using its lead products for C-reactive protein and prothrombin time to showcase the platform capability of its technology.



Our intent is to proceed thoughtfully with a preference for partnering by clinical area/platform, rather than on a product by product basis. I am particularly encouraged to see that there are indicators that point-of-care markets are developing as we had envisaged and we are now seeing a number of major multinationals seeking to establish a presence in the point-of-care market.

UBI has worked hard over the last two years to position itself to be in the right place at the right time, to capitalize on industry transformation. I believe UBI's platform technology is a unique offering, both for our current partner in the field of diabetes, and for future partners in other fields.

Yours faithfully

Mark Morrisson
Chief Executive Officer

Form 10-K



UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2009

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)

98-0424072

(I.R.S. Employer Identification Number)

Universal Biosensors, Inc.

1 Corporate Avenue, Rowville, 3178, Victoria

Australia

(Address of principal executive offices)

Telephone: +61 3 9213 9000

(Registrant's telephone number, including area code)

Not Applicable

(Zip Code)

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

Title of Each Class

Name of Each Exchange on Which Registered

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 [x]

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 [x]

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 [x] 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 [x]

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 [x]

(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 [x]

The approximate aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant was A\$66,649,269 (equivalent to US\$54,079,217) as of June 30, 2009.

The number of shares outstanding of each of the registrant's classes of common stock as of March 16, 2010:

Table with 2 columns: Title of Class, Number of Shares. Row: Common Stock, US\$0.0001 par value, 157,292,845

DOCUMENTS INCORPORATED BY REFERENCE:

Certain information contained in the registrant's definitive Proxy Statement for the 2010 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

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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 the timing and amounts of revenues from LifeScan, Inc. (“LifeScan”);
- our expectations with respect to the services we provide to and, the development projects we undertake for, LifeScan;
- our expectations with respect to sales of blood glucose test strips by LifeScan and the quantities of blood glucose test strips to be manufactured by us for LifeScan;
- our expectations with respect to regulatory submissions, approvals and market launches of the blood glucose test;
- our expectations with respect to our own research and development programs;
- 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 regulatory submissions and approvals of our own tests in development;
- our estimates regarding our research and development expenses;
- our ability to protect our intellectual property; and
- our estimates regarding our capital requirements, the sufficiency of our cash resources and our need for additional financing.

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

PART I

ITEM 1. BUSINESS.

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

Business overview

We are a specialist medical diagnostics company focused on the research, development and manufacture of in vitro diagnostic test devices for consumer and professional point-of-care use. 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 beside the patient (at the “point-of-care”) to provide accurate and quick results to enable a new treatment to be implemented or an existing treatment to be immediately reviewed.

Our office, research and development and manufacturing facilities are located in Melbourne, Australia.

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., an affiliate of Johnson & Johnson (“LifeScan”). Key inventors for much of this licensed and owned intellectual property are employees of Universal Biosensors Pty Ltd.

We use our technology base and our expertise to develop 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. Although we will be the sole manufacturer of blood glucose test strips during 2010, we generally act as a non-exclusive manufacturer of the blood glucose test strips. LifeScan will establish its own manufacturing capability and, in the future, is likely to manufacture 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 generally.

We are also developing other tests using the electrochemical cell technology. We are developing a C-reactive protein test on our immunoassay platform to assist in the diagnosis and management of inflammatory conditions. 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 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. 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.

General development of our business

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

In April 2002, Universal Biosensors Pty Ltd employed a core scientific and technical team in Australia which, over the 10 years prior to our incorporation, had been integral to the development of the suite of novel electrochemical cell technologies owned by LifeScan and licensed to us.

Also in April 2002, we entered into a license agreement with LifeScan (“License Agreement”) pursuant to which LifeScan granted us a worldwide, royalty free, exclusive license, with a limited right to sub-license, to 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. In October 2007, at the time of execution of the Master Services and Supply Agreement (refer to the details below), the License Agreement was amended to: a) clarify the fields in which LifeScan has exclusive rights as the scope of the fields of diabetes and blood glucose management generally; and b) to grant us a license to certain new patents outside of LifeScan’s field of use.

Also in April 2002, we entered into a development and research agreement with LifeScan (“Development and Research Agreement”) pursuant to which we agreed to undertake contract research and development for LifeScan in the area of diabetes management and the development of a blood glucose test for diabetics. The research and development activities are supervised by a steering committee comprised of representatives from both LifeScan and us. The research and development activities are undertaken by Universal Biosensors Pty Ltd pursuant to a development subcontract with us. In consideration of us undertaking the research and development activities, LifeScan makes quarterly payments to us. Between April 2002 and December 2009, we have received contract research funding of A\$14,415,089 pursuant to the Development and Research Agreement. The amount of the quarterly payments over this period has varied and will continue to vary over time. The initial term of the Development and Research Agreement was for two years. This term was subsequently extended by written amendment until December 31, 2006, at which time, the agreement automatically renewed for successive one year periods on the same terms and conditions unless either LifeScan or we give written notice of termination not less than nine months prior to the end of the relevant one year period, or the agreement is otherwise terminated in accordance with its terms. In October 2007, at the time of execution of the Master Services and Supply Agreement, the Development and Research Agreement was amended to conform the intellectual property provisions in the Development and Research Agreement with those in the Master Services and Supply Agreement such that LifeScan would own all intellectual property developed by us under the Development and Research Agreement and we receive a license to such intellectual property outside of the LifeScan field of diabetes and blood glucose management generally. In May 2009, the Development and Research Agreement was further amended to increase the range of development and research funding that LifeScan may pay us in 2010 and to include a new mechanism for determining research and development programs whereby we proposes development and research work, and then the program of development and research is approved by the joint steering committee.

In June 2003 we acquired certain plant and equipment from Memcor Australia Pty Ltd (a subsidiary of Water Application and Systems Corporation). This plant and equipment included some pilot scale manufacturing equipment designed for research and development as well as office and laboratory furniture and equipment. We issued shares to Water Application and Systems Corporation valued at A\$1,753,156 in consideration of this plant and equipment.

In August 2003, we established office, research and development facilities at 103 Ricketts Road in Melbourne, Australia. We subsequently relocated to larger office, research and development and manufacturing

facilities at 1 Corporate Avenue, Rowville in Melbourne, Australia in August 2007. We completed the fit out of the new facilities in 2008.

From September 2001 to December 2009 we have spent A\$27,898,099 relating to the acquisition of manufacturing and research and development equipment, office furniture and equipment and fit out of the new facilities.

On October 29, 2007 we entered into a Master Services and Supply Agreement 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 a version of the blood glucose test strips we developed for LifeScan. On December 11, 2008, we entered into an additional services addendum to provide manufacturing process support to assist LifeScan to establish LifeScan's own manufacturing line for new blood glucose test strips at a location of its choosing. On December 11, 2008, the Master Services and Supply Agreement was amended to reflect certain definitional matters in the document. On May 15, 2009, the Master Services and Supply Agreement was amended and restated to incorporate the amendments made in December 2008 and to reflect changes resulting from a change of blood glucose test strip. The Master Services and Supply Agreement is structured as an umbrella agreement which enables LifeScan and us to enter into a series of additional arrangements for the supply by us of additional services and products in the field of blood glucose monitoring. LifeScan is responsible for securing regulatory approvals and is responsible for sales and marketing of the blood glucose product. In November 2009, the strip and meter system received its initial regulatory clearance to sell in Europe and in January 2010, LifeScan launched the product in the Netherlands under the trade name "One Touch Verio". LifeScan will continue to be responsible for regulatory strategy and clearances and sales and marketing for the blood glucose product.

Since 2004, as part of our efforts to create new platforms from the electrochemical cell, we have carried out our own research and development activities on a point-of-care dry immunoassay blood test for C-reactive protein for use in the diagnosis and management of inflammatory conditions and since early 2008, a second point-of-care dry immunoassay to measure the amount of D-dimer in the blood. D-dimer is a well established marker currently being used as a point-of-care test for the detection and monitoring of several conditions associated with thrombotic disease, particularly deep venous thrombosis (clots in the leg) and pulmonary embolism (clots in the lung). In another program to extend our technology, since early 2005, we have carried out research and development activities on a point-of-care prothrombin time blood test. All of these tests are based on our underlying electrochemical cell technology platform. We continue to invent and create new intellectual property as we extend the technology.

For both the C-reactive protein (immunoassay) and prothrombin time (enzyme activity) tests, we have now developed working prototypes. Our strategy with each of our non-blood glucose products is to enter into collaborative arrangements or strategic alliances with life sciences companies or other industry participants to complete the development and commercialization of our products. We have successfully taken our prothrombin time test to a point where we believe that we have significantly reduced the risk of technical failure of the product. We do not currently propose to complete the remaining development steps for this prothrombin time test until the path to commercialization for this product is assured and thus we have elected to deploy our resources away from this project until our partnering efforts have been successful. 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 when our efforts might be successful.

Our total research and development expenses for the fiscal years ended December 31, 2009 and 2008 was A\$26,483,330. Over the same period we received A\$2,507,315 in research and development payments from LifeScan. We also received over the same period grant monies of A\$300,613 through an Australian Commonwealth Government R&D Start Grant which is reflected as a reduction of our research and development costs. In addition to this, we received a milestone payment from LifeScan of A\$17,722,641 triggered by the first grant to LifeScan of regulatory clearance to sell the blood glucose product.

Between incorporation and November 2006, we were funded by private and venture capital investors and raised an aggregate total of A\$19,056,636. On December 5, 2006, we closed our initial public offering raising

A\$18 million and our shares were quoted in the form of CHESS Depository Interests, or CDIs, on the ASX on December 13, 2006. Our CDIs continue to be quoted on the ASX under the trading code “UBI”. On December 4, 2007, we closed a renounceable rights issue of new ordinary shares in which we raised A\$34,246,043. Between April 2002 to December 2009, in addition to the funding from LifeScan, Universal Biosensors Pty Ltd has also received grant monies of A\$2,366,063 through an Australian Commonwealth Government R&D Start Grant which is reflected as a reduction of our costs and A\$410,000 through a State of Victoria Grant to support the establishment of a medical diagnostic manufacturing facility in Victoria, Australia which is reflected as a reduction in fixed assets.

We made a net profit of A\$1,430,463 for the year ended December 31, 2009. We recognized a net loss of A\$11,995,886 and A\$8,817,238 in the years ended December 31, 2008 and 2007, respectively. Our accumulated losses from inception to December 31, 2009 are A\$22,922,688. Our ability to generate future profits is dependent on our ability to generate sufficient revenues under the Master Services and Supply Agreement and/or from the sale of any of our own products.

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:

- manufacturing blood glucose test strips for LifeScan as required;
- providing post market support services to LifeScan in connection with the blood glucose test;
- continuing to undertake contract research and development work on behalf of LifeScan and seeking to develop additional products in the field of diabetes and blood glucose monitoring for LifeScan;
- extending the electrochemical cell technology by developing new non-blood glucose tests;
- 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.

Plan of Operations for the Remainder of the Fiscal Year Ending December 2010

Our plan of operations over the remainder of the fiscal year ending December 2010 is to:

- manufacture blood glucose test strips to satisfy LifeScan’s demand requirements;
- provide the necessary post-market support for LifeScan in connection with the blood glucose test;
- continuing to undertake contract research and development work on behalf of LifeScan and seeking to develop additional products in the field of diabetes and blood glucose monitoring for LifeScan;
- advance our research and development activities with respect to our C-reactive protein test and D-dimer test up to a point where they provide credible evidence of the value of these tests for potential partners; and
- 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.

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, 2009, 2008, 2007, 2006 and 2005, 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 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 first test we have developed with LifeScan is a test for the self-monitoring of blood glucose and utilizes an electrochemical cell at the end of the test strip. 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. We are also seeking to extend the utility of electrochemical cells beyond their historic domain of the measurement of blood glucose to the measurement of other blood borne biomarkers using ligand binding (“immunoassay”) 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 immediately 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

The industry in which we operate, the global in vitro diagnostics (IVD) industry, can be segmented according to the location where the sample is tested. Historically most testing has been performed by trained scientists running sophisticated analyzers and consequently testing has required the sample taken from the patient be transported to a dedicated test site. These dedicated, or centralized testing sites include hospital laboratories and commercial pathology laboratories. In recent years, and for a variety of reasons, significant interest has developed in techniques and technologies that allow testing to be performed proximate (in time and location) to the patient. It is now estimated by professional market researchers that nearly 30% of IVD industry derived revenue now comes from point-of-care tests and that the growth rate for this sector is nearly double that for the centralized sector.

Point-of-care testing can be further segmented to 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, it is our belief that a significant number of tests currently performed in centralized settings are better suited to being performed at the point-of-care, but lack a suitable technology platform to see them adapted for, and consequently adopted at, the point-of-care. We believe our electrochemical cell technology can be a suitable platform for adapting central laboratory performed 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, leading to an improved clinical and/or economic outcome. To demonstrate our platform, 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

To date, we have focused the majority of our efforts on the development of blood glucose tests, by virtue of our business relationship with LifeScan. Electrochemical cell technologies have not been widely used in tests other than for blood glucose testing due to technical issues which we are working to overcome. Our strategy is to demonstrate we can 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 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 indicative only.

<u>Point-of-Care Test</u>	<u>Development Stage</u>	<u>Next Anticipated Milestones</u>
Immunoassay C-reactive protein test	<ul style="list-style-type: none">• Development work undertaken since 2004• Working prototype developed• A minimum of one additional year of development/ product validation work required	<ul style="list-style-type: none">• Commence product validation in 2010• Establish manufacturing process• Continue efforts to enter into collaborative arrangements or strategic alliances with third parties to complete the development and commercialization of those products
Prothrombin time test	<ul style="list-style-type: none">• Development work undertaken since early 2005• Working prototype developed• A minimum of one additional year of development/ product validation work required	<ul style="list-style-type: none">• We do not currently propose to complete the remaining development steps for this test until we have entered into a collaborative arrangement or strategic alliances with a third party with respect to the completion of development and commercialization of that product
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 2011• Establish manufacturing process• Continue efforts to enter into collaborative arrangements or strategic alliances with a third party with respect to the completion of development and commercialization of that product

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 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.

Manufacture of test strips, handheld meters and control solution

Although we will be the sole manufacturer of blood glucose test strips during 2010, the Master Services and Supply Agreement provides that we will generally act as a non-exclusive manufacturer of the enhanced blood glucose test strips for LifeScan. LifeScan will establish its own manufacturing capability and, in the future, is likely to manufacture a large proportion of its own requirements. We commenced manufacture of the blood glucose test strips in our facility in Corporate Avenue, Rowville, Melbourne, in December 2009. We intend to manufacture the disposable test strips for each of our existing and future point-of-care tests developed for partners using proprietary manufacturing equipment. If we are successful in securing a partner for one or more of our non-blood glucose tests and the development of that test is successful, if our existing facilities and equipment continue to be utilized for the manufacture of blood glucose test strips, we will need to secure additional or alternative facilities.

The raw material for the blood glucose test strips comprises films and separators for constructing the strips and chemicals. We obtain the films and separators from two established companies and we anticipate regular supply of materials from these suppliers. A number of non-reactive chemicals can be sourced from any one of a number of chemical suppliers. The key chemical in the test strips we have developed are enzymes which we currently source from one supplier. We expect to have a reliable supply of these enzymes.

LifeScan is responsible for the manufacture of the blood glucose test meters and the supply of the control solution used to confirm accurate operation of the meters. With respect to the meters for our own products, we intend to outsource to contractors, the manufacture of the reusable meters and the control solution used to confirm accurate operation of the meters. We believe that outsourcing the manufacture of the meters and the control solution for our products will minimize the capital investment required by us yet maintain quality standards, help control costs and take advantage of the expertise such third parties have in the design and production of meters and control solutions.

Distribution

We manufacture and supply blood glucose tests strips on behalf of LifeScan. LifeScan 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. LifeScan are 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. 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 with LifeScan, we have an exclusive license to a suite of patents, patent applications and know-how to use and exploit the licensed 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 patents, patent applications and know-how owned by LifeScan.

Pursuant to the Development and Research Agreement, we have a limited license to the patents, patent applications and know-how 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.

Universal Biosensors Pty Ltd's owned patent applications and the patents and patent applications licensed to us by LifeScan are essential in the manufacturing and commercialization of each of the point-of-care diagnostic tests being developed by us.

The following sets out details of our owned and licensed patents and patent applications, based on information current as of December 31, 2009.

Patent Family 1 — Electrochemical Detection Method. Patents under Patent Family 1 are currently either pending or granted in a range of jurisdictions within the Americas, Europe, Asia and Australasia. Patent Family 1 relates to an electrochemical detection method for detecting agglutination. The last of the patents to expire within Patent Family 1 will expire on January 16, 2024.

Patent Family 2 — Strip Ejection System. Patents under Patent Family 2 are currently pending or published in a range of jurisdictions within the Americas, Europe, Asia and Australasia. This patent family relates to a system that enables a disposable strip for a meter based sensor device to be transported within the device, moved to a use position and ejected for disposal after use without the operator directly contacting the disposable strip.

Patent Family 3 — Patent Family Fluid Transfer — Fluid Transfer Mechanism (derived from United States of America Provisional patent application no. 60/774,678 and International Patent Application No. PCT/IB2007/000370). Patents under Patent Family 3 are currently pending or published in a range of jurisdictions within the Americas, Europe, Asia and Australasia. This patent family relates to a fluid transfer device for transferring liquid from a first chamber to a second chamber separated by a barrier having at least one opening fluidly connecting the chambers with an opening sized so retention force keeps the liquid in the first chamber until an initiation input is introduced to the liquid that is sufficient to overcome the retention force.

Patent Family 4 — Patent Family Magnetic Particle Mobility — Electrochemical Detection of Magnetic Particle Mobility (United States of America Provisional patent application no. 60/831,240, International Patent Application No. PCT/IB2007/001990, Taiwan and Thailand). Patents under Patent Family 4 are currently pending or published in a range of jurisdictions within the Americas, Europe, Asia and Australasia. This patent family relates to a method for electrochemically monitoring the mobility of particles in a fluid in response to an external field by monitoring an electrical characteristic of the fluid in an electrochemical cell.

Patent Family 5 — Patent Family Protease Sensor — Apparatus and Method for Electrochemical Protease Sensor, United States of America Provisional patent application no. 60/983,029, International Patent Application No. PCT/IB2008/002849 and Taiwan. 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 (PT) and thrombin potential. The PCT application is published and is due for national stage entry in April 2010.

Patent Family 6 — Patent Family Automatic Information Transfer — Automatic Information Transfer by Color Encoded Fields (United States of America Provisional patent application no. 61/081,610, International Patent Application No. PCT/IB2009/006634, Taiwan and Thailand). Patents under Patent Family 6 are currently pending in a range of jurisdictions within Asia. This patent family relates to a method of transferring parametric information from a test strip based on color encoded fields. The PCT application is pending and due for national stage entry in January of 2011.

Patent Family 7 — Patent Family Enhanced Immunoassay Sensor — Enhanced immunoassay sensor (United States of America Provisional patent application no. 61/129,688, International Patent Application No. PCT/IB2009/006688, Taiwan and Thailand). Patents under Patent Family 7 are currently pending in a range of jurisdictions within Asia. This patent family relates to a biosensor for detecting target analyte in a fluid sample based on electrochemical reactions. The PCT application is pending due for national stage entry in January of 2011.

Patent Family 8 — Patent Family Electrochemical On-Board Control Detection — Electrochemical on-board control detection (United States of America Provisional patent application no. 61/170,440). A conversion to non-provisional application is due in April of 2010. The PCT application is pending and due for national stage entry in January 2011.

Patent Family A — Electrochemical Cells. Patents under Patent Family A are currently granted under the European Patent Convention, in Australia and the Americas. 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. The last of the patents to expire within Patent Family A will expire on April 12, 2015.

Patent Family B — Defining an Electrode Area. Patents under Patent Family B are currently granted in Australia, Singapore and the Americas. This patent family relates to a method for defining an electrode area in an electrochemical sensing device. The last of the patents to expire within Patent Family B will expire on April 11, 2016.

Patent Family C — Electrochemical Cell. Patents under Patent Family C are currently either pending or granted in a range of jurisdictions within the Americas, Europe, Asia and Australasia. This patent family relates to a method and an electrochemical biosensor for determining the concentration of an analyte in a carrier. The last of the patents to expire within Patent Family C will expire on May 31, 2017.

Patent Family D1 — Electrochemical Method. Patents under Patent Family D1 are currently either pending or granted in a range of jurisdictions within the Americas, Europe, Asia and Australasia. 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. The last of the patents to expire within Patent Family D1 will expire on November 15, 2016.

Patent Family D2 — Electrochemical Cell. Patents under Patent Family D2 are currently either pending or granted in a range of jurisdictions within the Americas, Europe, Asia and Australasia. This patent family relates to an electrochemical cell for determining the concentration of an analyte in a carrier. The last of the patents to expire within Patent Family D2 will expire on November 15, 2016.

Patent Family F — Sensor Connector Means. Patents under Patent Family F are currently either pending or granted in a range of jurisdictions within the Americas, Europe, Asia and Australasia. This patent family relates to a means for providing an electrical connection between a measuring device and a disposable electrochemical sensor of the type used for quantitative analysis, for example, of glucose levels in blood, for pH measurement. The last of the patents to expire within Patent Family F will expire on March 4, 2019.

Patent Family G — Method of Filling an Amperometric Cell and Improved Electrochemical Cell. Patents under Patent Family G are currently granted in a range of jurisdictions within the Americas and Australasia. This patent family relates to disposable electrochemical sensors of the type used for quantitative analysis, for example, of glucose levels in blood, or the like. The last of the patents to expire within Patent Family G will expire on July 15, 2020.

Patent Family H — Method and Apparatus for Automatic Analysis. Patents under Patent Family H are currently granted in a range of jurisdictions within the Americas. This patent family relates to a method for analyzing the concentration of an analyte in a sample and to an automatic analyzing apparatus. The last of the patents to expire within Patent Family H will expire on August 13, 2018.

Patent Family I — Heated Electrochemical Cell. Patents under Patent Family I are currently granted in a range of jurisdictions within the Americas. This patent family relates to a method and apparatus for determining the concentration of an analyte in a sample by heating the sample and measuring the concentration of the analyte or the concentration of a species representative thereof in the sample at a predetermined point on a reaction profile by means that are substantially independent of temperature. The last of the patents to expire within Patent Family I will expire on March 11, 2019.

Patent Family J — Sensor with Improved Shelf Life. Patents under Patent Family J are currently granted in a range of jurisdictions within the Americas. This patent family relates to extending the shelf life of apparatus, such as electrochemical cells, sensor elements and the like, comprising one or more metal electrodes by stabilizing the metal electrodes using a coating which includes a sulphur containing moiety in its molecular structure. The last of the patents to expire within Patent Family J will expire on March, 16, 2019.

Patent Family K — Electrochemical Methods and Devices for Use in the Determination of Haematocrit corrected Analyte Concentrations. Patents under Patent Family K are currently either pending or granted in a range of jurisdictions within the Americas, Europe, Asia and Australasia. This patent family relates to analyte determination, particularly the electrochemical determination of blood analytes. The last of the patents to expire within Patent Family K will expire on January 25, 2021.

Patent Family M — Method of Preventing Short Sampling of a Capillary or Wicking Fill Device. Patents under Patent Family M are currently granted in a range of jurisdictions within the Americas. This patent family relates to a device, and a method for using the device, for ensuring that a capillary or wicking fill device, such as a capillary or wicking action filled electrochemical sensors suitable for use in analyzing blood or interstitial fluids, is fully filled. The last of the patents to expire within Patent Family M will expire on April 4, 2023.

Patent Family N1 — Electrochemical Method for Measuring Chemical Reaction Rates. Patents under Patent Family N1 are currently either pending or granted in a range of jurisdictions within the Americas, Europe, Asia and Australasia. 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. The last of the patents to expire within Patent Family N1 will expire on January 1, 2022.

Patent Family N4 — Immunosensor. Patents under Patent Family N4 are currently either pending or granted in a range of jurisdictions within the Americas, Europe, Asia and Australasia. This patent family relates to a device and method for performing immunoassays. The device is a quantitative, inexpensive, disposable immunosensor that requires no wash steps and thus generates no liquid waste. The last of the patents to expire within Patent Family N4 will expire on July 13, 2021.

Patent Family O — Electrochemical Cell. Patents under Patent Family O are currently either pending or granted in a range of jurisdictions within the Americas, Europe and Asia. This patent family relates to electrochemical cells including two working and counter electrodes for determining the concentration of a reduced or oxidized form of a redox species with greater accuracy than can be obtained using an electrochemical cell having a single working and counter electrode. The last of the patents to expire within Patent Family O will expire on January 22, 2026.

Patent Family P — Electrochemical Cell Connector. Patents under Patent Family P are currently either pending or granted in a range of jurisdictions within the Americas, Europe and Asia. This patent family relates to a connector to provide electrical connection between an electrochemical cell of a strip type sensor and meter circuitry. The last of the patents to expire within Patent Family P will expire on January 6, 2023.

Patent Family Q — Direct Immunosensor Assay. Patents under Patent Family Q are currently either pending or granted in a range of jurisdictions within the Americas, Europe, Asia and Australasia. This patent family relates to a disposable immunosensor and method for performing immunoassays. The last of the patents to expire within Patent Family Q will expire on March 20, 2023.

Patent Family R — Mediator Stabilized Reagent Compositions and Methods for Their Use in Electrochemical Analyte Detection Assays. Patents under Patent Family R are pending in a range of jurisdictions within the Americas, Europe and Asia. This patent family relates to electrochemical reagent formulations in which the mediator is storage stabilized. The electrochemical reagent formulations enable an extended storage life for test strips for analyte determination, such as determination of blood glucose concentration.

Patent Family S — Method and Apparatus for Electrochemical Analysis. Patents under Patent Family S are published in the Americas.

Patent Application T — Method and Apparatus for Rapid Electrochemical Analysis. Patents under Patent Family T are pending in a range of jurisdictions within the Americas, Europe and Asia. This patent application relates to an improved method and apparatus for electrochemical analysis. The published United States Patent Application No. was filed on September 30, 2005.

Patent Application U — Methods and Apparatus for Analyzing a Sample in the Presence of Interferents. Patents under Patent Family U are pending in a range of jurisdictions within the Americas, Europe, Asia and Australasia. This patent application relates to methods and apparatus for determining analyte concentrations in a rapid and accurate manner. The published United States Patent Application was filed on March 31, 2006.

Patent Application V — Systems and Methods for Discriminating Control Solution from a Physiological Sample. Patents under Patent Family V are pending in a range of jurisdictions within the Americas, Europe, Asia and Australasia. This patent application relates to systems and methods for discriminating between a control solution and a blood sample. The published United States Patent Application was filed on March 31, 2006.

Patent Application W — Biosensor Apparatus and Methods of Use. Patents under Patent Family W are pending or published in a range of jurisdictions within the Americas, Europe and Asia. The published United States Patent Application was filed on November 21, 2005.

Patent Application X — Systems and Methods of Discriminating Control Solution from a Physiological Sample. Patents under Patent Family X are pending in a range of jurisdictions within the Americas, Europe, Asia and Australasia. The United States Provisional Patent Application was filed on September 28, 2007.

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. In the event that LifeScan elects not to proceed with the prosecution of a patent application licensed to us by them, we have the right to assume and continue at our own expense the prosecution of any patent or patent applications. LifeScan is responsible for payment of maintenance fees for all patents licensed to us by them in all agreed jurisdictions. In the event LifeScan discontinues such maintenance payments, we may maintain the licensed patent solely at our own expense. We will prosecute and maintain such patents where appropriate to attempt to protect our rights in our technologies.

Our ability to build and maintain our proprietary position for our technology and products will depend on our success in obtaining effective claims and those claims being enforced once granted and, with respect to intellectual property licensed 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 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. The Master Services and Supply Agreement sets out the circumstances under which LifeScan may return defective products.

Dependence on single customer.

As shown in the table below, we currently receive a significant portion of our income from LifeScan pursuant to the Development and Research Agreement and the Master Services and Supply Agreement.

	Period from Inception to December 31, 2009	2009	2008	2007
	A\$	A\$	A\$	A\$
Revenue from products	132,733	132,733	—	—
Revenue from services	5,971,825	2,850,071	3,121,754	—
Research and development income	14,415,089	1,337,125	1,170,190	1,192,015
Milestone payment	17,722,641	17,722,641	—	—
Interest income	5,408,492	809,459	2,542,060	1,440,102
Fee income	<u>1,131,222</u>	<u>—</u>	<u>1,131,222</u>	<u>—</u>
Total income	<u>44,782,002</u>	<u>22,852,029</u>	<u>7,965,226</u>	<u>2,632,117</u>
Income from LifeScan as a % of total income	<u>88%</u>	<u>96%</u>	<u>68%</u>	<u>45%</u>

For fiscal 2010, the Development and Research Agreement sets out a range of values that the Company or Universal Biosensors Pty Ltd will be paid depending on the level of research and development services required by LifeScan. In subsequent years, the steering committee will recommend the level of funding consistent with LifeScan's requirements. The Development and Research Agreement currently automatically renews for successive one year periods each December on the same terms and conditions unless either LifeScan or we give 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 agreement is otherwise terminated in accordance with its terms.

In 2009, we received various inflows from LifeScan including A\$3,087,849 received in February in connection with the provision by us to LifeScan of certain manufacturing support services and a milestone payment of A\$17,722,641 in December which was triggered upon receipt of initial regulatory clearance to sell the blood glucose product. The blood glucose monitoring test was launched in the Netherlands in January 2010. We anticipate that we will become increasingly dependent on LifeScan for contract research services

and revenue from the manufacturing and supply of test strips for the blood glucose test and from the sale of the blood glucose tests strips by LifeScan. 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.

Australian Government Agreements

Universal Biosensors Pty Ltd currently receives grant funding under two grant agreements with the Commonwealth of Australia and the State of Victoria, Australia. We receive the Commonwealth of Australia grant as compensation for expenses incurred in respect of certain research activities into dry chemistry immunosensors. This grant reduces the related research and development expenses as and when the relevant research expenses are incurred. We receive the State of Victoria Grant to support the establishment of a medical diagnostic manufacturing facility in Victoria, Australia. The State of Victoria grant monies are recognized against the acquisition costs of the related plant and equipment as and when the related assets are purchased. We have received a reduction in our costs of A\$2,366,063 under the Commonwealth of Australia grant and A\$410,000 under the grant from the State of Victoria, Australia. The Commonwealth of Australia and the State of Victoria may terminate their respective grant agreement on different bases, including by giving us written notice of termination if we are in breach of the relevant agreement and if the breach is not capable of being remedied, or if capable of being remedied it is not remedied after receipt of written notice, if we fail to submit reports as required under the relevant grant agreement, if our research and development activities or the quality of those activities do not satisfy the grant eligibility criteria, if there is a change of control of us or if we become insolvent. With respect to the Commonwealth of Australia R&D Start Grant, in certain limited circumstances where we fail to use our best endeavors to commercialize the development program within a reasonable time of completion of the program or upon termination of a grant due to our breach of agreement or our insolvency, we may be required to repay some or all of the grant. If required to repay the grant amounts, we may be required to reallocate funds needed to continue the commercialization of our products and such repayment may have a material adverse effect on our cash position and us. To date, we have not been required to repay any amounts paid to us under these grants. We consider that the likelihood of being required to repay grant funding is remote because we continue to act in good faith with respect to the grants

Competitive conditions of our business

Our revenue is highly dependent on the success of the blood glucose product we have developed with LifeScan. LifeScan have launched the blood glucose product in the Netherlands, named "One Touch Verio", in January 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 if the product will be successful, whether customers will prefer it over competitive offerings, nor the rate at which it might be adopted. Furthermore, LifeScan has not yet launched the product in other territories and the timing and choice remains LifeScan's. Although during 2010 we will be the sole manufacturer of blood glucose test strips, the Master Services and Supply Agreement provides that we will generally act as a non-exclusive manufacturer of the enhanced blood glucose test strips for LifeScan. We anticipate that in the future, LifeScan will establish its own manufacturing capability and is likely to manufacture a large proportion of its own requirements of any blood glucose test strips we develop for them. Although we developed the manufacturing process for the blood glucose tests strips, our experience as a commercial manufacturer is limited. There is a risk that our manufacturing costs may not be able to compete with the cost at which LifeScan may be able to manufacture the blood glucose test strips which we develop. If we are unable to reduce our costs to compete effectively 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. Our intent is to develop tests that illustrate the platform potential for the electrochemical cell technology as an enabling technology.

With the exception of blood glucose testing, most point-of-care testing is currently conducted in professional settings where the test requester is a health care professional. 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 historic providers of testing who operate in centralized settings.

We will face competition from approved and marketed products as well as products in development, for both for point-of-care settings and the central laboratory environment. We expect our C-reactive protein test to compete with existing point-of-care technologies from competitors such as Cholestech Corporation (now part of Inverness Medical Innovations), Orion Corporation and Axis-Shield plc. 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, Roche Holding Ltd, Olympus Medical Systems Corporation, Abbott Laboratories and Beckman Coulter, Inc. All 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 C-reactive protein 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 have successfully taken our prothrombin time test to a point where we believe that we have significantly reduced the risk of technical failure of the product. We do not propose to complete the remaining development steps until our partnering efforts are successful and thus we have elected to deploy our resources away from this project. Should our partnering efforts be successful, and the product brought successfully to market, it will face competition from approved and marketed products in both the point-of-care and central laboratory market places.

We expect 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 Inverness Medical Innovations). All 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 D-dimer test can be 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.

Employees

At March 16, 2010, we had 74 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 (the research, development and manufacture of in vitro diagnostic test devices for consumer and professional point-of-care use) and predominantly in one geographical area (Australia).

ITEM 1A. RISK FACTORS.

Investing in our shares or CDIs involves a high degree of risk. Before you invest in our shares or CDIs, you should understand the high degree of risk involved. You should carefully consider the following risks and other information in this Form 10-K, including our financial statements and related notes appearing elsewhere in this Form 10-K, before you decide to invest in our shares or CDIs. If any of the events described below actually occurs, our business, financial condition and operating results could be harmed. In such an event, the market price of our CDIs would likely decline and you could lose part or all of your investment.

The product developed with our partner, LifeScan, is yet to be successful in the market place.

The global diabetes market place is intensely competitive and dominated by multinationals such as LifeScan, Roche, Abbott and Bayer. The first product we developed with LifeScan was launched in the Netherlands in January 2010. To our knowledge, at the date of this document, LifeScan has not yet launched the product in other territories and the decision to introduce the product to new territories and the timing of any such launch is LifeScan's. We do not yet know if the product will be successful, whether customers will prefer it over competitive offerings, nor the rate at which it might be adopted.

Our ability to become profitable or maintain profitability in the future will be adversely affected if the blood glucose product and any of the other products we develop with LifeScan in the future fail to achieve or maintain market acceptance. Revenue from services fees and strip manufacturing fees for the blood glucose product are anticipated to account for a significant part of our revenue for the foreseeable future. If the blood glucose product and any future products we develop with LifeScan are not successful in the market place, our revenues from services fees and strip manufacturing fees will be reduced or eliminated. We cannot be sure that the blood glucose product and any future product will be successful in the marketplace or that LifeScan will be successful in securing a significant market share or that it will launch the products into key markets. We believe that market acceptance will depend on, amongst other things, the ability to provide and maintain evidence of safety, efficacy and cost effectiveness of the product and benefits over existing products. In addition, market acceptance depends on the effectiveness of marketing strategies employed by LifeScan to sell the products. LifeScan and LifeScan's competitors have products that are established in the blood glucose testing market, and LifeScan may not be able to convince users to switch to the new product or its competitors may introduce a new product which impacts on sales of the blood glucose test. Our commercial opportunity will be reduced or eliminated if LifeScan's competitors develop and commercialize products that are safer, more effective, are more convenient, are less expensive, or that reach markets sooner than the blood glucose products we develop with LifeScan. Scientific, clinical or technical developments by our competitors may render the products we develop with LifeScan obsolete or non-competitive. If the products we develop obtain regulatory approvals, but are not successful and fail to compete effectively in the marketplace, our business will suffer which would have a material adverse effect on our business and financial position.

LifeScan has the sole rights to commercialize the blood glucose products we develop with them and makes the key decisions on product choice and product launch.

LifeScan has the sole rights to commercialize the blood glucose products which we develop with them. LifeScan decides which research and development programs it will pay for, the decision whether or not to launch new blood glucose products we develop with them and, if launched, the timing of such launch, the jurisdictions in which the relevant product will be launched and the nature of any such launch. Decisions made by LifeScan with respect to the commercialization of the blood glucose products we develop with them will affect the extent and timing of revenues to us. 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.

We currently derive the vast majority of our revenue from the initial blood glucose product and we anticipate this will account for a significant part of our revenue for the foreseeable future. There is no guarantee that we will receive revenue under the Master Services and Supply Agreement, in a timely fashion or at all.

The vast majority of our revenue is derived from LifeScan. Our business is, therefore currently dependent on the level of services we provide to LifeScan, the number of test strips that we manufacture for LifeScan and the sales of the blood glucose test strips. Our business will be directly affected by changes in LifeScan's requirements and the level of sales of the blood glucose test strips. Our business will also be affected by economic factors and other trends that affect LifeScan and the blood glucose testing market generally. The market for blood glucose testing is intensely competitive and is subject to rapid change. If we or LifeScan are unable to anticipate or keep pace with change in the market place and the direction of technological innovation, our research and development activities may become less useful for LifeScan. If LifeScan utilizes less of our research and development services, our operating results may suffer. Although we will be the sole manufacturer with capacity to manufacture the blood glucose test strips during 2010, we generally act as a non-exclusive manufacturer of the blood glucose test strips we developed with LifeScan. LifeScan will establish its own manufacturing capability and, in the future, is likely to manufacture a large proportion of its own requirements. There is a risk that our manufacturing costs or product quality may not be able to compete with LifeScan's own operations. Our revenues will decline if we manufacture less than we currently anticipate and some of the manufacturing equipment we have acquired may need to be redeployed to other programs.

Additionally, adverse economic and other factors may cause a reduction in the overall demand for the blood glucose testing product thereby decreasing our revenues. If such factors adversely affect the industry, they may cause LifeScan to decrease the number of services and products it requires from us and may reduce the level of sales of the blood glucose test strips, thereby reducing or eliminating our revenues from the blood glucose market. There can be no assurance that economic and other factors that might adversely affect LifeScan or the blood glucose industry generally will not adversely affect our results of operations.

We currently only have limited revenue from the sale or manufacturing of point-of-care tests.

We are at an early stage of our development as a specialist medical devices company. We were incorporated in 2001 and have a limited operating history on which to evaluate our business and prospects. The blood glucose test product which we developed with LifeScan has been launched and we are receiving some initial revenues from the manufacture and sale of that product. We do not have, and may never have, any of our own products that generate revenues or substantial revenues. To date, we have funded our operations primarily through the issue of shares, from payments received under the Development and Research Agreement, various payments received under the Master Services and Supply Agreement and from government and state grants received by Universal Biosensors Pty Ltd.

We made a net profit of A\$1,430,463 for the year ended December 31, 2009. Our accumulated losses from inception to December 31, 2009 are A\$22,922,688. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Our ability to generate profits in the future will be subject to a number of factors, including without limitation:

- the market acceptance and the success of sales and marketing efforts of the blood glucose product we developed with LifeScan in key jurisdictions;
- our ability to manufacture sufficient quality and quantity of the blood glucose test strips for LifeScan at a cost effective price;
- our ability to perform the required services under the Master Services and Supply Agreement and the level of revenue received from those services;
- LifeScan determining to launch future blood glucose products we develop for them;

- the level of revenue received by us from LifeScan from the manufacture by us of blood glucose test strips and from service fees calculated with reference to the sales of the blood glucose tests strips by LifeScan;
- the timing of any decision that LifeScan could potentially make to pay out the service fee stream;
- our ability to generate new blood glucose products for LifeScan in the future and the terms upon which we undertake such development activities;
- continued income from LifeScan under our Development and Research Agreement;
- the occurrence and cost of any product liability claims or recalls with respect to the blood glucose product;
- our ability to enter into collaborative, licensing and other arrangements in relation to our own products and the terms and conditions of any such arrangements;
- the successful development, product validation, regulatory clearance and scale up and manufacture of our C-reactive protein, prothrombin time, D-dimer tests and future point-of-care tests;
- the timing and success of registration of our products and our ability to maintain regulatory clearances, pass regular audits and respond to any issues that are raised by regulators from time to time;
- the development of the C-reactive protein, prothrombin time and D-dimer point-of-care test markets and point-of-care test markets in general;
- successful market acceptance and the success of sales and marketing efforts of our products by our collaboration partners and the revenue generated by sales of products;
- the ability of our products to be preferred over the products of our competitors;
- the emergence of competing technological developments;
- the rate of progress and cost of our product development activities;
- the expenses we incur in manufacturing, and developing products;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs of any litigation we may become involved in; and
- the acquisition of businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

As a result of the matters set out above and other risks and uncertainties, we may experience significant fluctuations in our operating results for the foreseeable future and we may experience larger than expected future losses and may never become profitable again. These fluctuations may be due to a number of factors, many of which are outside of our control, and may result in volatility of the price of our shares traded in the form of CDIs on the Australian Securities Exchange. If we fail to remain profitable, or if we are unable to fund our losses, the holders of our shares could lose all or part of their investment.

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 for the manufacture of the blood glucose test strip. Our net income will decrease if our manufacturing costs increase or are in excess of what we have anticipated. If our costs of manufacture per strip exceed the cap in the Master Services and Supply Agreement, we will suffer a loss on the sale of those strips. In that event, the Master Services and Supply Agreement provides a mechanism whereby the issue can be referred to the steering committee which administers the Master Services and Supply Agreement for resolution. We have the

right to terminate the Master Services and Supply Agreement should we not be able to negotiate suitable relief.

Termination of our Master Services and Supply Agreement with LifeScan would eliminate our ability to receive revenues from the commercialization of blood glucose products.

The Master Services and Supply Agreement imposes a number of material obligations on us. If the Master Services and Supply Agreement with LifeScan was terminated as a result of either party defaulting on its material obligations, either 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, upon termination we would cease to have the potential to receive revenues from the sale of blood glucose strips, which would have a material adverse effect on us.

Termination of our License Agreement would restrict or eliminate our ability to develop our existing or future point-of-care tests.

Pursuant to a License Agreement, we currently hold a license from LifeScan to a range of patents, patent applications and know-how in all fields excluding the fields of diabetes and blood glucose monitoring generally. The License Agreement imposes material obligations on us, including a best endeavors obligation to exploit the licensed intellectual property. If we were to breach the License Agreement and LifeScan was entitled to, and did, validly terminate the License Agreement, this would seriously restrict or eliminate the ability to develop and commercialize our C-reactive protein test, prothrombin time test or our D-dimer test or any future tests we intend to develop. The termination of the License Agreement would have a material adverse effect on us as it would eliminate our existing commercialization opportunities.

Our Development and Research Agreement with LifeScan provides an ongoing source of income for us, the termination of which would result in the loss of that income.

We undertake contract research and development activities for LifeScan pursuant to a Development and Research Agreement. We receive income under the Development and Research Agreement. If terminated, we would lose an important source of income.

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 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 the Master Services and Supply Agreement or other problems that could seriously harm our business.

We face the risk of product liability claims.

We, and our commercial partners, may be exposed to the risk of product liability claims that are inherent in the testing, manufacturing, marketing and sale of diagnostic tests. This risk will relate to the products which we have or may develop with LifeScan as well as other non-blood glucose products we develop. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for the product we have developed with LifeScan or our own products;
- injury to our reputation and/or injury to the reputation of LifeScan or other commercial partners;
- costs of related litigation;

- management's attention and the attention of our commercial partners being diverted to the claims;
- substantial monetary awards to end users and others;
- impairment of our ability to generate sales of the product the subject of the litigation as well as our other potential products, resulting in loss of revenues;
- increases in insurance premiums or the inability to obtain or maintain insurances on commercially acceptable terms; and
- LifeScan being unable to commercialize the blood glucose products we have developed with them or the inability for us to commercialize our products.

We have obligations to LifeScan and indemnify LifeScan under the Master Services and Supply Agreement with respect to liability arising in connection with the blood glucose tests strips supplied by us and with respect to certain matters concerning the design, validation and manufacture of the blood glucose test strips. We have obtained product liability insurance in connection with the blood glucose test strips. We intend to seek appropriate product liability insurance with respect to any other products we take to market. However, we may not be able to maintain insurance coverage at a reasonable cost, with coverage that we consider reasonable or that will be adequate to satisfy any liability that may arise. 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, which may harm our business. A product liability claim or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could result in significant costs and significant harm to our business. Any claim for damages under the Master Services and Supply Agreement or other claim against us could be substantial. If we are not able to maintain adequate coverage at a reasonable cost, our ability to perform under the Master Services and Supply Agreement may be compromised.

We face the risk of recalls of our products or of the products we have developed with LifeScan.

LifeScan may be exposed to product recalls and adverse public relations if they determine the blood glucose product should be recalled or the blood glucose products are alleged to cause injury or illness, or if they are alleged to have violated government regulations. To the extent such recall or action is attributable to us, we may be liable to reimburse LifeScan for the reasonable costs of such action. The costs of any such action may be significant and may have a material adverse effect on us. A product recall could result in substantial and unexpected expenditures, which would reduce operating profit and cash flow. In addition, a product recall may divert significant of our and LifeScan's management attention. Product recalls may lead to decreased demand for the products we have developed with LifeScan. Product recalls may also lead to increased scrutiny by regulatory agencies and increased litigation.

We will likewise be exposed in the future to product recalls and adverse public relations with respect to our own products if we determine our products should be recalled or our products are alleged to cause injury or illness, or if they are alleged to have violated government regulations. The costs of any such action may be significant and may have a material adverse effect on us.

We have obtained recall liability insurance with respect to the blood glucose product. However, as a third party supplier to LifeScan of blood glucose strips, the coverage of recall insurance available is limited and we may not be able to maintain insurance coverage at a reasonable cost, with coverage that we consider reasonable or that will be adequate to satisfy any liability that may arise. If we are unable to maintain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we may not be able to satisfy our insurance obligations under the Master Services and Supply Agreement and may be exposed to significant liabilities, which may harm our business.

We may in the future manufacture defective test strips that have to be discarded, or be subject to liability should product be recalled, which increases our costs of operations and may delay shipment of product to customers.

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. There may be delays in the manufacture and shipment of tests strips to LifeScan.

We are dependent on our suppliers to deliver various components in conformity with our specifications. If our suppliers are unable to provide materials in conformance with specifications we may be required to discard materials and there may be delays in the manufacture and shipment of tests strips to LifeScan.

There is a risk that we will not be able to enter into collaborative arrangements or strategic alliances with respect to our products which may mean that we are required to delay, reduce the scope of or eliminate some or all of our development programs.

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. There is a risk we may not be able to enter into such collaborative arrangements or alliances on acceptable terms, if at all. As a result, 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 invested and management time may be rendered unproductive and worthless.

We have not established any internal sales and marketing capacity and to achieve commercial success, we must enter into and maintain successful arrangements with others to sell, market and distribute our products.

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.

There is a significant degree of technical development risk associated with the tests we are developing.

The development of our C-reactive protein test, D-dimer test (and our immunoassay platform generally), and prothrombin time test and any new diagnostic tests which we develop will take a number of years to complete, will be costly to develop and the outcomes of our development activities will be uncertain. Even if funding is available for these projects, we still need to undertake a significant amount of technical risk reduction and product development of these tests. Some of these tests still have a significant degree of technical risk and development work and product validation may not be successful or the outcomes of the

development activities may not warrant the commercialization of the relevant product. As a result, significant monies invested and management time may be rendered unproductive and worthless.

Although the development of the blood glucose test is completed, there will be technical risk associated with any new blood glucose products we may agree to develop with LifeScan. The development of any such product will be time consuming and costly and the outcomes of our development activities uncertain. Development and validation of these products may not be successful or the outcomes of the development activities may not warrant the commercialization by LifeScan of the relevant product. As a result, significant monies invested and management time may be rendered unproductive and worthless.

Clinical testing is a time consuming, expensive and uncertain process.

Before the FDA or other regulatory agency approves a diagnostic test for marketing, it must be tested for safety and performance in laboratory and clinical trials. These studies can be costly, time consuming and the results unpredictable. The completion of any clinical trial could be delayed as a result of a number of factors including slower than expected rates of patient recruitment and enrollment, unforeseen safety issues or poor performance. Our partner may not fully reimburse us for these costs. Any unanticipated costs or delays in our clinical trial could cause us to expend substantial additional funds that are not reimbursed by a partner or cause us to miss milestones which trigger a financial payment or cause us or a partner to delay or modify our plans significantly, which would harm our business, financial condition and results of operations.

Even if the clinical trials are complete, we do not know if they will produce clinically meaningful results sufficient to support an application for marketing approval. If we achieve success at any stage of a study, that success may not continue. Interim results of trials do not predict final results. There is a risk that these clinical trials may not be successful or may not be successful with respect to a particular condition or that marketing authorization may not be granted in the future. If we or a partner are not able to successfully complete clinical trials of our products, and if we are unable to obtain marketing authorization of those products, we may not be profitable or poor results or failure in trials might trigger dissolution of the termination of the partnership.

Diagnostic tests are subject to extensive regulation and we or third parties may not be successful in obtaining clearances for some or all of the point-of-care tests we are developing.

The development, manufacturing, sales and marketing of diagnostic tests are subject to extensive regulation in all major markets. The process of obtaining regulatory clearance is costly and time consuming and we or third parties may not be successful in obtaining clearances for some or all of the point-of-care tests we are developing. Products cannot be sold without regulatory clearance. LifeScan is responsible for determining the commercialization strategy and is responsible for obtaining all necessary regulatory clearances with respect to blood glucose products. LifeScan has obtained regulatory clearances for the initial blood glucose product in Europe. 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.

Regulatory oversight continues once products have been brought to market. Failure to comply with regulatory requirements may result in administrative or judicially imposed sanctions. There may be a need in the future to recall released products which have been developed by us in the event of material defects in design or manufacture or quality-related issues, or failure by us to comply with regulatory requirements. Any such recalls may have a material adverse effect on us. Furthermore, regulatory requirements are subject to change and some changes may have adverse effects on us.

Even if the products we develop for LifeScan, or others receive regulatory approval, we may still face development and regulatory difficulties that may delay or impair future sales and we would be subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our product.

Following regulatory authorization to sell products, relevant regulatory authorities may, nevertheless, impose significant restrictions on the indicated uses, manufacturing, labeling, packaging, storage, advertising, promotion and record keeping or impose ongoing requirements for post-approval studies and adverse event reporting. In addition, regulatory agencies subject a marketed product, its manufacturer and the manufacturer's facilities to continual review and periodic inspections. Potentially costly responses may be required including product modification, or follow-up or post-marketing clinical trial may be required as a condition of approval to further substantiate safety or efficacy, or to investigate specific issues of interest to the regulatory authority. Previously unknown problems with a product, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the product, and could include withdrawal of the product from the market. If we discover previously unknown problems with a product or our manufacturing facilities or the manufacturing facilities of a contract manufacturer, a regulatory agency may impose restrictions on that product, on us or on our third-party contract manufacturers, including requiring us to withdraw the product from the market.

If we or our commercial partners fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend regulatory authorization;
- suspend ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed;
- impose restrictions on our operations, including closing our manufacturing facilities or terminating licenses to manufacture; or
- seize or detain products or require a product recall.

Any of the foregoing could seriously harm the commercialization of our products and our results and operations may be seriously harmed.

In addition, the law or regulatory policies governing diagnostic tests may change. New statutory requirements may be enacted or additional regulations may be enacted that could prevent or delay regulatory approval of our products. We cannot predict the likelihood, nature or extent of adverse government guidance or regulation that may arise from future legislation or administrative action. If we are not able to maintain regulatory compliance, we might not be permitted to market our products and our business could suffer.

Our products, even if approved by foreign regulatory agencies and launched may not be accepted by customers.

Success of products developed by us are ultimately dependent on the market acceptance and level of sales of those products. Our ability to be or maintain profitability in the future will be adversely affected if any of the products developed by us, after receiving regulatory approval, fail to achieve or maintain market acceptance. If products developed by us are not successful in the market place, our revenues from sales of those products will be reduced or eliminated. We believe that 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 to sell the products.

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 effected. 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.

Currency fluctuations may expose us to increased costs and decreases in revenue.

Due to the global reach of our business, we are exposed to market risk from changes in foreign currency exchange rates.

Our functional currency changed to Australian dollars with effect from December 1, 2006. Prior to December 1, 2006, our functional currency was United States dollars. The functional currency of Universal Biosensors Pty Ltd is and has been Australian dollars for all years. For details in relation to our functional currency, refer to our financial statements in this Form 10-K.

We are exposed to market risk from changes in foreign currency rates causing increased costs, particularly changes in the Australia, United States and Euro dollars. The majority of our cash reserves are in Australian dollars and the majority of our expenses are incurred in Australian dollars although we continue to expend cash in other currencies. In particular, large scale manufacturing equipment is purchased in both United States dollars and Euros and any appreciation in these currencies against the Australian dollar will increase our cost of acquiring such equipment but may have a positive effect on any revenues which we source from the U.S. or Europe (as applicable). The same principles apply in respect of our costs in other jurisdictions.

Similarly, we are exposed to market risk from changes in foreign currency rates with respect to our revenues. Currently, the vast majority of our revenue is in U.S. dollars. The appreciation in the Australian dollar against the U.S. will result in a decrease in our revenues.

We use 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. Our foreign currency hedging activities depend largely upon the accuracy of our forecasts of future sales, expenses and monetary assets and liabilities. As such, our foreign currency forward contracts may exceed or not cover our full exposure to exchange rate fluctuations. If these hedging activities are unsuccessful, we may experience significant unexpected fluctuations in exchange rates. Although we believe our foreign exchange policies are reasonable and prudent under the circumstances, we may experience losses from un-hedged currency fluctuations, which could be significant.

The failure to secure adequate supplies of the raw materials and components required to manufacture products developed by us could compromise the commercialization and manufacture of products developed by us.

In common with most major manufacturers in our industry, certain raw materials and components come from preferred suppliers, making us vulnerable to supply disruption, which could harm our business. Our suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to follow our protocols and procedures, failure to comply with applicable regulations, or equipment malfunction, any of which could delay or impede their ability to meet our demand. Additionally, we do not currently have long term contractual arrangements with certain of our suppliers. As a result we may not be able to guarantee the supply of certain of our materials or the acceptability of the terms upon which those materials are supplied.

We may have difficulty locating and qualifying on a timely basis alternative suppliers for any preferred suppliers and switching components may require product redesign and new submissions to the FDA or other regulatory bodies, either of which could significantly delay production. A failure of a supplier to comply with their supply obligations may cause a delay in our ability to supply product, which may have an adverse effect on us. There may be delays in the manufacture and supply of product if raw materials are not available on commercially acceptable terms, if there is a supply interruption or if we are unable to obtain alternative suppliers when required. LifeScan is likewise subject to supply risks which may delay their ability to supply customers with the blood glucose product, which may have a consequential adverse effect on our business and results of operations.

We currently outsource some development and the manufacturing of our meters.

We currently outsource some development and manufacturing activities with respect to the meters for our non-blood glucose tests. We anticipate that we will outsource commercial manufacture of meters as our current manufacturing facilities are not suitable for the commercial scale production of meters. 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. We may be required to enter into long-term manufacturing agreements that contain exclusivity provisions and/or substantial termination penalties. In addition, contract manufacturers may have a limited number of facilities in which our products can be produced and any interruption of the operation of those facilities could result in the cancellation of shipments and loss of product, resulting in delays and additional costs. Our contract manufacturers 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 or other problems that could seriously harm our business. In addition, our contract manufacturers will be subject to ongoing inspections and regulation of regulatory authorities, including by the TGA and the FDA.

In connection with the anticipated roll out of the blood glucose product, LifeScan will need to order and have manufactured a large quantity of meters from its existing suppliers. 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.

We, and our contract manufacturers, are required to produce our clinical product and commercial product under FDA and E.U. current Good Manufacturing Practices in order to meet acceptable standards. If such standards change, our ability and the ability of contract manufacturers to produce our products when we require may be affected.

Our contract manufacturer may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products. The ability to find an acceptable manufacturer or to change manufacturers may be difficult for a number of reasons, including that the number of potential manufacturers for specialty components is limited and we may not be able to negotiate agreements with manufacturers on commercially reasonable terms, the complex nature of the meters, and the requirement for the FDA or other applicable regulatory bodies to approve any replacement manufacturer prior to manufacturing, which requires new testing and compliance inspections.

If we were required and able to change manufacturers, the FDA or other applicable regulatory body would also require that we demonstrate structural and functional comparability between the same products manufactured by different organizations and may require comparability studies.

We may require substantial additional capital which may not be available in the future.

If additional commercial manufacturing capacity was required or if we are successful in advancing more than one point-of-care test to regulatory clearance, or if we are unable to enter into collaborative arrangements or strategic alliances with respect to our products, significant additional capital may be required. There can be no assurance that the funds will be available on a timely basis, on favorable terms, or at all. If we are unable

to raise adequate funds, 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 success of our business is dependent upon the growth of the point-of-care testing market. If that market fails to develop as we anticipate, our results will be adversely affected.

Our business plan 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, or to the point where it attracts the interest of major companies. 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. Point-of-care testing may not be endorsed by professional bodies that influence the practice of medicine. Payers may not provide coverage for new tests, or provide coverage at a favorable rate. These factors may inhibit the adoption of point-of-care testing. 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 our business model may need to be rewritten. This may require us to incur more cost and/or our anticipated growth will be adversely affected and our results will suffer.

Even if we successfully secure a partner, the degree of market acceptance of any approved products will depend on a variety of factors, including:

- timing of market introduction and the number and clinical profile of competitive products;
- our partner's ability to secure the support of key clinicians and physicians for products;
- relative convenience and ease of administration;
- cost-effectiveness compared to existing diagnostic tests;
- availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third-parties; and
- other advantages over other test methods.

The success of a C-reactive protein test is dependent upon the acceptance of the use of C-reactive protein in a point-of-care setting for the management of inflammatory conditions. If that use of C-reactive protein fails to develop as we anticipate, our ability to secure a partner and our results will be adversely affected.

The use of C-reactive protein as a marker for inflammatory conditions is generally widely accepted, but 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. The emergence of this market will require acceptance from health care professionals and the endorsement by professional bodies that influence the practice of medicine as well as support from payors and demand from patients. Clinical data may not provide sufficient support for the use of point-of-care C-reactive protein testing, 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 commercialize our C-reactive protein testing.

The market for a prothrombin time test may be significantly reduced if new therapies appearing on the market are widely accepted and significantly reduce the need for testing. This may render the market for a point-of-care prothrombin time test unattractive for a partner.

A number of new oral anti coagulants are entering the market which may eliminate or significantly reduce the need for prothrombin time testing. 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. Uncertainty as to the size and longevity of the prothrombin test market may cause our efforts to enter into a collaborative arrangement with respect to this product unproductive.

The performance of the point-of-care tests developed by us may not be perceived as being comparable with established laboratory methods, which may limit our ability to enter into partners with respect to these products.

Health care professionals who perform point-of-care testing or recommend point-of-care testing for their patients will need to be convinced of the health and economic benefits provided by point-of-care tests developed by us. These health care professionals will always have the option of referring tests to centralized testing if they are unconvinced by the performance of the tests developed by us. If we are unable to demonstrate to healthcare professionals' satisfaction that the performance of our point-of-care tests closely match or provide some benefits over the testing undertaken by hospitals and pathology laboratories, market acceptance of our product will be limited and our business will suffer.

If we are unable to anticipate or keep pace with change in the market place and the direction of technological innovation and customer demands, our products may become less useful or obsolete and our operating results will suffer.

The in vitro diagnostics market is a highly competitive market and we and any partners face competition from large, well-established medical device manufacturers with significant resources.

Hundreds of technology companies globally are developing technologies and products and many of these companies will compete with us for the attention of the limited pool of global multinationals. If our platforms or the attributes of the products that can be produced by our platform are perceived to be inadequate or uncompetitive with other offerings, potential partners may prefer to partner with one of our competitors. If we are unable to find a partner our business will suffer.

The market for in vitro diagnostics is intensely competitive, price sensitive, subject to rapid change, and affected by new product introductions and other activities of industry participants. If we are unable to anticipate or keep pace with change in the market place and the direction of technological innovation and customer demands, products developed by us may become less useful or obsolete and our operating results will suffer. Because products developed by us have long development and government approval cycles, we and any partner must anticipate changes in the market place and the direction of technological innovation and customer demands. We and our 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 or the market place may conclude that our products are obsolete. Any developments adversely affecting the markets for products developed by us would force us to reduce production or discontinue manufacturing which would cause our operating results to suffer. If clinical trials call into question the effectiveness of products developed by us, or if more effective technologies are introduced, our business will suffer.

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. We and any partner will face competition from approved and marketed products as well as products in development. There can be no assurances given with respect to our or any partner's ability to compete in the competitive markets in which we operate.

Our commercial opportunity will be reduced or eliminated if our competitors or LifeScan's competitors develop and commercialize products that are safer, more effective, are more convenient, are less expensive, or that reach the market sooner than our products. Scientific, clinical or technical developments by our competitors may render products we develop or the products we develop for LifeScan obsolete or non-competitive. Further, public announcements regarding the development of any such competing products could adversely affect the market price of our shares. We anticipate that we will face increased competition in the future as new companies enter the markets and as scientific developments progress. If the products we develop

obtain regulatory approvals, but do not compete effectively in the marketplace, our business will suffer. Even if we or any partner can show competitive product advantages, customers may be resistant to changing their supplier.

Many of our competitors have significantly greater financial resources and expertise in conducting clinical trials, obtaining regulatory approvals, undertaking and managing manufacturing and sales and marketing of products than we do. Early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements they may have with large and established companies. In addition, these third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring therapies and therapy licenses complementary to our programs or advantageous to our business.

Additionally, existing and potential competitors hold intellectual property rights that could allow them to develop or sell the right to develop new products that could compete effectively with our point-of-care tests. Many of these companies are larger than we and can enjoy several competitive advantages, including:

- significantly greater name recognition;
- established relationships with healthcare professionals, patients and insurance providers;
- large, direct sales forces and/or established independent distribution networks;
- additional product lines and the ability to offer rebates, bundled products, and higher discounts or incentives;
- greater financial and human resources for product development, sales and marketing and patent litigation.

If we or any partner are unable to compete effectively in the in vitro diagnostics market place, our business will be harmed. Our commercial opportunity will be reduced or eliminated if competitors develop and commercialize products that are more effective, are more convenient, are less expensive, that reach the market sooner than products developed by us, or that are otherwise preferred over our products. Developments by competitors may render the products we develop obsolete or noncompetitive. Further, public announcements regarding the development of any such competing products could adversely affect the market price of our securities on the ASX. If products developed by us obtain regulatory clearances, but do not compete effectively in the marketplace, our business will suffer.

If we are unable to maintain protection for our intellectual property or if LifeScan is unable to maintain protection of the intellectual property which it licenses to us, the value of our technology and diagnostic tests may be adversely affected.

Our ability to obtain patents, maintain trade secret protection and operate without infringing the proprietary rights of third parties is an integral part of our business. Our diagnostic tests are based predominantly on intellectual property rights that have been licensed to us from LifeScan. 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 of the maintenance and protection of our licensed patent portfolio.

A number of companies, universities and research institutions have or may be granted patents that cover technologies similar to the technologies owned by or licensed to us, or they may have technologies that we may need to complete development of a particular product. We may choose to seek, or be required to seek, licenses under third-party patents, which would likely require the payment of license fees or royalties or both. A license may not be available to us on commercially reasonable terms, or at all. We may also be unaware of existing patents or other proprietary rights of third parties that may be infringed by our point-of-care tests. As patent applications can take many years to issue, there may be other currently pending applications which may later result in issued patents that are infringed by our point-of-care tests.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the medical devices industry. The prosecution and enforcement of patents licensed to us by LifeScan are not within our control, and without these technologies, our product may not be successful and our business would be harmed if the patents were infringed or misappropriated without action by such third parties. LifeScan is responsible for the prosecution and maintenance of the intellectual property it license to us and are therefore to a large extent dependant on them with respect to the defense of proceedings and the prosecution of infringers of the licensed intellectual property rights. Without access to these technologies, our ability to conduct our business would be impaired significantly. Defending ourselves against third-party claims, including litigation in particular, would be costly and time consuming and would divert management's attention from our business, which could lead to delays in our development or commercialization efforts. If third parties are successful in their claims, we might have to pay substantial damages, pay license fees, stop marketing the infringing product or take other actions that are adverse to our business.

Infringement actions may need to be brought if we or LifeScan (with respect to the intellectual property licensed to us) believe that a third party is infringing our protected intellectual property. Any such litigation will be costly, time consuming and divert management's attention, and the outcome of any such litigation may not be favorable to us.

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

As with most growth companies, our future success is substantially dependent on our key personnel. Certain key personnel would be difficult to replace and the loss of any such key personnel may adversely impact the achievement of our objectives. Our ability to operate successfully and manage the business depends significantly on attracting and retaining additional highly qualified personnel. The loss of any key personnel may be disruptive or have a material adverse effect on the future of our business. The competition for qualified employees in scientific research and medical diagnostic industries is particularly intense and there are a limited number of persons with the necessary skills and experience.

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. Security holders should obtain, and only rely upon, their own independent taxation advice about the United States and Australian consequences of receiving distributions on our shares or CDIs and disposing of securities in us having regard to their own specific circumstances. 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.

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 16, 2010, 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\$1.60 on March 16, 2010. We may experience a material decline in the market price of our CDIs, regardless of our operating performance. 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. Price declines in our shares could result from a variety of factors, including many outside our control.

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. 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. 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" having been issued pursuant to an exemption from the registration requirements of the Securities Act of 1933, as amended ("Securities Act") or pursuant to Regulation S promulgated under the Securities Act. Therefore, resale of these shares to "U.S. Persons" as defined in Regulation S may only be made in an offshore transaction in compliance with Regulation S promulgated under the Securities Act, or pursuant to an effective Registration Statement under the Securities Act, or pursuant to an available exemption from the registration requirements of the Securities Act, and in each case, in accordance with all applicable securities laws.

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, under current rules, beginning with our fiscal year ending in 2010, our independent auditors will have to 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 has the power to influence matters requiring the approval of stockholders. Approximately 14% 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, who 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 9% of our shares. Messrs Denver, Hanley and Dr Adam's interest in the issued shares (excluding options) of PFM Cornerstone Ltd are approximately 2%, 3% and 2% respectively. Mr. Heinberg also holds approximately 0.22% of PFM Cornerstone Ltd. 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. Johnson & Johnson Development Corporation holds approximately 12% of our shares. For details of our substantial stockholders and the interests of our directors, refer to "Item 12 — Security Ownership of Certain beneficial Owners and Management and Related Stockholder Matters".

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 CHES Depositary 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 as though they were holders of the legal title. 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. In addition, these provisions may frustrate or may prevent any attempts by our stockholders to replace or remove our current management by making it more difficult to remove our current directors. These 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 liability of certain Australian independent registered public accounting firms, such as PricewaterhouseCoopers Australia (an Australian partnership which we refer to as "PwC Australia"), with respect to claims arising out of their audit reports on companies financial statement, is subject to the limitations set forth in the Professional Standards Act 1994 of New South Wales, Australia (the "Professional Standards Act"), and The Institute of Chartered Accountants in Australia (NSW) Scheme adopted by The Institute of Chartered Accountants in Australia and approved by the New South Wales Professional Standards Council pursuant to the Professional Standards Act (the "NSW Accountants Scheme") or, in relation to matters occurring prior to October 7, 2007, the predecessor scheme. The Professional Standards Act and the NSW Accountants Scheme may limit the liability of PwC Australia for damages with respect to certain civil claims arising in, or governed by the laws of, New South Wales directly or vicariously from anything done or omitted in the performance of their professional services to us, in the case of PwC Australia, including, without limitation, PwC Australia's audits of our financial statements, 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.

In addition there is equivalent professional standards legislation in place in each state and territory in Australia and amendments have been made to a number of Australian federal statutes to limit liability under those statutes to the same extent as liability is limited under state and territory laws by professional standards legislation.

These limitations of liability may limit recovery upon the enforcement in Australian courts of any judgment under US or other foreign laws rendered against PwC Australia based on or related to its audit report on our financial statements. Substantially all of PwC Australia's assets are located in Australia. However, the Professional Standards Act and the NSW Accountants Scheme have not been subject to judicial consideration and therefore how the limitation will be applied by the courts and the effect of the limitation on the enforcement of foreign judgments are untested.

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. We relocated to the premises at 1 Corporate Avenue, Rowville in August 2007. We completed upgrading and fit out of the capacity of this facility during 2008 at an estimated cost of A\$1,829,923. 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. We expended cash of approximately A\$2,990,007, A\$9,594,920 and A\$9,058,265 in the years ended December 31, 2009, 2008 and 2007, respectively, in relation to the acquisition of manufacturing equipment, upgrading our manufacturing facility and purchases of other plant and equipment. In the period December 31, 2009 to March 16, 2010, we have committed an additional A\$1,000,000 to the acquisition of additional 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, 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 legal or arbitration proceedings pending against us or Universal Biosensors Pty Ltd, which may have a material effect on our business.

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 Depositary Interests, or CDIs, under the ASX trading code "UBI". The Clearing House Electronic Subregister System, or "CHESS", is an electronic system which manages the settlement of transactions executed on the ASX and facilitates the paperless transfer of legal title to ASX quoted securities. CHESS cannot be used directly for the transfer of securities of 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 beneficial ownership of these securities on the ASX which are not able to be electronically traded in CHESS. CDIs are exchangeable, at the option of the holder, into shares of our common stock at a ratio of 1:1. The main difference between holding CDIs and holding the underlying securities (in this case our shares) is that a holder of CDIs has beneficial ownership of the equivalent number of our shares instead of legal title. Legal title is held by CHESS Depositary Nominees Pty Ltd, or CDN, and the shares are registered in the name of CDN and held by CDN on behalf of and for the benefit of the holders of CDIs. CDN is a wholly owned subsidiary of ASX.

Holder 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 2008		
First Quarter	A\$1.48	A\$0.83
Second Quarter	A\$0.95	A\$0.76
Third Quarter	A\$0.88	A\$0.70
Fourth Quarter	A\$0.78	A\$0.51
Fiscal Year 2009		
First Quarter	A\$0.66	A\$0.41
Second Quarter	A\$1.20	A\$0.56
Third Quarter	A\$1.40	A\$0.83
Fourth Quarter	A\$1.98	A\$1.30

Security details

As of March 16, 2010, there were 157,292,845 shares of our common stock issued and outstanding and 9,952,576 employee options that are exercisable for an equivalent number of shares of common stock (5,808,324 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, 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.

Holder

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 number of our registered holders of shares at specific dates:

<u>Date</u>	<u>Total Number of Registered Holders</u>	<u>Number of Holders that are United States Residents</u>
At March 16, 2010	1,483	11

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, 2009.

Plan Category	Equity Compensation Plan Information		
	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights (A\$)	Number of Securities Remaining for Future Issuance
Equity compensation plans approved by security holders	10,039,486	0.85	(1)
Equity compensation plans not approved by security holders(2)	<u>330,000</u>	<u>0.78</u>	(1)
Total	<u>10,369,486</u>	<u>0.85</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) The grant of options and the issue of shares to any of our directors requires stockholder approval. On May 15, 2009, and June 29, 2009, our Board approved the grant of 37,500 and 142,500 zero price employee options (“ZEPOs”), respectively, to our Executive Director/ Chief Executive Officer, Mr. Mark Morrisson. On November 10, 2009 our Board approved the grant of 150,000 market price employee options and 581 restricted shares of common stock, to Mr. Mark Morrisson. Shareholder approval for the grant of the ZEPOs, Employee Options and the issue of Restricted Shares to Mr. Mark Morrisson is being sought at the 2010 Annual General Meeting.

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

Renounceable Rights Issue

On December 4, 2007, we closed a renounceable rights issue of new shares of common stock to raise an aggregate total of A\$32,518,792 at an issue price of A\$1.20 per share. The renounceable rights issue was underwritten by Wilson HTM Corporate Finance Ltd, an underwriter based in Brisbane, Australia (“Underwriter”). We paid the Underwriter a management fee of A\$599,306 and an underwriting commission of A\$1,027,381 in connection with the renounceable rights issue. In addition, we reimbursed the Underwriter for certain of their outgoings, costs and expenses incurred in connection with the renounceable rights issue. We raised A\$30,892,105 net of fees and commissions paid to the Underwriter in our renounceable rights issue in Australia.

Our underwriter paid A\$450,000 for sub-underwriting part of the renounceable rights issue to PFM Cornerstone Ltd., a corporation of which our directors Messrs. Hanley, Denver and Dr. Adam each held issued shares as at December 31, 2007 representing approximately 2.6%, 2.5% and 2.3% interests (excluding granted options), respectively, and of which each is a director and an executive officer. Our recently appointed director, Mr. Heinberg, also holds a small non-controlling number of shares in PFM Cornerstone Ltd. These fees

represented more than 5% of the revenues of PFM Cornerstone Ltd. for fiscal year 2007. In addition, PFM Cornerstone Ltd held 13,376,406 of our issued shares as at December 31, 2007.

Generally, as a result of securities law restrictions, only shareholders with registered addresses in Australia and New Zealand and United States based shareholders who are accredited or institutional investors were able to subscribe for shares in the rights offer. With respect to the shares issued outside of the United States, we issued these shares in reliance upon exemptions from registration under Regulation S under the Securities Act, as modified by the January 7, 2000 No Action Letter issued by the Securities Exchange Commission to ASX. The renounceable rights issue constituted an “offshore transaction” for the purposes of the Securities Act as shares offered in the initial public offer were only available to Australian residents. Restrictions have been applied to our securities to prevent the resale of the securities into the United States. With respect to a small number of shares issued in the United States to accredited investors, we issued these shares in reliance upon exemptions from registration under Regulation D under the Securities Act. The shares purchased pursuant to Regulation D are “restricted securities” that are only able to be re-sold in the United States if such shares are sold pursuant to an exemption from registration or are registered under the Securities Act. All shares issued in the private placement in the United States rank equally in all respects with all other shares on issue. All shares issued in the renounceable rights offer rank equally in all respects with all other shares on issue.

The funds raised under the renounceable rights issue were for working capital requirements which enabled us to continue to expand our manufacturing capability, acquire inventory and otherwise perform our obligations under the Master Services and Supply Agreement with LifeScan. The funds were also used for the continued development of our existing pipeline of point-of-care tests and to identify and develop additional tests.

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, 2007 to December 31, 2009. We issued these shares in reliance upon exemptions from registration under Regulation S under the Securities Act of 1933, as amended.

<u>Period Ending</u>	<u>Number of Options Exercised and Corresponding Number of Shares Issued</u>	<u>Option Exercise Price</u> (A\$)	<u>Proceeds Received</u> (A\$)
2007			
January, 2007	79,745	\$0.33	26,571
April, 2007	7,250	\$0.38	2,722
July, 2007	28,998	\$0.38	10,889
August, 2007	10,874	\$0.37	4,070
August, 2007	79,745	\$0.33	26,590
November, 2007	36,248	\$0.33	11,924
November, 2007	18,124	\$0.33	5,962
November, 2007	<u>159,490</u>	\$0.37	<u>59,699</u>
	<u>420,474</u>		<u>148,428</u>
2008			
May, 2008	18,124	\$0.35	5,047
2009			
August, 2009	36,248	\$0.31	11,221
September, 2009	25,374	\$0.31	7,853
November, 2009	13,332	\$0.89	11,865
November, 2009	25,373	\$0.28	7,059
November, 2009	8,000	\$0.70	5,600
November, 2009	<u>30,000</u>	\$1.18	<u>35,400</u>
	<u>138,327</u>		<u>78,998</u>

The funds raised 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 10, 2009	40,670	A\$69,952

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

There were no repurchases of equity securities in 2009.

ITEM 6. SELECTED FINANCIAL DATA.

The following table represents our selected financial data for the dates and periods indicated. This data should be read together with, and is qualified in its entirety by reference to, “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” as well as our financial statements and notes thereto appearing in “Item 15. Financial Statement Schedules” of this Form 10-K. The selected financial data for the fiscal years ended December 31, 2009, 2008 and 2007 and the period from inception to December 31, 2009 has been derived from our consolidated audited financial statements, included elsewhere herein. The selected financial data for the fiscal years ended December 31, 2005 and 2006 have been derived from our consolidated audited financial statements which are not included herein. Such financial statements are prepared in accordance with United States generally accepted accounting principles (“U.S. GAAP”) and are presented in Australian dollars (except as otherwise noted) following our election in October 2008 to change our reporting currency from U.S. Dollars to Australian Dollars (refer to Financial Statement Footnote 3 “Summary of Significant Accounting Policies.”)

	Period from Inception (September 14, 2001) to December 31, 2009	Years Ended December 31,				
		2009	2008	2007	2006	2005
		A\$	A\$	A\$	A\$	A\$
Revenue						
Revenue from products	\$ 132,733	\$ 132,733	\$ —	\$ —	\$ —	\$ —
Revenue from services	5,971,825	2,850,071	3,121,754	—	—	—
Research and development income	14,415,089	1,337,125	1,170,190	1,192,015	2,654,280	2,757,817
Milestone payment	17,722,641	17,722,641	—	—	—	—
Total revenue	38,242,288	22,042,570	4,291,944	1,192,015	2,654,280	2,757,817
Operating costs & expenses						
Cost of goods sold(1)	458,162	458,162	—	—	—	—
Cost of services	3,290,995	169,241	3,121,754	—	—	—
Research and development (2 and 3)	43,814,091	14,898,072	11,585,258	7,157,216	3,466,604	2,086,824
General and administrative(4)	19,998,333	5,635,569	5,510,127	4,226,757	2,511,182	922,088
Total operating costs & expenses	67,561,581	21,161,044	20,217,139	11,383,973	5,977,786	3,008,912
Profit/(loss) from operations	(29,319,293)	881,526	(15,925,195)	(10,191,958)	(3,323,506)	(251,095)
Other income/(expense)						
Interest income	5,408,492	809,459	2,542,060	1,440,102	443,769	128,282
Interest expense	(19,125)	(9,636)	(9,489)	—	—	—
Fee income	1,131,222	—	1,131,222	—	—	—
Other	(106,190)	(250,886)	265,310	(210,382)	87,076	(6,147)
Total other income/(expense)	6,414,399	548,937	3,929,103	1,229,720	530,845	122,135
Net profit/(loss) before tax	(22,904,894)	1,430,463	(11,996,092)	(8,962,238)	(2,792,661)	(128,960)
Income tax benefit/(expense)	(17,794)	—	206	145,000	(163,000)	—
Net profit/(loss)	<u>\$(22,922,688)</u>	<u>\$ 1,430,463</u>	<u>\$(11,995,886)</u>	<u>\$(8,817,238)</u>	<u>\$(2,955,661)</u>	<u>\$(128,960)</u>
Basic net profit/(loss) per share	\$ (0.28)	\$ 0.01	\$ (0.08)	\$ (0.07)	\$ (0.06)	\$ —
Average weighted number of shares used as denominator in calculating basic net profit/(loss) per share	80,967,756	157,013,578	156,970,679	129,637,286	49,408,822	43,573,580
Diluted net profit/(loss) per share	\$ (0.28)	\$ 0.01	\$ (0.08)	\$ (0.07)	\$ (0.06)	\$ —
Average weighted number of shares used as denominator in calculating diluted net profit/(loss) per share	80,967,756	161,354,802	156,970,679	129,637,286	49,408,822	43,573,580

Notes:

1 Includes non-cash compensation expense (cost of goods sold)	\$ 21,207	\$ 21,207	\$ —	\$ —	\$ —	\$ —
2 Net of research grant income in these amounts	\$2,366,063	\$ —	\$300,613	\$872,513	\$578,653	\$614,284
3 Includes non-cash compensation expense (research and development) . . .	\$1,802,226	\$653,474	\$661,497	\$339,882	\$147,373	\$ —
4 Includes non-cash compensation expense (general and administrative)	\$1,255,228	\$404,090	\$299,611	\$277,833	\$273,694	\$ —

Years Ended December 31,

	2009	2008	2007	2006	2005
	A\$	A\$	A\$	A\$	A\$
Balance Sheet Data:					
Cash and cash equivalents	31,291,011	28,334,864	41,958,285	30,184,756	4,434,274
Total assets	56,083,468	52,505,321	63,512,160	37,879,601	6,203,277
Long-term debt	—	—	—	—	—
Convertible preference shares(1)	—	—	—	—	3,000,000
Total stockholders' (deficit) equity	51,314,002	48,703,230	59,749,624	35,281,927	5,683,519

(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 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 Form 10-K. 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. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Form 10-K, particularly in "Risk Factors."

Results of Operations

Overview

Established in 2001, 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 diagnostic blood test devices we are developing comprise a novel disposable test strip and a reusable meter. These simple to use portable devices require a finger prick of blood and are designed to be used beside the patient (at the "point-of-care") to provide accurate and quick results to enable treatment to be immediately reviewed. We have rights to an extensive patent portfolio comprising of certain 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., an affiliate of Johnson & Johnson.

We have developed a blood glucose test (used in the management of diabetes) with LifeScan which was launched by LifeScan in the Netherlands in January 2010. We intend to develop other tests in the field of diabetes and blood glucose management generally, for LifeScan.

We are developing an immunoassay point-of-care test to measure the amount of C-reactive protein in the blood to assist in the diagnosis and management of inflammatory conditions. We have also undertaken work on a second point-of-care dry immunoassay to measure the amount of D-dimer in the blood. D-dimer is a well established marker currently being used as a point-of-care test for the detection and monitoring of several potentially life threatening conditions associated with thrombotic disease, particularly deep venous thrombosis (clots in the leg) and pulmonary embolism (clots in the lung). We also intend to leverage our intellectual property platform to develop additional immunoassay based point-of-care test devices by taking proven disease biomarkers currently used in the central laboratory environment and adapting those diagnostic tests to the point-of-care setting.

We have also undertaken development work on a prothrombin time test for monitoring the therapeutic range of the anticoagulant, warfarin. We have successfully taken our prothrombin time test to a point where we believe that we have significantly reduced the risk of technical failure of the product. We do not currently propose to complete the remaining development steps for this test until the path to commercialization for this product is assured and thus we have elected to deploy our resources away from this project until our partnering efforts have been successful.

All of our operating activities are undertaken through our wholly-owned subsidiary, Universal Biosensors Pty Ltd which is located in Australia. We have funded our operations primarily through the sale of our equity securities, payments from LifeScan, Inc., an affiliate of Johnson & Johnson (“LifeScan”), in connection with the Development and Research Agreement, various payments under the Master Services and Supply Agreement and revenue from certain services provided to LifeScan and government and state grants.

Master Services and Supply Agreement with LifeScan

On October 29, 2007, we entered into a Master Services and Supply Agreement 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 an original version of the initial blood glucose test strips we developed for LifeScan (“Master Services and Supply Agreement”). On December 11, 2008, the Master Services and Supply Agreement was amended to reflect certain definitional matters in the document. On May 15, 2009, the agreement was amended and restated to incorporate the amendments made in December 2008 and to reflect changes resulting from a change to the blood glucose test strip. The Master Services and Supply Agreement is structured as an umbrella agreement which enables LifeScan and us to enter into a series of additional arrangements for the supply by us of additional services and products in the field of blood glucose monitoring. We commenced manufacture of the initial blood glucose test strips in our facility in Corporate Avenue, Rowville, Melbourne, in December 2009.

Development and Research Agreement with LifeScan

On April 1, 2002, we entered into a Development and Research Agreement with LifeScan pursuant to which we agreed to perform certain research and development activities for LifeScan in the area of diabetes management to extend and develop the glucose sensor technology owned by LifeScan. At the time of execution of the Master Services and Supply Agreement, the Development and Research Agreement was amended to conform the intellectual property provisions in the Development and Research Agreement with those in the Master Services and Supply Agreement such that LifeScan would own all intellectual property developed by us under the Development and Research Agreement and we would receive a license to such intellectual property outside of the LifeScan field of diabetes and blood glucose management generally. In May 2009, the Development and Research Agreement was further amended to increase the range of development and research funding that LifeScan may pay us in 2010 and to include a new mechanism for determining research and development programs whereby we propose development and research work, and then the program of development and research is approved by the joint steering committee.

In consideration of undertaking the development and research, LifeScan makes quarterly payments to us. From April 2002 to December 31, 2009, we have received aggregate contract research funding from LifeScan of A\$14,415,089. We received A\$1,337,125, A\$1,170,190 and A\$1,192,015 in 2009, 2008 and 2007, respectively. In subsequent years, the steering committee will recommend the level of funding consistent with LifeScan's requirements. The Development and Research Agreement automatically renews for successive one year period on the same terms and conditions unless either party has given to the other party prior written notice of termination not less than nine months prior to the end of the relevant one year period, in which case the Development and Research Agreement will terminate at the end of the relevant one year period, or the agreement is otherwise terminated in accordance with its terms.

License Agreement with LifeScan

In 2002, we entered into a License Agreement with LifeScan pursuant to which LifeScan granted to us a worldwide, royalty free, exclusive license to certain electrochemical cell technologies in all fields of use excluding the LifeScan Fields of diabetes and blood glucose management generally. LifeScan has retained all rights in the LifeScan Field. Under the License Agreement, we have a right to sub-license, make, have made, use, and sell under and exploit in any way a range of key patents, patent applications and know-how owned by LifeScan, relating to electrochemical cell technologies in all fields excluding the LifeScan Fields, the rights to which are retained by LifeScan. We must pay LifeScan 50% of any royalties or payments we receive under any such sublicense. We are also contractually bound to use our best efforts to exploit the licensed intellectual property outside the LifeScan Fields, for example, in our C-reactive protein, prothrombin time tests and D-dimer tests. At the time of execution of the Master Services and Supply Agreement, the License Agreement was amended to: a) clarify the scope of the LifeScan Field in which LifeScan have exclusive rights to the relevant patents; and b) to grant us a license to certain new patents outside of the LifeScan Field.

The License Agreement may be terminated by LifeScan in the event that we fail to exploit the licensed patents and patent applications or if we are liquidated or wound up or commit a persistent and material breach of our obligations under the License Agreement and fail to rectify the breach within 90 days of written notice from LifeScan requiring it to do so. The License Agreement otherwise continues on a perpetual basis until the expiration of the last licensed LifeScan patent or patent application. LifeScan may also convert the license from an exclusive license to a non-exclusive license in certain limited circumstances where we fail to comply with the requirements of the License Agreement.

R&D Start Grant

On October 1, 2004, Universal Biosensors Pty Ltd entered into a grant agreement with the Commonwealth of Australia under the R&D Start Grant Program. The Commonwealth of Australia has provided Universal Biosensors Pty Ltd with a grant of 50% of the eligible expenditure on a program for the development of a single step, disposable immunosensor platform up to a maximum grant amount of A\$2,366,063 payable over the period to September 30, 2007, at which time the grant was to formally terminate. Universal Biosensors Pty Ltd submitted for and received approval for the grant to be extended to September 30, 2009. We have ongoing obligations beyond the program completion date, including continuing to use our best endeavors to commercialize the immunosensor platform on normal commercial terms within a reasonable time of completion of the program.

Grant payments are made in accordance with an agreed schedule and are subject to the satisfaction by Universal Biosensors Pty Ltd of certain specified technical milestones and conditions and the Commonwealth of Australia having sufficient funding available. In addition, we are required to commit the necessary eligible expenditure, submit all progress reports due and demonstrate satisfactory progress and expenditure on the program. The Commonwealth of Australia may terminate the grant agreement for breach of the agreement by us, for failure to undertake the required research, if there is a change in control of Universal Biosensors Pty Ltd or us, or on the grounds of insolvency. In certain limited circumstances where Universal Biosensors Pty Ltd fails to use its best endeavors to commercialize the program 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. We consider that the likelihood of being

required to repay any of the grant funding is remote because we continue to act in good faith with respect to the grant. Research and development grants received were Nil, A\$300,613 and A\$872,513 in the fiscal years ended December 31, 2009, 2008, 2007 and A\$2,366,063 from inception to December 31, 2009, respectively.

Victorian State Government Grant

On October 28, 2006, Universal Biosensors Pty Ltd entered into an agreement with the State of Victoria acting through its Department of Innovation, Industry and Regional Development. The State of Victoria has agreed to grant payments up to A\$540,000 to support the establishment of a medical diagnostic manufacturing facility in Victoria 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 us 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 we 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 we choose not to proceed with these initiatives or if we become insolvent. We consider that the likelihood of being required to repay any of the grant funding is remote because we continue to act in good faith with respect to the grant. Victorian State government grants received were A\$130,000, A\$130,000 and A\$150,000 in the fiscal years ended December 31, 2009, 2008, 2007 and A\$410,000 from inception to December 31, 2009, respectively.

Critical Accounting Estimates and Judgments

Our consolidated financial statements are prepared in accordance with 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.

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 (formerly Statement of Financial Accounting Standards No. 123(R) — Accounting for Stock-Based Compensation).

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

Share price at valuation date

In order to value options over shares of common stock which we granted in 2003 and 2006, by virtue of the fact that our securities were not traded at that time on any public exchange, we have valued our options consistent with the shares that were issued in certain private capital raisings undertaken by the Company around the respective valuation dates of the options, as these prices are most indicative of the fair value of the Company's equity in the market to a willing participant at and around the applicable valuation date of the options. Although we raised capital by issuing preferred shares, for the purposes of valuing our options we regarded our ordinary and preferred shares as being equivalent in relevant economic aspects and therefore the capital raisings served as a suitable valuation point with respect to the valuation of our options. In this regard we note that the preference shares carried the right to convert to ordinary basis on a one to one basis, and all were converted during 2006 in conjunction with our initial public offering.

We consider that value of the shares we issued in the capital raisings undertaken by us in 2003 and 2006 (as applicable) most accurately represent the value of our common stock for valuation purposes at the time of

those capital raisings. We summarize the per-share subscription value of the relevant shares issued by us below.

<u>Date of Capital Raising</u>	<u>Value per Preferred Stock</u>
	A\$
December 2003	0.39
June 2006	0.45
August 2006	0.45

Based on these valuation points, we applied an assumed per share price of A\$0.39 with respect to the options we granted in 2003 and A\$0.45 for the options we granted in 2006.

The value of the options granted post 2007 have 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.

On December 12, 2007 as a result of the impact of the closing of the rights offering, the exercise prices of each option granted by the Company prior to November 19, 2007 was reduced by a maximum of A\$0.10 in accordance with the terms of the options and a formula set out in the Listing Rules of the ASX. The table below reflects the changes to the exercise price and the fair value of option as a result of the rights offering:

<u>Grant Date of Option</u>	<u>Pre Rights Offering</u>		<u>Post Rights Offering</u>	
	<u>Exercise Price</u>	<u>Fair Value of Option</u>	<u>Exercise Price</u>	<u>Fair Value of Option</u>
	A\$	A\$	A\$	A\$
Dec-03	\$0.39	\$0.11	\$0.30	\$0.11
Jan-06	\$0.45	\$0.30	\$0.35	\$0.27
Mar-07	\$1.25	\$0.78	\$1.18	\$0.79
Sep-07	\$1.27	\$0.77	\$1.20	\$0.78
Oct-07	\$1.20	\$0.77	\$1.13	\$0.78

Volatility

With respect to the options granted in 2003 and 2006, we had insufficient available share price data to accurately estimate the volatility of our shares of common stock. As a result, we examined and based our volatility for these options by reference to the annual volatilities of a number of ASX listed companies of a similar size and with similar operations to us, over a range of historic estimation periods. Based on our analysis we selected an annual volatility of 40%-45% for the options granted in 2003 and 55% for the options granted in 2006. These figures were within the range of observed volatilities for comparable listed companies.

With respect to the options granted post 2007, 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. Our shares in the form of CDIs were first quoted on ASX on December 13, 2006 with an initial offering price of A\$0.50. The share price at valuation date was as follows:

<u>Option Grant Date</u>	<u>Share Price</u> A\$	<u>Volatility</u>
March 23, 2007	\$1.21	74%
September 19, 2007	\$1.21	72%
October 29, 2007	\$1.19	76%
March 17, 2008	\$0.91	76%
August 20, 2008	\$0.71	71%
February 17, 2009	\$0.43	77%
May 15, 2009	\$1.04	81%
June 29, 2009	\$0.95	80%
November 10, 2009	\$1.73	78%

Consequently, the high level and varying movement on our shares was the key driver for the volatility increasing from 55% at December 31, 2006 to volatility in the 70% — 80% range for options issued subsequent to December 2006.

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.

Research and Development Expenditure

Research and development expenses consists of costs incurred to further our 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.

We receive grant funding under 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. The grants are recognized against the related research and development expenses as and when the relevant research expenditure is incurred. Grants received in advance of incurring the relevant expenditure are treated as deferred research grants and included in “Current Liabilities” on the balance sheet as we do not control the monies until the relevant expenditure has been incurred. Grants due to us are included in “Current Assets” as accrued income on the balance sheet.

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.

The Company adopted ASC 740 (formerly FIN No. 48 — Accounting for Uncertainty in Income Taxes) effective January 1, 2007 which has not had a material impact on the Company's consolidated financial statements.

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.

Results for the Year Ended December 31, 2009

Revenue from Products

In November 2009, LifeScan received initial regulatory clearance to sell their blood glucose product which we have been assisting to develop. We commenced manufacture of the blood glucose test strips required for this product in our facility in Rowville, Melbourne, in December 2009, ahead of the January 2010 market launch in the Netherlands.

Pursuant to the Master Services and Supply 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. As we produced less than the specified quantity of test strips for the December 2009 quarter, we are considered to be in the "interim costing period". In the interim costing period, the Company is establishing its commercial scale manufacturing and therefore is not expected to generate any 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 to be profitable in the sale of blood glucose test strips.

Revenue from Services

During the year ended December 31, 2009, we performed various services for LifeScan based on their requirements. Different remuneration arrangement applied depending on the service provided. The major service provided to LifeScan during the 2009 financial year was to enable LifeScan to establish its own manufacturing line for blood glucose sensor strips. There were various other minor services provided in the blood glucose field.

Milestone Payment

The Company received a milestone payment of A\$17,722,641 triggered by the first grant to LifeScan of regulatory clearance to sell the blood glucose product.

Research and Development Income

We receive research and development income under the Development and Research Agreement with LifeScan. The Development and Research Agreement provides details of the amount to be charged to LifeScan each year for the research and development services carried out by us. The annual research and development income received from LifeScan is agreed with LifeScan from time to time and is subject to us continuing our research and development activities in the blood glucose area, the provision of quarterly reports and other obligations under the Development and Research Agreement. We have and continue to satisfy the requirements of the Development and Research Agreement.

Income is recognized when services have been performed, the amount of the payment can be reliably measured and collectability is reasonably assured. The recognition is not based on the completion of any milestones, or on a percentage of completion basis. The income derived from the Development and Research Agreement is recognized over the period in which the agreed upon research services are completed. Under the Development and Research Agreement, we are not matching the income to a specific expenditure but to a specified period of research.

Research and development income for the fiscal years ended December 31, 2009, 2008 and 2007 were primarily derived from LifeScan under the Development and Research Agreement and totaled A\$1,337,125, A\$1,170,190 and A\$1,192,015, respectively.

Research and Development Expenses

Our operating expenses to date have substantially been for research and development activities. All research and development costs, including those funded by an Australian research and development grant program, are expensed as incurred.

These expenses are related to developing our 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 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.

Research and development expenses for the fiscal years ended December 31, 2009, 2008, 2007 and for period from inception to December 31, 2009 are as follows:

	Period from Inception to December 31, 2009	Years Ended December 31,		
		2009	2008	2007
		A\$	A\$	A\$
Research and development expenses	46,180,154	14,898,072	11,885,871	8,029,729
Research grants received recognized against related research and development expenses	<u>(2,366,063)</u>	<u>—</u>	<u>(300,613)</u>	<u>(872,513)</u>
Research and development expenses as reported	<u>43,814,091</u>	<u>14,898,072</u>	<u>11,585,258</u>	<u>7,157,216</u>

A significant portion of our research and development expenses relate to activities undertaken to achieve the deliverable included in milestone payment.

We expect that our expenses will increase during 2010 as we expand our research and development programs and expand our organization's manufacturing capability.

We cannot predict what it will cost to complete our research and development programs or when or if they will be completed and 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 programs. In the event that third parties assume responsibility for certain research or development activities, the estimated completion dates of those activities will be under the control of the third party rather than with us. We cannot forecast with any certainty, which programs, if any, will be subject to future collaborative arrangements, in whole, or in part, and how such arrangements would affect our research and development plans or capital requirements.

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 were A\$5,635,569, A\$5,510,127 and A\$4,226,757 in 2009, 2008 and 2007, respectively. We expect that our general and administrative expenses will increase as we expand our legal, accounting, marketing and sales staff, add infrastructure and incur additional costs related to operating as a company whose shares in the form of CDIs are quoted on the ASX and compliance costs associated with being a domestic United States issuer subject to SEC reporting requirements.

Fair value of stock options issued to employees

As of January 1, 2006, we adopted ASC 718 (formerly Statement No. 123(R) — Share Based Payment). The impact of the change in accounting policy applied prospectively resulted in the stock option expense being A\$1,078,771, A\$961,108, A\$617,715 and A\$3,078,661 for the years ended December 31, 2009, 2008, 2007 and for the period from inception to December 31, 2009.

Comparison of the Years Ended December 31, 2009 and 2008

Revenue

In the last quarter of 2009, we commenced the manufacture of the blood glucose strips in our facility and we also received a milestone payment of A\$17,722,641 triggered by the first grant to LifeScan of regulatory clearance to sell the blood glucose. In relation to our manufacturing operations, pursuant to the Master Services and Supply 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. As we produced less than the specified quantity of test strips for the December 2009 quarter, we are considered to be in the "interim costing period". In the interim costing period, the Company is establishing its commercial scale manufacturing and therefore is not expected to generate any 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 to be profitable in the sale of blood glucose test strips. Revenue from services in 2009 is primarily in connection with the provisions by us to Lifescan of certain manufacturing support services.

Our research and development income for 2009 and 2008 was A\$1,337,125 and A\$1,170,190, respectively, recognized pursuant to the Development and Research Agreement.

During the 2008 financial year, the only other income we generated was from LifeScan for the provision of certain services relating to the development and scale up of the production of a blood glucose sensor strip. Under this arrangement, no margin was earned as the costs of providing the services were equal to the revenue recognized.

Research and development expenses

Research and development expenses include:

- consultant and employee related expenses, which include 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 expenses increased in 2009, as reflected below:

	<u>Years Ended December 31,</u>	
	<u>2009</u>	<u>2008</u>
	<u>A\$</u>	<u>A\$</u>
Research and development expenses	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>14,898,072</u>	<u>11,585,258</u>

A substantial portion of our research and development expenditure was expended towards finalizing our research and development program for the blood glucose project which concluded towards the end of 2009. We also worked on three non-glucose development programs, including two programs to develop immunoassay based tests (one immunoassay test being a test for C-reactive protein and the other being a test for D-dimer) and a prothrombin time test. Our strategy is to enter into collaborative arrangements or strategic alliances with life sciences companies or other industry participants to complete the development and commercialization of our products. 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 when our efforts might be successful.

General and administrative expenses

General and administrative expenses increased to A\$5,635,569 in 2009 from A\$5,510,127 in 2008. General and administrative expenses consist principally of salaries and related costs, including stock options 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. This increase in expenses reflects growth in the size and complexity of our operations, as well as the incremental costs of having our shares in the form of CDIs quoted on the ASX and compliance costs associated with being a domestic United States issuer subject to SEC reporting requirements. We expect that our general and administrative expenses will increase as we expand our legal, accounting, marketing and sales staff, add infrastructure and incur additional costs related to operating as a company whose shares in the form of CDIs are quoted on the ASX, including directors' and officers' insurance, investor relations programs, increased director fees and increased professional fees.

Interest income

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 level of funds invested for most of the year. We commenced the 2008 financial year with A\$28,334,864 in cash and short-term investments. The cash and bank balance at the end of the 2009 financial year was A\$31,291,011. Of this, the milestone payment of A\$17,722,641 was received in December 2009 upon the receipt of regulatory clearance of the blood glucose product.

Fee Income

The Company received an initial non-refundable fee of A\$1,131,222 in January 2008 in consideration for the grant of certain rights to LifeScan pursuant to the Master Services and Supply Agreement. This revenue is recorded under the caption "Other income" in the consolidated statements of operations.

Fair value of stock options issued to employees

The non-cash compensation expense increased to A\$1,078,771 in 2009 from A\$961,108 in 2008 as a result of options granted to employees on a consistent basis and increase in the number of personnel.

Net profit

The Company made a net profit of A\$1,430,463 in 2009 largely as a result of increased revenue.

Comparison of the Years Ended December 31, 2008 and 2007

Revenue

Under the terms of our arrangement with LifeScan, during 2008 we provided certain services relating to the development and scale up of the production of a blood glucose sensor strip. Production scale up includes activities such as producing strips and testing strips. Under this arrangement, no margin was earned as the costs of providing the services were equal to the revenue recognized.

Amounts billed to LifeScan have been recorded under the caption "Revenue from services" in the consolidated statements of operations. Research and development expenditure attributable to services performed on behalf of LifeScan have been recorded separately under the caption "Cost of services" in the consolidated condensed statements of operations.

No such services were provided in 2007.

Our research and development income for 2008 and 2007 was A\$1,170,190 and A\$1,192,015, respectively, recognized pursuant to the Development and Research Agreement.

Research and development expenses

Research and development expenses increased to A\$11,585,258 in 2008 from A\$7,157,216 in 2007. Our operating expenses were substantially for research and development activities. 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. All research and development costs, including those funded by an Australian research and development grant program, are expensed as incurred. Included in the research and development expenses are Australian research grants of A\$300,613 and A\$872,513 received for the R&D Start Grant Program for 2008 and 2007, respectively.

Research and development expenses include:

- consultant and employee related expenses, which include 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.

General and administrative expenses

General and administrative expenses increased to A\$5,510,127 in 2008 from A\$4,226,757 in 2007. General and administrative expenses consist principally of salaries and related costs, including stock options 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. This increase in expenses reflects growth in the size and complexity of our operations, as well as the incremental costs of having our shares in the form of CDIs quoted on the ASX and compliance costs associated with being a domestic United States issuer subject to SEC reporting requirements.

Interest income

Interest income increased to A\$2,542,060 in 2008 from A\$1,440,102 in 2007. The increase in interest income is attributable to the greater level of funds invested during the year. We commenced the 2007 financial year with A\$41,958,285 in cash and short-term investments. Of this A\$34,246,043 was raised by way of a renounceable rights issue in November and December 2007. The cash and bank balance at the end of the 2008 financial year was A\$28,334,864.

Fee Income

The Company received an initial non-refundable fee of A\$1,131,222 in January 2008 in consideration for the grant of certain rights to LifeScan pursuant to the Master Services and Supply Agreement. This revenue is recorded under the caption "Other income" in the consolidated statements of operations.

Fair value of stock options issued to employees

The non-cash compensation expense increased by 56% from 2007 to 2008 as a result of options granted to employees on a consistent basis and increase in the number of personnel granted options.

Income tax benefit

Income tax benefit during the 2007 and 2008 year relates to the reversal of provision for income tax.

Net loss

Net loss increased to A\$11,995,886 in 2008 from A\$8,817,238 in 2007 as a result of increased activity during the 2008 financial year thus resulting in increased research and development expenses and general and administrative expenses. The loss was partially offset by revenues received from LifeScan for provision of certain services.

Liquidity and Capital Resources

Since inception, our operations have mainly been financed through the issuance of equity securities. Additional funding has come through payments received from LifeScan under the Development and Research Agreement, revenue from services, various payments under the Master Services and Supply Agreement and a one-time payment for manufacturing process support and research grants and interest on investments. Through to December 31, 2009, we had received aggregate net cash proceeds from the following: (a) A\$32,502,129 from the renounceable rights issue; (b) A\$37,178,516 from the issuance of equity securities other than those issued under the renounceable rights offer; (c) A\$14,415,089 from LifeScan under our Development and Research Agreement; (d) A\$5,971,825 from LifeScan as revenue from services performed; (e) A\$2,776,063 as contributions from government and state grants; (f) A\$1,131,222 from LifeScan as an initial fee under our Master Services and Supply Agreement; (g) A\$17,722,641 from LifeScan received on regulatory clearance to sell the blood glucose product and (g) A\$5,408,492 from interest on investments. As of December 31, 2009, we had A\$31,291,011 in cash, cash equivalents and short-term investments. Our cash and investment balances are held in money market accounts and short-term instruments. Cash in excess of immediate requirements is invested in short-term instruments with regard to liquidity and capital preservation.

For the year ended December 31, 2009, net cash provided by operating activities was A\$5,867,156. This consisted of a milestone payment of A\$17,722,641 received on regulatory clearance of the blood glucose product and a net profit for the period of A\$1,430,463 which included A\$2,851,285 of non-cash depreciation

and amortization and non-cash stock option expense of A\$1,078,771. Net cash used in investing activities during the year ended December 31, 2009 was A\$2,990,007, which included purchase of plant and equipment of A\$844,199 and the balance deposits towards manufacturing equipment. These deposits have not been treated as "Property, plant and equipment" in the balance sheet but as "Prepayments" as title has not yet passed to us. Net cash provided by financing activities during the year ended December 31, 2009 was A\$78,998.

For the year ended December 31, 2008, we used net cash of A\$7,140,386 for operating activities. This consisted of a net loss for the period of A\$11,995,886, which included A\$2,266,847 of non-cash depreciation and amortization and non-cash stock option expense of A\$961,108. Net cash used in investing activities during the year ended December 31, 2008 was A\$6,471,419, which included additional fit out of our new facilities and purchase of plant and equipment of A\$5,978,685, transfer of term investments with initial maturity between four to six months to term investments having a maturity of less than three months and deposits towards manufacturing equipment. The term investments had a face value of A\$3,123,501. We also made deposits towards manufacturing equipment of A\$3,616,235. These deposits have not been treated as "Property, plant and equipment" in the balance sheet but as "Prepayments" as title has not yet passed to us. Net cash used in financing activities during the year ended December 31, 2008 was A\$11,616.

For the year ended December 31, 2007, we used net cash of A\$7,769,274 for operating activities. This consisted of a net loss for the period of A\$8,817,238, which included A\$708,699 of non-cash depreciation and amortization, and non-cash stock option expense of A\$617,715. Net cash used in investing activities during the year ended December 31, 2007 was A\$12,181,766, which included purchase of plant and equipment of A\$9,058,265 reflecting the commencement of the expansion of our manufacturing capabilities and leasehold improvements to the Rowville premises and A\$3,123,501 placed as term investments with maturity between four to six months. Net cash provided by financing activities during the year ended December 31, 2007 was A\$32,667,220 resulting from the renounceable rights offer which raised A\$32,518,792 and A\$148,428 raised by way of employees exercising their options.

As at December 31, 2009, we had cash and cash equivalents of A\$31,291,011 as compared to A\$28,334,864 as of December 31, 2008. The increase in cash and cash equivalents balance is predominantly as a result of the receipt of the milestone payment of A\$17,722,641 which was triggered on regulatory clearance of the blood glucose product.

In October 2007, we entered into a Master Services and Supply Agreement with LifeScan. The Master Services and Supply Agreement was amended and restated in May 2009. In February 2009, we received A\$3,087,849 in connection with the provision by us to LifeScan of certain manufacturing support services. In December 2009, we received a milestone payment of A\$17,722,641 which was triggered on regulatory clearance to sell the blood glucose product. The receipt and timing of any further revenue under the Master Services and Supply Agreement, which was amended and restated on May 15, 2009, is uncertain and is largely dependent on the volume of blood glucose strips manufactured by us and LifeScan and ultimately sold by LifeScan and the level of contract research work awarded to us by LifeScan.

Choice and timing of market entry(ies) for blood glucose products covered by the Master Services and Supply Agreement are at LifeScan's discretion. If at any time LifeScan indicates that it will not proceed with the rollout of the blood glucose test covered by the Master Services and Supply Agreement, or if the product does not obtain regulatory approval in any other jurisdictions, we will use the installed manufacturing equipment for the products we are developing for other biomarkers, subject to us having entered into collaborative arrangements or strategic alliances with respect to the relevant products. To reach that point, development efforts will need to continue to be successful. Our strategy is to enter into collaborative arrangements or strategic alliances with life sciences companies or other industry participants to complete the development and commercialization of our products. 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 when our efforts might be successful.

The total cost of the projects which we are undertaking is subject to a range of factors. As a result, we consider that at this stage of our development we are unable to provide investors with reliable details in relation

to the potential cost of our project to us. We believe that with our cash, cash equivalents and the interest we earn on these balances, the Company will be able to perform under the Master Services and Supply Agreement and to progress the Company's other development programs. In the event we are unable to generate revenue from the manufacturing and supply of the blood glucose test, we will need to revise our business plans. Notwithstanding this, by actively managing our cash flows, controlling costs and revising our development plans as necessary we believe we have sufficient cash reserves to continue as a going concern through the next 12 months. In order to achieve our objectives, we may require additional funding and/or to revise our business plans. The amount and timing of these future funding requirements, if any, is uncertain. To meet these financing requirements, we may raise funds through public or private equity offerings, debt financings, and through other means, including collaborations and license agreements or other means determined by the Directors at that time.

We note our forecasted ability to maintain our financial resources to support our operations for this period is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue one or more of our planned research, development and manufacturing activities.

Operating Capital and Capital Expenditure Requirement

The sale of additional equity securities, if undertaken, may result in dilution to our shareholders. If we raise additional funds in the future through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research, development and manufacturing activities, which could materially harm our business.

As a result of the numerous risks and uncertainties associated with our business strategy, we are unable to estimate the exact amounts of our capital and working capital requirements. We estimate our total capital expenditures in 2010 to be in the range of A\$3,000,000 to A\$4,000,000 for the purchase of equipment to support our activities under the Master Services and Supply Agreement, capacity expansion, for ongoing development of our existing products, and for other ongoing research and development activities. Our future funding requirements will depend on many factors, including, but not limited to:

- our business and product development strategies;
- expenses we incur in manufacturing and developing products and the services and development programs we undertake from LifeScan;
- changes to our operations to enable us to perform services required under the Master Services and Supply Agreement;
- the sales of blood glucose test strips by LifeScan and the quantities of blood glucose test strips to be manufactured by us for LifeScan;
- the timing and amount of receipts of revenue from LifeScan under the Master Services and Supply Agreement;
- costs and timing of regulatory approvals and market launches of the blood glucose test;
- the costs of undertaking and success of our research and development efforts;
- any need to further scale up of our manufacturing operations to meet demand for blood glucose strips under the Master Services and Supply Agreement, or for our point-of-care tests, including additional costs related to the fit out of our manufacturing facility in Melbourne, Australia and the acquisition of additional manufacturing equipment;
- the rate of progress and cost of our product development activities;
- the timing and success of any corporate collaborations or strategic alliances with respect to our tests in development, including revenues expected from such collaborations;

- the timing and amount of revenue generated by sales of our point-of-care tests;
- costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish; and
- the acquisition of businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Off-Balance Sheet Arrangement

As of December 31, 2009, the future minimum lease payments under non-cancelable operating leases (with initial or remaining lease terms in excess of one year) are:

	<u>A\$</u>
Less than 1 year	519,598
1 — 3 years	1,093,608
3 — 5 years	714,243
More than 5 years	<u>—</u>
Total minimum lease payments	<u><u>2,327,449</u></u>

The above relates to our operating lease obligations in relation to the lease of our premises.

Contractual Obligations

Our future contractual obligations primarily for future rental payment obligations on the current office and manufacturing space, including financing costs, at December 31, 2009 were as follows:

	<u>Total</u>	<u>Payments Due by Period</u>			
		<u>Less than 1 Year</u>	<u>1-3 Years</u>	<u>3-5 Years</u>	<u>More than 5 Years</u>
	A\$	A\$	A\$	A\$	A\$
Long-Term Debt Obligations	—	—	—	—	—
Asset Retirement Obligations(1) . . .	1,842,547	—	—	1,842,547	—
Operating Lease Obligations(2)	2,327,449	519,598	1,093,608	714,243	—
Purchase Obligations(3)	1,000,000	1,000,000	—	—	—
Other Long-Term Liabilities on Balance Sheet under GAAP(4) . . .	<u>262,436</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>262,436</u>
Total	<u><u>5,432,432</u></u>	<u><u>1,519,598</u></u>	<u><u>1,093,608</u></u>	<u><u>2,556,790</u></u>	<u><u>262,436</u></u>

(1) Represents legal obligations associated with the retirement and removal of long-lived assets.

(2) Our operating lease obligations relate to the lease of our premises and certain office equipment.

(3) Represents commitments for plant and equipment

(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 such as those specified under the Master Services and Supply Agreement including contract research work. We operate predominantly in one geographical area, being Australia.

Recent Accounting Pronouncements

In March 2008, the Financial Accounting Standards Board (“FASB”) issued SFAS No. 161, “Disclosures about Derivative Instruments and Hedging Activities”. The new standard is intended to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity’s financial position, financial performance, and cash flows. The Company adopted ASC 815 — Derivative and Hedging (formerly SFAS No. 161) effective January 1, 2009 which has not had a material impact on the Company’s consolidated financial statements.

In January, 2009, the company adopted ASC 808 — Collaborative Arrangements (formerly EITF Issue 07-01: “Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property”). This issue addresses the income statement classification of payments made between parties in a collaborative arrangement. ASC 808 has not had a material impact on the Company’s consolidated financial statements.

On July 1, 2009, the FASB issued SFAS No. 168, “The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles”, also known as FASB Accounting Standards Codification (“ASC”) 105, “Generally Accepted Accounting Principles” (“ASC 105”) (the Codification”). ASC 105 establishes the exclusive authoritative reference for U.S. GAAP for use in financial statements, except for SEC rules and interpretive releases, which are also authoritative GAAP for SEC registrants. The Codification will supersede all existing non-SEC accounting and reporting standards. For convenience, we have provided references to the Codification throughout this report in addition to the current GAAP source reference.

In April 2009, the FASB issued ASC 825 — Financial Instruments (formerly Staff Position No. FAS 107-1 and APB 28-1, “Interim Disclosures about Fair Value of Financial Instruments”) (“ASC 825”). ASC 825 amends FASB Statement No. 107, “Disclosures about Fair Value of Financial Instruments” to require disclosures about fair value of financial instruments in interim reporting periods. These disclosures were previously only required in annual financial statements. The adoption of ASC 825 did not have a material impact on our consolidated financial statements as this only requires additional disclosures.

In May 2009, the FASB issued ASC 855 — Subsequent Events (formerly SFAS No. 165 — Subsequent Events), which is effective for interim and annual periods ending after June 15, 2009 (“ASC 855”). ASC 855 establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. ASC 855 did not have a material impact on our consolidated financial statements.

In October 2009, the FASB issued Accounting Standards Update No. 2009-13, “Multiple-Deliverable Revenue Arrangements” (“ASU No. 2009-13”). ASU No. 2009-13 amends guidance included within ASC Topic 605-25 to require an entity to use an estimated selling price when vendor specific objective evidence or acceptable third party evidence does not exist for any products or services included in a multiple element arrangement. The arrangement consideration should be allocated among the products and services based upon their relative selling prices, thus eliminating the use of the residual method of allocation. ASU No. 2009-13 also requires expanded qualitative and quantitative disclosures regarding significant judgments made and changes in applying this guidance. ASU No. 2009-13 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 ASU No. 2009-13 in fiscal 2009.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Foreign Currency Market Risk

We transact business in various foreign currencies, including U.S. dollars and Euros. We have established a foreign currency hedging program using forward contracts to hedge the net projected exposure for each currency and the anticipated sales and purchases in U.S. dollars and Euros. The goal of this hedging program is to economically guarantee or lock-in the exchange rates on our foreign exchange exposures. The Company

does not hold or issue derivative financial instruments for trading purposes. However, derivatives that do not qualify for hedge accounting are accounted for as trading instruments.

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

	<u>2009 (*)</u>	<u>Fair Value</u>
<i>Anticipated Transactions and Related Derivatives</i>		
AUD Functional Currency:		
Forward exchange agreements (Sell AUD/Buy Euros)		
Contract amount	A\$811,303	A\$763,891
Average contractual exchange rate	0.5865	

* Expected maturity or transaction date

As at balance date, there were no anticipated transactions and related derivatives which extended beyond the 2010 financial year.

Interest Rate Risk

Our exposure to interest income sensitivity, which is affected by changes in the general level of Australian interest rates, particularly 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 and will fall in value in the event market interest rates increase. 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.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements we are required to include in this Item 8 are included in this report beginning on page F-1.

Supplementary Financial Information

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

	Year Ended December 31, 2009			
	Quarter Ended March 31	Quarter Ended June 30	Quarter Ended September 30	Quarter Ended 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

	Year Ended December 31, 2008			
	Quarter Ended March 31	Quarter Ended June 30	Quarter Ended September 30	Quarter Ended December 31
	A\$	A\$	A\$	A\$
Revenue				
Revenue from products	\$ —	\$ —	\$ —	\$ —
Revenue from services	—	1,240,801	1,880,953	—
Research and development income	279,298	274,213	259,740	356,939
Total revenue	279,298	1,515,014	2,140,693	356,939
Operating costs & expenses				
Cost of goods sold	—	—	—	—
Cost of services	—	1,240,801	1,880,953	—
Research and development (1 and 2)	1,940,629	2,065,317	1,234,887	6,344,425
General and administrative(3)	1,389,013	1,432,689	1,303,981	1,384,444
Total operating costs & expenses	3,329,642	4,738,807	4,419,821	7,728,869
Loss from operations	(3,050,344)	(3,223,793)	(2,279,128)	(7,371,930)
Other income/(expense)				
Interest income	773,957	702,517	634,275	431,311
Interest expense	—	(9,489)	—	—
Fee income	1,131,222	—	—	—
Other	(16,228)	(67,433)	314,405	34,566
Total other income/(expense)	1,888,951	625,595	948,680	465,877
Net loss before tax	(1,161,393)	(2,598,198)	(1,330,448)	(6,906,053)
Income tax benefit/(expense)	3,054	(2,848)	—	—
Net loss	<u>\$ (1,158,339)</u>	<u>\$ (2,601,046)</u>	<u>\$ (1,330,448)</u>	<u>\$ (6,906,053)</u>
Basic and diluted net loss per share	\$ (0.01)	\$ (0.02)	\$ (0.01)	\$ (0.04)
Average weighted number of shares used to compute per share data	156,958,812	156,969,888	156,976,936	156,976,936

Notes:

1. Net of research grant income in these amounts \$ 240,751 \$ 59,862 \$ — \$ —
2. Includes non-cash compensation expense (research and development) \$ 77,844 \$ 253,212 \$ 152,495 \$ 177,946
3. Includes non-cash compensation expense (general and administrative) \$ 95,764 \$ 55,910 \$ 67,340 \$ 80,597

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

None.

ITEM 9A(T). CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures. With the participation of our management, including the Company's principal executive officer and principal financial officer, our management has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")) as of the end of the period covered by this report. Based upon that evaluation, the Company's principal executive officer and principal financial officer have concluded that:

- information required to be disclosed by the Company in this report and other reports that the Company files or submits under the Exchange Act would be accumulated and communicated to the Company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure;
- information required to be disclosed by the Company in this report and other reports that the Company files or submits under the Exchange Act would be recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms; and
- the Company's disclosure controls and procedures are effective as of the end of the period covered by this report to ensure that material information relating to the Company and its consolidated subsidiaries is made known to them, particularly during the period in which the periodic reports of the Company, including this report, are being prepared.

Changes in Internal Control Over Financial Reporting. During the most recent quarter ended December 31, 2009, there has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) that has materially affected, or is reasonably likely to materially affect, our 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 authorization 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 Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2009. 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 Chief Executive Officer and Chief Financial Officer, concluded that, as of December 31, 2009, our internal control over financial reporting was effective.

This annual report on Form 10-K does not include an attestation report of our registered public accounting firm regarding internal controls over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the SEC that permit us to provide only management's report in this annual report on Form 10-K.

Mark Morrisson

Chief Executive Officer and Executive Director

Salesh Balak

Chief Financial Officer

March 16, 2010

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 2010 (the "2010 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 2010 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 Chief Executive Officer and Chief Financial Officer. This code of ethics may be accessed and reviewed through our website at www.universalsbiosensors.com. We intend to satisfy any disclosure requirement under item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of the Code of Ethics for our Chief Executive Officer and Chief Financial Officer, by posting such information on our website at www.universalsbiosensors.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 2010 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 2010 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 2010 Proxy Statement under the captions “Management of the Company — Compensation of Directors”, “Executive Compensation” and “Management of the Company — Board Committees — Compensation Committee Interlocks and Insider Participation.”

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

The information regarding the security ownership of certain beneficial owners and management is incorporated by reference to the 2010 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 2010 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 2010 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 2010 Proxy Statement under the caption “Independent Public Accountants — Audit Fees.”

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENTS AND SCHEDULES.

(a)(1) Financial Statements

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(a)(2) Financial Statement Schedules — All financial statement schedules are omitted because they are not applicable, not required under the instructions or all the information required is set forth in the financial statements or notes thereto.

(a)(3) and (b) Exhibits — See accompanying Index to Exhibits.

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/ Mark Morrisson

Mark Morrisson
Chief Executive Officer and Executive Director

Date: March 16, 2010

POWER OF ATTORNEY

Each person whose signature appears below hereby constitutes and appoints Mark Morrisson 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/ Mark Morrisson</u> Mark Morrisson	Chief Executive Officer and Executive Director (Principal Executive Officer)	March 16, 2010
<u>/s/ Salesh Balak</u> Salesh Balak	Chief Financial Officer (Principal Financial Officer)	March 16, 2010
<u>/s/ Andrew Denver</u> Andrew Denver	Director	March 16, 2010
<u>/s/ Denis Hanley</u> Denis Hanley	Director	March 16, 2010
<u>/s/ Andrew Jane</u> Andrew Jane	Director	March 16, 2010
<u>/s/ Elizabeth Wilson</u> Elizabeth Wilson	Director	March 16, 2010
<u>/s/ Colin Adam</u> Colin Adam	Director	March 16, 2010
<u>/s/ Marshall Heinberg</u> Marshall Heinberg	Director	March 16, 2010

Consolidated Financial Statements and Schedules

UNIVERSAL BIOSENSORS, INC. (A Development Stage Enterprise)

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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 statement of operations, changes in stockholder's equity and comprehensive income and cash flows present fairly, in all material respects, the financial position of Universal Biosensors, Inc. and its subsidiaries (a development stage enterprise) at December 31, 2009 and December 31, 2008, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2009 and cumulatively, for the period from September 14, 2001 (date of inception) to December 31, 2009 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes 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. We believe that our audits provide a reasonable basis for our opinion.

PricewaterhouseCoopers

March 16 , 2010
Sydney

UNIVERSAL BIOSENSORS, INC.
(A Development Stage Enterprise)
CONSOLIDATED BALANCE SHEETS

	<u>December 31,</u> <u>2009</u>	<u>December 31,</u> <u>2008</u>
	A\$	A\$
ASSETS		
Current assets:		
Cash and cash equivalents	31,291,011	28,334,864
Inventories, net.	305,124	—
Accrued income	118,305	118,305
Accounts receivables	415,397	31,657
Prepayments	2,289,149	3,730,246
Other current assets	<u>364,339</u>	<u>535,000</u>
Total current assets	34,783,325	32,750,072
Property, plant and equipment	27,898,099	23,522,706
Less accumulated depreciation	<u>(6,597,956)</u>	<u>(3,767,457)</u>
Property, plant and equipment — net.	<u>21,300,143</u>	<u>19,755,249</u>
Total assets	<u><u>56,083,468</u></u>	<u><u>52,505,321</u></u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	434,207	630,977
Accrued expenses	1,201,893	838,697
Financial instruments	47,412	—
Deferred income	559,931	—
Employee entitlements provision.	<u>421,040</u>	<u>435,387</u>
Total current liabilities	2,664,483	1,905,061
Non-current liabilities:		
Asset retirement obligations	1,842,547	1,699,133
Employee entitlements provision.	<u>262,436</u>	<u>197,897</u>
Total non-current liabilities	<u>2,104,983</u>	<u>1,897,030</u>
Total liabilities	<u><u>4,769,466</u></u>	<u><u>3,802,091</u></u>
Stockholders' equity:		
Preferred stock, \$0.01 par value. Authorized 1,000,000 shares; issued and outstanding nil in 2009 (2008: nil) Common stock, \$0.0001 par value. Authorized 300,000,000 shares; issued and outstanding 157,155,933 shares in 2009 (2008: 156,976,936)	15,716	15,698
Additional paid-in capital	74,566,698	73,338,995
Accumulated deficit	(24,353,151)	(12,357,265)
Current year earnings/(loss)	1,430,463	(11,995,886)
Accumulated other comprehensive income	<u>(345,724)</u>	<u>(298,312)</u>
Total stockholders' equity	<u>51,314,002</u>	<u>48,703,230</u>
Total liabilities and stockholders' equity	<u><u>56,083,468</u></u>	<u><u>52,505,321</u></u>

See accompanying notes to the financial statements

UNIVERSAL BIOSENSORS, INC.
(A Development Stage Enterprise)

CONSOLIDATED STATEMENTS OF OPERATIONS

	Period from Inception (September 14, 2001) to December 31, 2009	Years Ended December 31,		
		2009	2008	2007
		A\$	A\$	A\$
Revenue				
Revenue from products	\$ 132,733	\$ 132,733	\$ —	\$ —
Revenue from services	5,971,825	2,850,071	3,121,754	—
Research and development income	14,415,089	1,337,125	1,170,190	1,192,015
Milestone payment	17,722,641	17,722,641	—	—
Total revenue	38,242,288	22,042,570	4,291,944	1,192,015
Operating costs & expenses				
Cost of goods sold(1)	458,162	458,162	—	—
Cost of services	3,290,995	169,241	3,121,754	—
Research and development (2 and 3)	43,814,091	14,898,072	11,585,258	7,157,216
General and administrative(4)	19,998,333	5,635,569	5,510,127	4,226,757
Total operating costs & expenses	67,561,581	21,161,044	20,217,139	11,383,973
Profit/(loss) from operations	(29,319,293)	881,526	(15,925,195)	(10,191,958)
Other income/(expense)				
Interest income	5,408,492	809,459	2,542,060	1,440,102
Interest expense	(19,125)	(9,636)	(9,489)	—
Fee income	1,131,222	—	1,131,222	—
Other	(106,190)	(250,886)	265,310	(210,382)
Total other income/(expense)	6,414,399	548,937	3,929,103	1,229,720
Net profit/(loss) before tax	(22,904,894)	1,430,463	(11,996,092)	(8,962,238)
Income tax benefit/(expense)	(17,794)	—	206	145,000
Net profit/(loss)	<u>\$ (22,922,688)</u>	<u>\$ 1,430,463</u>	<u>\$ (11,995,886)</u>	<u>\$ (8,817,238)</u>
Basic net profit/(loss) per share	\$ (0.28)	\$ 0.01	\$ (0.08)	\$ (0.07)
Average weighted number of shares used as denominator in calculating basic net profit/(loss) per share	80,967,756	157,013,578	156,970,679	129,637,286
Diluted net profit/(loss) per share	\$ (0.28)	\$ 0.01	\$ (0.08)	\$ (0.07)
Average weighted number of shares used as denominator in calculating diluted net profit/(loss) per share	80,967,756	161,354,802	156,970,679	129,637,286

Notes:

1 Includes non-cash compensation expense (cost of goods sold)	\$ 21,207	\$ 21,207	\$ —	\$ —
2 Net of research grant income in these amounts . .	\$ 2,366,063	\$ —	\$ 300,613	\$ 872,513
3 Includes non-cash compensation expense (research and development)	\$ 1,802,226	\$ 653,474	\$ 661,497	\$ 339,882
4 Includes non-cash compensation expense (general and administrative)	\$ 1,255,228	\$ 404,090	\$ 299,611	\$ 277,833

See accompanying notes to the financial statements.

UNIVERSAL BIOSENSORS, INC.
(A Development Stage Enterprise)

**CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
AND COMPREHENSIVE INCOME**

	Preference Shares		Ordinary shares		Additional Paid-in Capital	Accumulated Deficit	Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount A\$	Shares	Amount A\$				
Balance at inception (September 14, 2001)	—	—	—	—	—	—	—	—
Issuance of ordinary shares at \$0.0001 per share for cash on incorporation of the Company in September 2001	—	—	29,179,253	2,918	(2,685)	—	—	233
Balances at December 31, 2001	—	—	29,179,253	2,918	(2,685)	—	—	233
Issuance of ordinary shares at A\$0.05 per share for cash between January to March 2002	—	—	10,729,264	1,073	570,168	—	—	571,241
Issuance of ordinary shares at A \$0.48 per share for cash in June 2002	—	—	3,624,752	362	1,752,794	—	—	1,753,156
Comprehensive Income								
Net profit for period from inception to December 31, 2002	—	—	—	—	—	130,134	—	130,134
Foreign currency translation reserve, net of tax	—	—	—	—	—	—	(48,035)	(48,035)
Total Comprehensive Income	—	—	—	—	—	—	—	82,099
Balances at December 31, 2002	—	—	43,533,269	4,353	2,320,277	130,134	(48,035)	2,406,729
Issuance of preference shares at A\$0.40 per share for cash in December 2003	10,210,926	4,076,641	—	—	—	—	—	4,076,641
Comprehensive Income								
Net loss for period from inception to December 31, 2003	—	—	—	—	—	(416,871)	—	(416,871)
Foreign currency translation reserve, net of tax	—	—	—	—	—	—	(188,877)	(188,877)
Total Comprehensive Income	—	—	—	—	—	—	—	(605,748)
Balances at December 31, 2003	10,210,926	4,076,641	43,533,269	4,353	2,320,277	(286,737)	(236,912)	5,877,622
Comprehensive Income								
Net loss	—	—	—	—	—	(168,669)	—	(168,669)
Foreign currency translation reserve, net of tax	—	—	—	—	—	—	(153,615)	(153,615)
Total Comprehensive Income	—	—	—	—	—	—	—	(322,284)
Balances at December 31, 2004	10,210,926	4,076,641	43,533,269	4,353	2,320,277	(455,406)	(390,527)	5,555,338
Comprehensive Income								
Net loss	—	—	—	—	—	(128,960)	—	(128,960)
Foreign currency translation reserve, net of tax	—	—	—	—	—	—	226,571	226,571
Total Comprehensive Income	—	—	—	—	—	—	—	97,611
Exercise of stock options issued to employees	—	—	79,745	8	30,562	—	—	30,570
Balances at December 31, 2005	10,210,926	4,076,641	43,613,014	4,361	2,350,839	(584,366)	(163,956)	5,683,519
Issuance of preference shares at A\$0.45 per share for cash	30,176,036	12,624,795	—	—	—	—	—	12,624,795
Conversion of preference shares to ordinary shares	(40,386,962)	(16,701,436)	40,386,962	4,039	16,697,397	—	—	—
Issuance of ordinary shares at A\$0.50 per share in private placement to American institutional and sophisticated investors in December 2006, net of issuance costs	—	—	8,000,000	800	3,999,200	—	—	4,000,000
Issuance of ordinary shares at A\$0.50 per share in a public offering in Australia and a concurrent placement in the US to institutional and sophisticated investors in December 2006, net of issuance costs	—	—	36,000,000	3,600	15,638,963	—	—	15,642,563
Comprehensive Income								
Net loss	—	—	—	—	—	(2,955,661)	—	(2,955,661)
Foreign currency translation reserve, net of tax	—	—	—	—	—	—	(134,356)	(134,356)
Total Comprehensive Income	—	—	—	—	—	—	—	(3,090,017)
Stock option expense	—	—	—	—	421,067	—	—	421,067
Balances at December 31, 2006	—	—	127,999,976	12,800	39,107,466	(3,540,027)	(298,312)	35,281,927
Issuance of ordinary shares at A\$1.20 per share, net of issuance costs	—	—	28,538,362	2,854	32,515,938	—	—	32,518,792
Comprehensive Income								
Net loss	—	—	—	—	—	(8,817,238)	—	(8,817,238)
Foreign currency translation reserve, net of tax	—	—	—	—	—	—	—	—
Total Comprehensive Income	—	—	—	—	—	—	—	(8,817,238)
Exercise of stock options issued to employees	—	—	420,474	42	148,386	—	—	148,428
Stock option expense	—	—	—	—	617,715	—	—	617,715
Balances at December 31, 2007	—	—	156,958,812	15,696	72,389,505	(12,357,265)	(298,312)	59,749,624
Transaction costs on shares issued in 2007	—	—	—	—	(16,663)	—	—	(16,663)
Comprehensive Income								
Net loss	—	—	—	—	—	(11,995,886)	—	(11,995,886)
Foreign currency translation reserve, net of tax	—	—	—	—	—	—	—	—
Total Comprehensive Income	—	—	—	—	—	—	—	(11,995,886)
Exercise of stock options issued to employees	—	—	18,124	2	5,045	—	—	5,047
Stock option expense	—	—	—	—	—	—	—	—
Balances at December 31, 2008	—	—	156,976,936	15,698	72,377,887	(24,353,151)	(298,312)	47,742,122
Comprehensive Income								
Net profit	—	—	—	—	—	1,430,463	—	1,430,463
Loss on derivatives and hedges, net of tax	—	—	—	—	—	—	(47,412)	(47,412)
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	73,605,590	(22,922,688)	(345,724)	50,352,894

Note

Note Common stock has a par value of US\$0.0001. — All share and per share amounts from inception to December 31, 2006 presented have been retroactively adjusted to give effect to a stock split undertaken in 2006. The par value of common stock was altered after the share split

See accompanying notes to the financial statements.

UNIVERSAL BIOSENSORS, INC.
(A Development Stage Enterprise)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Period from Inception to December 31, 2009	Years Ended December 31,		
	<u>2009</u>	<u>2009</u>	<u>2008</u>	<u>2007</u>
	A\$	A\$	A\$	A\$
Cash flows from operating activities provided by/(used in):				
Net profit/(loss)	(22,922,688)	1,430,463	(11,995,886)	(8,817,238)
Adjustments to reconcile net profit/(loss) to net cash provided by/(used in) operating activities:				
Net exchange difference	1,102,572	—	—	983,991
Depreciation and impairment of plant & equipment	7,132,568	2,851,285	2,266,847	708,699
Share based payments expense	3,078,661	1,078,771	961,108	617,715
Loss on fixed assets disposal	211,343	60,658	34,207	116,478
Change in assets and liabilities:				
Inventory	(305,124)	(305,124)	486,633	(486,633)
Accounts receivables	(1,053,698)	(114,713)	439,691	(931,864)
Prepaid expenses and other current assets	333,059	141,331	191,728	—
Accrued income	(108,855)	—	(38,494)	31,786
Income tax payable	—	—	(18,000)	(145,000)
Deferred revenue	290,904	290,904	—	—
Employee entitlements	683,476	50,192	264,286	5,835
Accounts payable and accrued expenses	<u>1,875,921</u>	<u>383,389</u>	<u>267,494</u>	<u>146,957</u>
Net cash provided by/(used in) operating activities	<u>(9,681,861)</u>	<u>5,867,156</u>	<u>(7,140,386)</u>	<u>(7,769,274)</u>
Cash flows from investing activities:				
Proceeds/(purchases) from sale of investment securities	—	—	3,123,501	(3,123,501)
Instalment payments to acquire plant and equipment	(5,762,043)	(2,145,808)	(3,616,235)	—
Purchases of property, plant and equipment	<u>(21,588,097)</u>	<u>(844,199)</u>	<u>(5,978,685)</u>	<u>(9,058,265)</u>
Net cash used in investing activities	<u>(27,350,140)</u>	<u>(2,990,007)</u>	<u>(6,471,419)</u>	<u>(12,181,766)</u>
Cash flows from financing activities:				
Gross proceeds from share issue	73,517,472	—	—	34,246,043
Transaction costs on share issue	(4,099,870)	—	(16,663)	(1,727,251)
Proceeds from borrowings	479,673	479,673	—	—
Repayment of borrowings	(479,673)	(479,673)	—	—
Proceeds from stock options exercised	<u>263,043</u>	<u>78,998</u>	<u>5,047</u>	<u>148,428</u>
Net cash provided by/(used in) financing activities	<u>69,680,645</u>	<u>78,998</u>	<u>(11,616)</u>	<u>32,667,220</u>
Net increase/(decrease) in cash and cash equivalents	32,648,644	2,956,147	(13,623,421)	12,716,180
Cash and cash equivalent at beginning of period	—	28,334,864	41,958,285	30,184,756
Effect of exchange rate fluctuations on the balances of cash held in foreign currencies	<u>(1,357,633)</u>	—	—	<u>(942,651)</u>
Cash and cash equivalents at end of period	<u>31,291,011</u>	<u>31,291,011</u>	<u>28,334,864</u>	<u>41,958,285</u>

See accompanying notes to the financial statements

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(1) Organization of the Company

Universal Biosensors, Inc. (the “Company”) was incorporated on September 14, 2001 in the United States, and its wholly owned subsidiary and operating vehicle, Universal Biosensors Pty Ltd, was incorporated in Australia on September 21, 2001. Collectively, the Company and its wholly owned subsidiary Universal Biosensors Pty Ltd are referred to as “Universal Biosensors” or the “Group”. The Company’s shares of common stock in the form of CHESS Depository Interests (“CDIs”) were quoted on the Australian Securities Exchange (“ASX”) on December 13, 2006 following the initial public offering in Australia of the Company’s shares of common stock. Our securities are not currently traded on any other public market.

The Company is a specialist medical diagnostics company focused on the research and development, manufacture and commercialization of a range of in vitro diagnostic tests 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 (“point-of-care”) to provide accurate and quick results to enable new treatment or an existing treatment to be immediately reviewed.

Universal Biosensors has rights to an extensive patent portfolio comprising certain patent applications owned by its wholly owned Australian subsidiary, Universal Biosensors Pty Ltd, and a large number of patents and patent applications licensed to us by LifeScan, Inc. (“LifeScan”), an affiliate of Johnson & Johnson Corporation.

Universal Biosensors has developed a blood glucose test (used in the management of diabetes) with LifeScan which was launched by LifeScan in The Netherlands in January 2010. Subject to mutually agreed terms, we intend to develop other tests in the field of diabetes and blood glucose management generally, for LifeScan. On October 29, 2007 Universal Biosensors entered into a Master Services and Supply Agreement 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 an original version of the initial blood glucose test strips we developed for LifeScan (“Master Services and Supply Agreement”). On December 11, 2008, Universal Biosensors entered into an additional services addendum to provide manufacturing process support to assist LifeScan to establish LifeScan’s own manufacturing line for blood glucose test strips at a location of its choosing. On December 11, 2008, the Master Services and Supply Agreement was amended to reflect certain definitional matters in the document. On May 15, 2009, the agreement was amended and restated to incorporate the amendments made in December 2008 and to update the commercial terms of the agreement to reflect a change from the original version of the initial blood glucose test strip to an enhanced version of the initial blood glucose test strip. The Master Services and Supply Agreement is structured as an umbrella agreement which enables LifeScan and the Company to enter into a series of additional arrangements for the supply by the Company of additional services and products in the field of blood glucose monitoring. The Company commenced manufacture of the initial blood glucose test strips in its facility in Corporate Avenue, Rowville, Melbourne, in December 2009.

Additionally, the Group will continue to provide research and development services to LifeScan in the area of diabetes management to extend and develop the glucose sensor technology owned by LifeScan under a development and research agreement (“Development and Research Agreement”).

The Company uses its technology base to develop other electrochemical-cell based tests. The Company does not currently intend to establish its own sales and marketing force to commercialize any of the non-blood glucose products which it develops. Rather, the Company’s efforts are focused on establishing collaborative partnerships for the tests derived from the platform. The Company is developing a C-reactive protein test on

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its dry immunoassay platform to assist in the diagnosis and management of inflammatory conditions. The Company is also developing a D-dimer test for 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). The Company has also 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. The Company has successfully taken the prothrombin time test to a point where the Company considers it has been significantly technically de-risked. The Company does not currently propose to complete the remaining development steps for this test until the path to commercialization for this product is assured and the partnering efforts for the test have been successful.

All business operations and research and development activities are undertaken in Melbourne, Australia by the Company's wholly owned subsidiary, Universal Biosensors Pty Ltd, under the Master Services and Supply Agreement and a research and development sub-contract and sub-license agreement between Universal Biosensors Pty Ltd and the Company.

The Group is considered a development stage enterprise as it is not generating significant revenue or positive cash flows from its commercial manufacturing operations.

(2) 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. The Company made a net profit of A\$1,430,463 for the year ended December 31, 2009. The Company recognized a net loss of A\$11,995,886 and A\$8,817,238 in the years ended December 31, 2008 and 2007, respectively. The Company's accumulated losses from inception to December 31, 2009 are A\$22,922,688. The Company's ability to generate future profits is dependant on its ability to generate sufficient revenues under the Master Services and Supply Agreement and/ or from the sale of any of its own products.

(3) 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. 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.

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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 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 deposits of cash and cash equivalents.

Product candidates developed by the Company may require approvals or clearances from the U.S. Food and Drug Administration or other international regulatory agencies prior to commercialized sales. There can be no assurance that the Company's product candidates will receive any of the required approvals or clearances. If the Company was denied approval or clearance of such approval was delayed, it may have a material adverse impact on the Company.

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

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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 market value. Inventories are principally determined under the average cost method.

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 a grant agreement to support the establishment of a medical diagnostic manufacturing facility in Victoria through 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.

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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 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, 2009, 2008, 2007 and for period from inception to December 31, 2009 are as follows:

	Period from Inception to December 31, 2009	Years Ended December 31,		
		2009	2008	2007
		A\$	A\$	A\$
Research and development expenses	46,180,154	14,898,072	11,885,871	8,029,729
Research grants received recognized against related research and development expenses	<u>(2,366,063)</u>	—	<u>(300,613)</u>	<u>(872,513)</u>
Research and development expenses as reported	<u>43,814,091</u>	<u>14,898,072</u>	<u>11,585,258</u>	<u>7,157,216</u>

A significant portion of our research and development expenses relate to activities undertaken to achieve the deliverable included in milestone payment.

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

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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.

The Company adopted ASC 740 — Income Taxes (formerly FASB Interpretation FIN No. 48 - Accounting for Uncertainty in Income Taxes) effective January 1, 2007 which has not had a material impact on the Company's consolidated financial statements.

We are subject to income taxes in the United States and Australia. U.S. federal income tax returns up to the 2008 financial year have been lodged. Internationally, consolidated income tax returns up to the 2008 financial year have been lodged.

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

Our overall ARO changed as follows:

	Years Ended December 31,	
	2009	2008
	A\$	A\$
<i>Movement in ARO</i>		
Opening balance at January 1	1,699,133	1,566,892
New obligations	—	—
Accretion expense	143,414	132,241
Ending balance at December 31	1,842,547	1,699,133

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 by using available market information and appropriate valuation methodologies.

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

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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. 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. On October 29, 2007 Universal Biosensors entered into a Master Services and Supply Agreement 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 an original version of the initial blood glucose test strips we developed for LifeScan. On May 15, 2009, the agreement was amended and restated to incorporate certain amendments made in December 2008 and to update the commercial terms of the agreement to reflect a change to an enhanced version of the blood glucose test strip. The Master Services and Supply Agreement is structured as an umbrella agreement which enables LifeScan and us to enter into a series of additional arrangements for the supply by us of additional services and products in the field of blood glucose monitoring.

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 ASU No. 2009-13, 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 ASU No. 2009-13 in fiscal 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, there is no impact on previously filed financial statements during the year.

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The deliverables under the arrangement described above are as follows:

- *milestone payment.* The Company received a milestone payment of A\$17,722,641 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. As we produced less than the specified quantity of test strips per quarter, we are considered to be in the “interim costing period”. In the interim costing period, the Company is establishing its commercial scale manufacturing and therefore is not expected to generate any profit, but is expected to recover most of its glucose manufacturing costs. As volumes increase beyond the specified quantity of blood glucose test strips sold per quarter, the interim costing period will cease to apply and a different pricing methodology will apply, at which time we expect to be profitable in the sale of blood glucose test strips; 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 efforts to enhance the product.

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.

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. Milestone payment is considered to be a substantive payment and the entire amount has been recognized as revenue when the regulatory approval was received. The regulatory approval to market the initial blood glucose product was received on November 4, 2009. Revenue for contract manufacturing is recognised in accordance with generally accepted accounting principles as outlined in ASC 605-10-S99 (formerly Staff Accounting Bulletin No. 104 — Revenue Recognition), 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

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ongoing efforts to enhance the product is also recognised 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 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" per Statement of Financial Accounting Concepts No. 6, Elements of Financial Statements and SEC Regulation S-X Article 5-03.

We perform other services for LifeScan 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;
- 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 transaction with LifeScan satisfies the revenue recognition criteria outlined in ASC 605 (formerly Staff Accounting Bulletin 101/104). 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 been providing 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

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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 Development and Research Agreement provides details of the amount to be charged to LifeScan each year for the provision of research and development services. Income is recognized ratably over the period to which it relates and when the amount of the payment can be reliably measured and collectibility is reasonably assured. For fiscal 2009, LifeScan paid the Company A\$1,337,125 under the Development and Research Agreement. For fiscal 2010, the Development and Research Agreement sets out a range of values that the Company or Universal Biosensors Pty Ltd will be paid depending on the level of research and development services required by LifeScan. In subsequent years, the steering committee will recommend the level of funding consistent with LifeScan's requirements.

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 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

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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" per Statement of Financial Accounting Concepts No. 6, Elements of Financial Statements and SEC Regulation S-X Article 5-03.

Interest revenue

Interest revenue is recognized as it accrues, taking into account the effective yield on the financial asset.

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 related statements and corresponding notes for and prior to December 31, 2007 have been revised to reflect Australian Dollars as the reporting currency for comparison to the financial results for the years ended December 31, 2008 and 2009. 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.

The functional currency of the Company for financial years up to December 31, 2005 was determined by management to be USD. This was based on the facts that the denomination of a significant proportion of transactions and the major source of finance were in USD.

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In 2006, the Company expanded significantly its Australian based research activities. At this time, all of the Company's directors became residents in Australia. Currently, with the exception of one director, all the other directors are Australian residents. Most of the Company's expenditure on research and development is Australian dollar denominated. It also began planning for and successfully accomplished a capital raising in Australian dollars and listed on the Australian Stock Exchange. The majority of cash and other monetary assets now held by the Company are denominated in Australian dollars.

Due to these changes in circumstance, management are of the view that the functional currency of the Company changed in 2006 to Australian dollars. This change was effective from December 1, 2006. The difference in the foreign exchange movements recognized in 2006 as a result of the change in functional currency was A\$44,430.

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.

The Company has recorded foreign currency transaction gains/(losses) of (A\$250,886), A\$265,310, (A\$210,382) and (A\$105,152) for each of the years ended December 31, 2009, 2008 and 2007 and the period from inception to December 31, 2009, respectively.

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

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

On consolidation, exchange differences arising from the translation of any net investment in foreign entities are taken to the Foreign Currency Translation Reserve ("FCTR").

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.

Patent and License Costs

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

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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, 2009, 2008 and 2007 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

Prior to January 1, 2006, the Company applied ASC 718 — Compensation — Stock Compensation (formerly Accounting Principles Board (APB) Opinion No. 25 — Accounting for Stock Issued to Employees) and related interpretations, in accounting for its fixed-plan stock options. For periods prior to January 1, 2006, the Company complied with the disclosure only provisions of ASC 718 (formerly FASB Statement No. 123 — Accounting for Stock-Based Compensation, or SFAS 123). No stock-based employee compensation cost was reflected in net income, as all options granted under those plans had an exercise price equal to or greater than the market value of the underlying common stock on the date of grant (or within permitted discounted prices as it pertains to the Employee Option Plan). Results for periods before January 1, 2006 have not been restated to reflect, and do not include the impact of, ASC 718 (formerly FASB Statement No. 123(R) — Share Based Payment, or SFAS 123(R)).

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 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

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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. All periods presented in these financial statements have been retroactively adjusted to give effect to the stock split in December 2006 (note 11). 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 March 2008, the Financial Accounting Standards Board ("FASB") issued ASC 815 — Derivative and Hedging (formerly SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities"). The new standard is intended to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity's financial position, financial performance, and cash flows. The Company adopted ASC 815 effective January 1, 2009 which has not had a material impact on the Company's consolidated financial statements.

In January, 2009, the company adopted ASC 808 — Collaborative Arrangements (formerly EITF Issue 07-01: "Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property"). This issue addresses the income statement classification of payments made between parties in a collaborative arrangement. ASC 808 has not had a material impact on the Company's consolidated financial statements.

On July 1, 2009, the FASB issued ASC 105 (formerly SFAS No. 168, "The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles", also known as FASB Accounting Standards Codification ("ASC") 105, "Generally Accepted Accounting Principles" ("ASC 105") (the Codification)). ASC 105 establishes the exclusive authoritative reference for U.S. GAAP for use in financial statements, except for SEC rules and interpretive releases, which are also authoritative GAAP for SEC registrants. The Codification will supersede all existing non-SEC accounting and reporting standards. For convenience, we have provided references to the Codification throughout this report in addition to the current GAAP source reference.

In April 2009, the FASB issued ASC 825 — Financial Instruments (formerly Staff Position No. FAS 107-1 and APB 28-1, "Interim Disclosures about Fair Value of Financial Instruments"). ASC 825 amends FASB Statement No. 107, "Disclosures about Fair Value of Financial Instruments" to require disclosures about fair value of financial instruments in interim reporting periods. These disclosures were previously only required in

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annual financial statements. The adoption of ASC 825 did not have a material impact on our consolidated financial statements as this only requires additional disclosures.

In May 2009, the FASB issued ASC 855 — Subsequent Events (formerly SFAS No. 165 — Subsequent Events), which is effective for interim and annual periods ending after June 15, 2009. ASC 855 establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. ASC 855 did not have a material impact on our consolidated financial statements.

In October 2009, the FASB issued Accounting Standards Update No. 2009-13, “Multiple-Deliverable Revenue Arrangements” (“ASU No. 2009-13”). ASU No. 2009-13 amends guidance included within ASC Topic 605-25 to require an entity to use an estimated selling price when vendor specific objective evidence or acceptable third party evidence does not exist for any products or services included in a multiple element arrangement. The arrangement consideration should be allocated among the products and services based upon their relative selling prices, thus eliminating the use of the residual method of allocation. ASU No. 2009-13 also requires expanded qualitative and quantitative disclosures regarding significant judgments made and changes in applying this guidance. ASU No. 2009-13 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 ASU No. 2009-13 in fiscal 2009.

(4) 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, 2009 are:

	A\$
2010	519,598
2011	537,526
2012	556,082
2013	567,931
2014 and thereafter	146,312
Total minimum lease payments	2,327,449

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Rent expense was A\$533,749, A\$514,984, A\$482,805 and A\$2,352,303 for the fiscal years ended December 31, 2009, 2008 and 2007 and for the period from inception to December 31, 2009, respectively.

Government research grants

Universal Biosensors Pty Ltd received a research grant from the Commonwealth of Australia under the R&D 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 to expire on September 30, 2007. However, the term of the grant was extended to September 30, 2009. The Commonwealth of Australia 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. Research and development start grant advances of nil (2008: A\$262,119) were received during 2009 and income of nil (2008: A\$300,613, 2007: A\$872,513, and period from inception to December 31, 2009: A\$2,366,063) was recognized with A\$118,305 recorded as accrued income at December 31, 2009 (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 at December 31, 2009 was A\$130,000 (2008: A\$130,000, 2007: A\$150,000 and period from inception to December 31, 2009: A\$410,000). This grant has been recognized against the acquisition cost of the related plant and equipment.

Guarantees

There are cross guarantees given by Universal Biosensors, Inc. and Universal Biosensors Pty Ltd as described in note 17. 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.

(5) Income Taxes

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

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

	Period from Inception to December 31, 2009		Years Ended December 31,					
			2009		2008		2007	
	\$	%	\$	%	\$	%	\$	%
Profit/(loss) before income taxes	(22,904,894)		1,430,463		(11,996,092)		(8,962,238)	
Computed by applying income tax rate of home jurisdiction	(6,871,468)	30	429,139	30	(3,598,828)	30	(2,688,671)	30
Research & development incentive	(6,144,630)	27	(3,524,333)	(246)	(702,124)	6	(983,029)	11
Disallowed expenses/(income):								
Share based payment	923,598	(4)	323,631	22	288,332	(3)	185,315	(2)
Other	6,416	(0)	(226,924)	(16)	2,600	(0)	20,157	(0)
Change in valuation allowance	12,324,710	(54)	2,998,487	210	4,010,020	(33)	3,484,228	(39)
Adjustment in respect of current income tax of prior years	(220,832)	1	—	—	(206)	0	(163,000)	1
Income tax expense/(benefit)	<u>17,794</u>	<u>(0)</u>	<u>(0)</u>	<u>(0)</u>	<u>(206)</u>	<u>0</u>	<u>(145,000)</u>	<u>2</u>

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

	As of December 31,	
	2009	2008
Deferred tax assets:		
Operating loss carry forwards	10,903,873	9,320,465
Unamortized capital raising cost	352,651	650,355
Depreciation and amortization	(392,582)	62,699
Asset retirement obligations	43,024	109,228
Employee entitlements	205,043	189,985
Other accruals	<u>587,802</u>	<u>268,388</u>
Total deferred tax assets	11,699,811	10,601,120
Valuation allowance for deferred tax assets	<u>(11,699,811)</u>	<u>(10,601,120)</u>
Net deferred tax asset	<u>—</u>	<u>—</u>

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

At December 31, 2009 the Company has A\$36,346,242 (A\$31,068,217 at December 31, 2008) 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.

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(6) Employee Incentive Schemes

(a) Stock Option Plan

All share and option amounts from inception to December 31, 2006 have been retroactively adjusted to give effect to the share split described in note 11. In 2004, the Company adopted an employee option plan (“Plan”). Options may be granted pursuant to the Plan to any person considered by the board to be employed by the Group on a permanent basis (whether full time, part time or on a long term casual basis). Each option gives the holder the right to subscribe for one share of common stock. The total number of options that may be issued under the Plan is such maximum amount permitted by law and the Listing Rules of the ASX. The exercise price and any exercise conditions are determined by the board at the time of grant of the options. Any exercise conditions must be satisfied before the options vest and become capable of exercise. The options lapse on such date determined by the board at the time of grant or earlier in accordance with the Plan. Options granted to date have had a ten year term 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 2007, 2008 and 2009 were 1,608,000 and 1,553,000 and 4,164,200, 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-09	Jun-09	Jun-09	May-09	Feb-09	Aug-08	Mar-08	Oct-07	Sep-07	Mar-07
Exercise Price (A\$)	\$ 1.72	Nil	\$ 0.94	Nil	\$ 0.50	\$ 0.70	\$ 0.89	\$ 1.13	\$ 1.20	\$ 1.18
Share Price at Grant Date (A\$)	\$ 1.73	\$ 0.95	\$ 0.95	\$ 1.18	\$ 0.43	\$ 0.71	\$ 0.91	\$ 1.19	\$ 1.21	\$ 1.21
Volatility	78%	80%	80%	81%	77%	71%	76%	76%	72%	74%
Expected Life	10 years	10 years	10 years	10 years	10 years	10 years	10 years	10 years	10 years	10 years
Risk Free Interest Rate	5.63%	5.49%	5.49%	4.87%	4.26%	5.85%	5.87%	6.13%	5.99%	5.86%
Fair Value of Option (A\$)	\$ 1.13	\$ 0.95	\$ 0.62	\$ 1.04	\$ 0.28	\$ 0.45	\$ 0.59	\$ 0.78	\$ 0.78	\$ 0.79

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

Share price at valuation date

In order to value options over shares of common stock which we granted in 2003 and 2006, by virtue of the fact that our securities were not traded at that time on any public exchange, we have valued our options consistent with the shares that were issued in certain private capital raisings undertaken by the Company around the respective valuation dates of the options, as these prices are most indicative of the fair value of the Company’s equity in the market to a willing participant at and around the applicable valuation date of the options. Although we raised capital by issuing preferred shares, for the purposes of valuing our options we regarded our ordinary and preferred shares as being equivalent in relevant economic aspects and therefore the capital raisings served as a suitable valuation point with respect to the valuation of our options. In this regard we note that the preference shares carried the right to convert to ordinary basis on a one to one basis, and all were converted during 2006 in conjunction with our initial public offering.

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We consider that value of the shares we issued in the capital raisings undertaken by us in 2003 and 2006 (as applicable) most accurately represent the value of our common stock for valuation purposes at the time of those capital raisings. We summarize the per-share subscription value of the relevant shares issued by us below.

<u>Date of Capital Raising</u>	<u>Value per Preferred Stock A\$ (Post Stock Split Described in Note 11)</u>
December 2003	0.39
June 2006.	0.45
August 2006.	0.45

Based on these valuation points, we applied an assumed per share price of A\$0.39 with respect to the options we granted in 2003 and A\$0.45 for the options we granted in 2006.

The value of the options granted post 2007 have 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.

On December 12, 2007 as a result of the impact of the closing of the rights offering, the exercise prices of each option granted by the Company prior to November 19, 2007 was reduced by a maximum of A\$0.10 in accordance with the terms of the options and a formula set out in the Listing Rules of the ASX. The table below reflects the changes to the exercise price and the fair value of option as a result of the rights offering:

<u>Grant Date of Option</u>	<u>Pre Rights Offering</u>		<u>Post Rights Offering</u>	
	<u>Exercise Price</u>	<u>Fair Value of Option</u>	<u>Exercise Price</u>	<u>Fair Value of Option</u>
	A\$	A\$	A\$	A\$
Dec-03	\$0.39	\$0.11	\$0.30	\$0.11
Jan-06	\$0.45	\$0.30	\$0.35	\$0.27
Mar-07	\$1.25	\$0.78	\$1.18	\$0.79
Sep-07.	\$1.27	\$0.77	\$1.20	\$0.78
Oct-07.	\$1.20	\$0.77	\$1.13	\$0.78

Volatility

With respect to the options granted in 2003 and 2006, we had insufficient available share price data to accurately estimate the volatility of our shares of common stock. As a result, we examined and based our volatility for these options by reference to the annual volatilities of a number of ASX listed companies of a similar size and with similar operations to us, over a range of historic estimation periods. Based on our analysis we selected an annual volatility of 40%-45% for the options granted in 2003 and 55% for the options granted in 2006. These figures were within the range of observed volatilities for comparable listed companies.

With respect to the options granted post 2007, 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. Our shares in the form of CDIs were first quoted on ASX on December 13, 2006 with an initial offering price of A\$0.50.

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Consequently, the high level and varying movement on our shares was the key driver for the volatility increasing from 55% at December 31, 2006 to volatility in the 70% — 80% range for options issued subsequent to December 2006.

Time to expiry

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

Risk free rate

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

Stock option activity during the current period is as follows:

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>
		A\$
Balance at December 31, 2008	<u>6,373,284</u>	<u>0.66</u>
Granted	4,164,200	1.16
Exercised	(138,327)	0.60
Lapsed	<u>(359,671)</u>	<u>0.95</u>
Balance at December 31, 2009	<u>10,039,486</u>	<u>0.85</u>

At December 31, 2009, the number of options exercisable was 5,808,324 (2008: 4,324,915 and 2007: 2,851,609).

The following table represents information relating to stock options outstanding under the plans as of December 31, 2009:

	Exercise Price	Options Outstanding		Options Exercisable Shares
		Shares	Weighted Average Remaining Life in Years	
	A\$			
2009	\$0.30	1,594,894	4.00	1,594,894
	\$0.35	1,638,395	6.00	1,638,395
	\$1.18	745,332	7.20	745,332
	\$1.20	620,332	7.70	415,326
	\$1.13	—	—	—
	\$0.89	1,112,333	8.20	742,641
	\$0.70	326,000	8.60	106,000
	\$0.50	124,000	9.10	41,330
	Nil	100,000	9.40	33,333
	\$0.94	1,473,200	9.50	491,073
	Nil	420,000	9.50	—
	\$1.72	1,885,000	9.90	—

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The table below sets forth the number of employee stock options exercised and the number of shares issued in the period from December 31, 2006. We issued these shares in reliance upon exemptions from registration under Regulation S under the Securities Act of 1933, as amended.

<u>Period Ending</u>	<u>Number of Options Exercised and Corresponding Number of Shares Issued</u>	<u>Weighted Average Exercise Price</u>	<u>Proceeds Received</u>
		A\$	A\$
2007	420,474	0.32	148,428
2008	18,124	0.35	5,047
2009	<u>138,327</u>	0.60	<u>78,998</u>
Total	<u>576,925</u>		<u>232,473</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 issue A\$1,000 worth of restricted shares of common stock to all 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 10, 2009	40,670	A\$69,952

(7) Economic Dependency

The Company has entered into the following agreements with LifeScan.

LifeScan License and Research and Development Agreement

Since April 2002 the Company has undertaken contracted research and development activities for LifeScan pursuant to a Development and Research Agreement. The Development and Research Agreement has historically been an important source of revenue for the Company. If the Development and Research Agreement was terminated, we would lose a source of income.

The Company also currently holds a license from LifeScan to a range of patents, patent applications and know-how, pursuant to a License Agreement. If the Company were to breach the License Agreement, which the Company does not intend to do, LifeScan might validly terminate the License Agreement. This would seriously restrict or eliminate the Company's development and commercialization activities.

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(A Development Stage Enterprise)

Notes to Consolidated Financial Statements — (Continued)
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Master Services and Supply Agreement

On October 29, 2007 Universal Biosensors entered into a Master Services and Supply Agreement 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 an original version of the blood glucose test strips we developed for LifeScan. On December 11, 2008, we entered into an additional services addendum to provide manufacturing process support to assist LifeScan to establish LifeScan's own manufacturing line for initial blood glucose test strips at a location of its choosing. On December 11, 2008, the Master Services and Supply Agreement was amended to reflect certain definitional matters in the document. On May 15, 2009, the agreement was amended and restated to incorporate the amendments made in December 2008 and to update the commercial terms of the agreement to reflect a change from the original version of the blood glucose test strip to an enhanced version of the blood glucose test strip. The Master Services and Supply Agreement is structured as an umbrella agreement which enables LifeScan and us to enter into a series of additional arrangements for the supply by us of additional services and products in the field of blood glucose monitoring.

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, Universal Biosensors Pty Ltd will lose rights to receiving some or all revenues from the sale of blood glucose strips and provision of additional services, which would have a material adverse effect on our business and financial condition.

We commenced manufacture of the blood glucose test strips in our facility in Corporate Avenue, Rowville, Melbourne, in December 2009. Our ability to maintain profitability in the future will be adversely affected if the blood glucose product and any of the other products we develop with LifeScan in the future fail to achieve or maintain market acceptance.

(8) 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:

Johnson & Johnson Development Corporation, a wholly owned subsidiary of Johnson and Johnson, owns approximately 12% of the Company's shares.

LifeScan, a wholly owned subsidiary of Johnson & Johnson, makes payments to the Company through the research and development agreement, Master Services and Supply Agreement and issuance of purchase orders to the Company to undertake additional services in the field of blood glucose monitoring. The terms of the arrangements are mentioned in note 7.

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The following transactions occurred with LifeScan:

	As of December, 31	
	2009	2008
	A\$	A\$
<i>Current Receivables</i>		
Reimbursement of expenses	—	31,919
Sale of goods	396,378	—
Sale of services	19,019	—
	415,397	31,919
<i>Revenue</i>		
Revenue from products	132,733	—
Revenue from services	2,850,071	3,121,754
Research and development income	1,337,125	1,170,190
Milestone payment	17,722,641	—
	22,042,570	4,291,944
<i>Operating costs & expenses</i>		
Support services provided by LifeScan	—	1,064,736

Other transactions with LifeScan are detailed as follows:

- the Company received an initial non-refundable fee of A\$1,131,222 in 2008 in consideration for the grant of certain rights to LifeScan pursuant to the Master Services and Supply Agreement
- the Company was reimbursed A\$477,898 in 2008 for certain expenditure incurred on behalf of LifeScan

Messrs Denis Hanley, Andrew Denver and Dr. Colin Adam are shareholders and directors of the Company and of PFM Cornerstone Ltd which was paid a total of A\$450,000 in the year ended December 31, 2007 from Wilson HTM Corporate Finance Ltd as sub-underwriting fee in connection with the renounceable rights issue. Mr. Cameron Billingsley is the company secretary and a stockholder of PFM Cornerstone Ltd. Mr. Charles Kiefel, who ceased to be a director of the Company in January 2010, is also a director and shareholder of PFM Cornerstone Ltd. Our recently appointed director, Mr. Heinberg, also holds a small non-controlling number of shares in PFM Cornerstone Ltd.

Dr. Elizabeth (Jane) Wilson is the spouse of Mr. Steven Wilson who is a substantial stockholder and officer of the parent company of Wilson HTM Corporate Finance Pty Ltd, the underwriter of the renounceable rights issue in 2007. Wilson HTM Corporate Finance Pty Ltd was paid A\$1,626,687 in connection with the Company's renounceable rights issue.

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(9) Property, Plant and Equipment

	As of December, 31	
	2009	2008
	A\$	A\$
Plant and equipment	13,271,715	13,003,248
Leasehold improvements	8,328,270	8,123,925
Capital work in process	6,298,114	2,395,533
	27,898,099	23,522,706
Accumulated depreciation	(6,597,956)	(3,767,457)
Property, plant & equipment, net	21,300,143	19,755,249

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, 2009, 2008 and 2007 was A\$2,770,434, A\$1,501,516 and A\$300,213, 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\$410,000 for the year ended December 31, 2009 (2008: A\$280,000). 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\$2,851,285, A\$2,266,847, A\$708,699 and A\$7,132,568 for the fiscal years ended December 31, 2009, 2008 and 2007 and for the period from inception to December 31, 2009, respectively.

The movement in accumulated depreciation for the 2009 and 2008 financial year is agreed to depreciation expense as follows:

	As of December, 31	
	2009	2008
	A\$	A\$
Movement in accumulated depreciation	2,830,499	2,195,236
Accumulated depreciation of fixed assets disposed	20,786	71,611
Depreciation expense for the financial year	2,851,285	2,266,847

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(10) Accrued Expenses

Accrued expenses consist of the following:

	As of December, 31	
	2009	2008
	A\$	A\$
Legal, tax and accounting fees	176,000	346,000
Salary and related on-costs	327,665	460,761
Research and development materials	698,228	—
Other	—	31,936
	1,201,893	838,697

(11) Stockholders' Equity — Common Stock

In fiscal year 2006, in connection with an initial public offering in Australia in the form of an offer of new shares of common stock in the capital of the Company ("Public Offer") and a concurrent separate offer of shares of common stock in the US to certain US Persons (as that term is defined in Regulation S promulgated under the US Securities Act of 1933) ("US Private Placement"), shareholders approved: a) the conversion of all series A convertible preferred stock into common stock; b) the adoption of a new certificate of incorporation which was filed with the State of Delaware on December 5, 2006; c) a subdivision of existing common stock by 3,624.7518771; and d) an issue and allotment of common stock to subscribers under the Public Offer and US Private Placement.

As noted in note 12, during fiscal year 2006 the Company also issued 30,176,036 series A convertible preferred stock in two separate private placements to institutional and sophisticated investors in both the US and Australia. This series A convertible preferred stock was subsequently converted into common stock on December 6, 2006. Before the stock split by 3,624.7518771, the Company had on issue 12,032 shares of common stock and 11,142 series A convertible preferred stock. After the conversion of all series A convertible preferred stock into shares of common stock, there were 23,174 shares of common stock on issue. Immediately following the subdivision on December 6, 2006, there were 83,999,976 shares on issue. All share and per share amounts from the period from inception to December 31, 2006 presented in the accompanying financial statements have been retroactively adjusted to give effect to the stock split.

The Company completed its Public Offer of 36,000,000 shares of common stock and concurrent US Private Placement of 8,000,000 shares in the US to institutional and accredited investors, raising A\$22 million in aggregate before costs. The Company listed on ASX on December 13, 2006.

In December 2007, we closed the renounceable rights issue of new ordinary shares by issuing 28,538,362 shares of common stock in which we raised A\$34,246,043.

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 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.

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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.

(12) Convertible preferred stock

Up until the time of the Company’s Australian initial public offering, the Company had on issue 40,386,962 Series A convertible preferred stock. The Company issued 3,758,844, series A convertible preferred stock on June 15, 2006 and 26,417,192 series A convertible preferred stock on August 30, 2006, raising a total of A\$12,624,795 before costs associated with the issues. Immediately prior to the issue of shares in connection with the Public Offer and the U.S. Private Placement, all the Company’s convertible preference shares were converted into common stock (refer note 11).

The rights and obligations attaching to the series A convertible preferred stock were derived by a combination of an Investor Rights Agreement (which was terminated in connection with the close of the Public Offer), the By-laws and Amended and Restated Certificate of Incorporation of the Company. Without limitation, the terms of issue of the series A convertible preferred stock were as follows:

- the right to receive notices of general meetings and to attend and vote at general meetings of the Company;
- each preferred share entitled the stockholder to such number of votes at a general meeting equal to the number of shares of common stock that the preferred stock would have converted into (whether or not it had been converted);
- rights of conversion into common stock;
- may participate in dividends declared in respect of that class of share at the discretion of the Board, the rights to which may not be similar to the rights of the holders of common stock;
- anti-dilution protection in certain circumstances; and
- a liquidation preference over common stockholders in the event of liquidation or a capital reduction of the Company.

The series A convertible preferred stock were convertible by the holders into shares of common stock at any time or could be compulsorily converted at the time of an initial public offering, subject to certain conditions. The conversion ratio was one share of common stock per convertible preference share, subject to variation for capital reconstructions and share dilutions.

In the event of a return of assets on liquidation or capital reduction or otherwise, the assets of the Company remaining after payment of its liabilities were applied first in paying the preferred stockholders an amount equal to the issue price of such preferred stock adjusted as necessary for capital reconstructions and secondly, to the common stockholders an amount equal to the relevant issue price. Thirdly an amount per preferred share equal to the amount of interest that would have accrued on the amount subscribed for by the

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preference stockholder if interest had accrued daily at a rate of 10% per annum from the date of issue. Finally, the balance of assets remaining (if any) was to have been distributed among the holders of preferred and common stock pari passu as if they constituted one class of shares.

(13) Retirement Benefits

Universal Biosensors Pty Ltd contributes to standard defined contributions superannuation funds on behalf of all employees at an amount up to nine percent 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\$698,919, A\$587,885, A\$507,270 and A\$2,473,101 for the fiscal years ended December 31, 2009, 2008 and 2007, and the period from inception to December 31, 2009, respectively.

(14) 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. All periods presented in the financial statements have been retroactively adjusted to give effect to the share split described in note 11. 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.

	Period from Inception to December 31, 2009	Year Ended December 31,		
		2009	2008	2007
Weighted average number of ordinary shares used as denominator in calculating:				
Basic net profit/(loss) per share	80,967,756	157,013,578	156,970,679	129,637,286
Diluted net profit/(loss) per share . . .	80,967,756	161,354,802	156,970,679	129,637,286

(15) 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.

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

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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.

No liability has arisen under these indemnities as at December 31, 2009.

(16) Segments

The Company operates in one segment. The principal activities of the Company are 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 operates predominantly in one geographical area, being Australia.

(17) 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".

(18) Subsequent Events

On January 11, 2010, there was a change in the Company's board of directors with the appointment of Marshall Heinberg and the retirement of Charles Keifel.

On January 28, 2010, the Company announced that LifeScan's new product incorporating technology developed by the Company has been made available for sale in Netherlands under the One Touch "Verio" brand.

The following options were exercised by employees under the Company's Employee Option Plan"

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<u>Exercise Date</u>	<u>Options Exercised</u>	<u>Type of Options</u>
February 1, 2010	40,000	Market price employee options
February 10, 2010	33,333	Zero exercise price options
February 15, 2010	4,000	Market price employee options
February 22, 2010	34,789	Market price employee options
February 25, 2010	18,124	Market price employee options
March 1, 2010	6,666	Market price employee options

With the exception of the above, there has not arisen in the interval between the end of the financial year to the date of this report any item, transaction or event of a material and unusual nature likely, in the opinion of the directors of the Company, to affect significantly the operations of the Company, the results of those operations, or the state of affairs of the Company in future financial years.

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Schedule ii — Valuation and Qualifying Accounts
(for the years ended December 31, 2007, 2008 and 2009 and for the period from inception
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	Balance at Beginning of Period	Additions		Deductions	Balance at End of Period
		Charged to Costs and Expenses	Charged to Other Accounts		
	A\$	A\$	A\$	A\$	A\$
<i>Year ended December 31, 2007</i>					
Deferred income tax valuation allowance . . .	2,092,417	3,484,228	503,884	—	6,080,529
<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>Period from inception to December 31, 2009</i>					
Deferred income tax valuation allowance . . .	—	12,324,710	(624,899)	—	11,699,811

INDEX TO EXHIBITS

<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 29, 2007, December 5, 2005)	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.1. October 2007 amendment incorporated by reference to our Form 10-Q filed on November 14, 2007 as Exhibit 10.2.
10.2	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 Amendment No. 4 to Form 10 filed on September 19, 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. Salesh Balak effective November 27, 2006	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.8
10.8	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

<u>Exhibit Number</u>	<u>Description</u>	<u>Location</u>
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. Mark Morrisson dated July 1, 2006	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.12
10.12	Employment agreement between Universal Biosensors Pty Ltd and Mr. Adrian Oates dated August 15, 2007	Filed herewith
10.13	Master Services and Supply Agreement by and between Universal Biosensors Pty Ltd, Universal Biosensors, Inc. and LifeScan, Inc. dated October 29, 2007	Incorporated by reference to our Quarterly Report on Form 10-Q filed on November 14, 2007 as Exhibit 10.1. Confidentiality treatment has been granted for portions of this exhibit. These confidential portions have been omitted and were filed separately with the SEC.
10.14	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
10.15	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
10.16	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.

<u>Exhibit Number</u>	<u>Description</u>	<u>Location</u>
10.17	Amendment to Development and Research Agreement (which amends the Development and Research Agreement by and between Universal Biosensors, Inc. and LifeScan, Inc. dated April 1, 2002 and filed on April 30, 2007 as Exhibit 10.2 to our Form 10, the Amendment to the Development and Research Agreement filed on June 12 as Exhibit 10.2 to Amendment No. 2 to our Form 10 and the Amendment to Development and Research Agreement filed on November 14, 2007 as Exhibit 10.3 to our Quarterly Report on Form 10-Q.	Incorporated by reference to our Quarterly Report on Form 10-Q filed on August 7, 2009 as Exhibit 10.2.
10.18	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.
10.19	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.
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 21.00
24.0	Power of Attorney	Included on signature page
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act	Filed herewith

<u>Exhibit Number</u>	<u>Description</u>	<u>Location</u>
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act	Filed herewith
32.0	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act	Filed herewith

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 24, 2010.

(a) Distribution of equity securities

As at March 24, 2010 there were:

- 157,252,175 fully paid shares of common stock held by 1,408 individual security holders. All issued shares of common stock carry one vote per share and carry the rights to dividends.
- 40,670 unquoted fully paid restricted shares of common stock held by 70 individual employees of the Company. All issued shares of common stock carry one vote per share and carry the rights to dividends.
- 9,952,576 options over shares of common stock held by 78 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	144	0
1,001 – 5,000	344	1
5,001 – 10,000	234	0
10,001 – 100,000	574	56
100,001 – and over	112	21
	1,408	78

There are 22 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*	22,651,074	14.404
Johnson & Johnson Development Corporation	18,231,729	11.594
CM Capital Investments Pty Ltd	14,121,272	8.980
PFM Cornerstone Limited	13,476,406	8.570
Kaasim Pty Ltd	8,582,636	5.458

* Shares held on trust for Messrs Denver, Hanley, Keifel 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	22,651,074	14.404
2. Johnson & Johnson Development Corporation	18,231,729	11.594
3. CM Capital Investments Pty Ltd (CM Capital Venture No.3)	14,121,272	8.980
4. PFM Cornerstone Limited	13,476,406	8.570
5. Kaasim Pty Ltd	8,582,636	5.458
6. National Nominees Limited	6,682,468	4.250
7. CM Capital Investments (CM Capital 3A)	3,508,112	2.231
8. Equity Trustees Limited	3,399,740	2.162
9. Mr Alastair Hodges	3,056,749	1.944
10. Mr Denis Michael Hanley	2,313,230	1.471
11. Litster & Associates Pty Ltd	2,229,035	1.417
12. Mr Garry Chambers	1,759,088	1.119
13. Mr Thomas William Beck and Mrs Lynne Carol Beck	1,690,768	1.075
14. Warragai Investments Pty Ltd	1,600,000	1.017
15. Sayers Investments (ACT) Pty Ltd	1,452,445	0.924
16. Mr Ronald Chatelier	1,337,085	0.850
17. Citicorp Nominees Pty Limited	1,241,740	0.790
18. Megreg Holdings Pty Ltd	1,212,160	0.771
19. Mr Andrew Denver & Mrs Linda Denver	1,181,812	0.752
20. Mr Christopher J La Croix & Mrs Kathleen M La Croix	1,166,718	0.742
	110,894,267	70.521
	157,252,175	

(d) Restricted Securities

As at 24 March 2010, there are 40,670 fully paid restricted shares of common stock issued to 70 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 Mark Morrisson (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
Rowville Victoria 3178
Australia
Telephone: +61 3 9213 9000
Facsimile: +61 3 9213 9099
Email: info@universalbiosensors.com
Website: www.universalbiosensors.com
ASX code: UBI

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

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

Share Registry

Registries Limited
Level 7, 207 Kent Street
Sydney New South Wales 2000
Australia
Telephone: +61 2 9290 9600
Facsimile: +61 2 9279 0664
Email: callcentre@registries.com.au
Website: www.registries.com.au

Auditor

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

Australian Legal Adviser

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

US Legal Adviser

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

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