Annual Report

Universal Biosensors, Inc.

Annual Report for the Year Ended December 31, 2008

Universal Biosensors

Contents

Chairman's Letter

Dear Shareholder,

On behalf of the Board, I am pleased to present the annual report of Universal Biosensors, Inc. ('Company') for the year ended December 31, 2008.

I am pleased to report that the Company has made excellent progress in advancing the products under development and in building capacity in product development, quality, regulatory and manufacturing expertise. The Company's relationship with Lifescan has been the main focus of efforts this year, as we have driven to develop and produce a blood glucose product capable of meeting the increased demands of patients with diabetes. These efforts have required that we demonstrate not only the safety and efficacy of our product to a Regulatory Agency but that we can meet the high standards required by Lifescan so they can launch a product bearing their name and logo. I am pleased to report that we have met all the challenges in this process to date and I have a high confidence that we will be able to produce a world class product.

The partnership we have created with Lifescan has been developing for many years and has strengthened over time. A fundamental part of the relationship has been the Company's ability to anticipate new requirements and be able to accommodate these into our base technology. Thus when Lifescan indicated the desire to further enhance the product we had developed for them we had already developed a solution. This enhanced product is the product that we are now developing. This new product was not covered by the Master Services and Supply Agreement but the agreement is such that it can be modified and we are currently in discussions with Lifescan to add this product to the agreement and to finalise other aspects of near term development efforts.

We continue to be successful with the development of non-glucose test products derived from the technology, with the main focus being on the dry immunoassay platform. This is a platform that would allow the Company to develop a number of tests using antibody-antigen reactions at the point of patient care similar to the way that the blood glucose test is used by diabetics. The current plans are that we would look for marketing partners that could provide the access to the target customer group for these products in a way that is similar to the role that Lifescan provides for us in blood glucose testing. Due to the progress that we have made in demonstrating a working product and the manufacturing process, we are now able to commence discussions regarding partnership arrangements for the C-reactive protein test and the prothrombin time test.

The effort and capability demonstrated by all your employees in 2008 has been exceptional. I was proud to be associated with such a talented and committed group. It is my hope and belief that 2009 should see the transition of the Company to the next stage of its development, that of a Company with products in the market.

I thank you for your continued help and support during a very eventful and successful year for the Company.

Yours faithfully

Andrew Denver
Chairman

CEO's Report

In February 2009 we announced that LifeScan had made the decision not to proceed with the registration of the product we had been developing with them but instead to proceed with the development of an even stronger product. We are in discussions with LifeScan with respect to the commercial terms for this enhanced product. The implication is that while our initial revenues will be delayed, a stronger product should give a stronger sales performance in the market, more than compensating for the short delay.

Blood glucose business

Since 2002, Universal Biosensors has worked closely with LifeScan, Inc., an affiliate of Johnson & Johnson in the development of blood glucose monitoring products. LifeScan is one of the world's leading manufacturers of blood glucose monitoring systems for home and hospital use. In unit terms, we estimate that the worldwide market for blood glucose monitoring systems is 14 billion sensor strips per annum. Market researchers Kalorama Information estimated LifeScan's share of the global diabetes diagnostic business in 2006 was 25%.

In the years since 2002 our partnership with LifeScan has strengthened as we have advanced the platform technology through research, into product development, and then into manufacturing. In 2007 we entered into a Master Services and Supply Agreement under which we have provided services to LifeScan in preparation for the launch of a blood glucose product. We are currently in discussions with LifeScan with respect to required amendments to the Master Service and Supply Agreement to reflect the change in focus to an enhanced product. I am hopeful we will be in a position to execute an upgraded agreement within the near term.

Over the rest of 2009, the work that remains for the enhanced glucose product is to complete product validation and manufacturing process qualification, and then to file the data package with regulators. The enhanced strip is capable of being manufactured on our existing equipment here in Rowville. LifeScan has the responsibility for regulatory filing and launch strategy once the validation and process qualification steps are completed. We are confident in LifeScan's ability to successfully market this new product to worldwide markets.

Product Pipeline

Our non-blood glucose products, tests for C-reactive protein, prothrombin time and d-dimer, continue to progress. A key aspect of our strategy with these products is to enter into a collaborative arrangement with a selected third party to assist in the development, and ultimately marketing of these tests. We believe our progress with C-reactive protein and prothrombin time tests currently puts us in a position to commence these discussions.

The Year Ahead

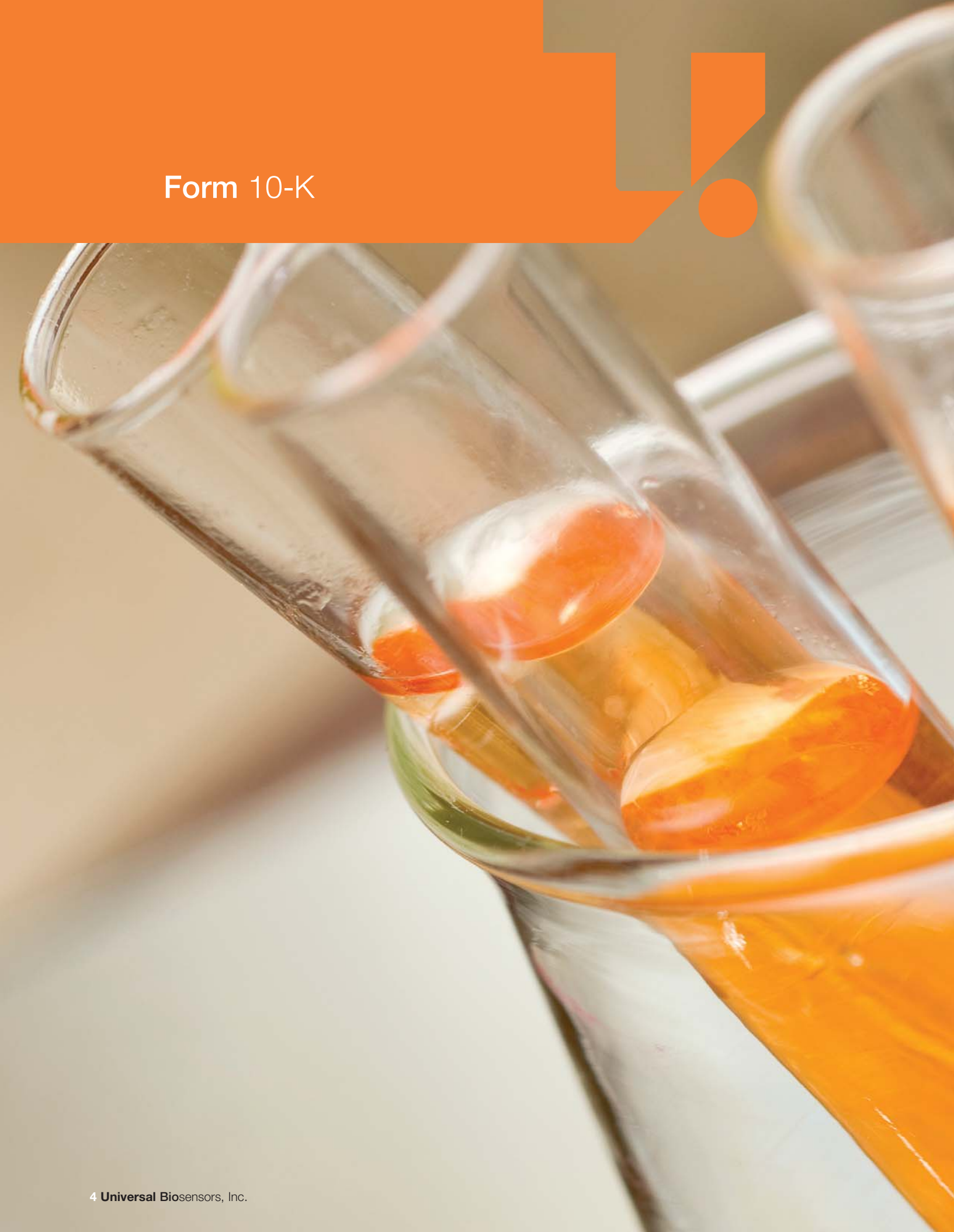
For the remainder of 2009 we will continue to build on the advances we have made with all our programs including to continue to prepare for the launch of a blood glucose product by our partner LifeScan, and to seek out discussions with potential collaborators for our C-reactive protein and prothrombin time tests.

In closing I would note 2008 was an exceptionally busy year for Universal Biosensors and much was demanded of our staff and Board. I would like to take this opportunity to thank them for their unwavering efforts as we look forward to another successful year and continuing to build on our significant achievements to date.

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, 2008

OR

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

Commission File Number: 0001279695

Universal Biosensors, Inc.

(Exact name of registrant as specified in its charter)

Delaware		**98-0424072**
(State or other jurisdiction of incorporation or organization)		*(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 ☑

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

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

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

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☑

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The approximate aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant was A$75,363,757 (equivalent to US$61,663,388) as of June 30, 2008.

The number of shares outstanding of each of the registrant's classes of common stock as of March 25, 2009:

Title of Class	Number of Shares
Common Stock, US$.0001 par value	156,976,936

DOCUMENTS INCORPORATED BY REFERENCE:

Certain information contained in the registrant's definitive Proxy Statement for the 2009 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;
- the progress of activities under our master services and supply agreement with LifeScan, Inc.
- the progress of discussions with LifeScan with respect to amendments to the master services and supply agreement to reflect a proposed change from the original initial blood glucose product to an enhanced blood glucose product and our expectations with respect to the services and development projects under the master services and supply agreement;
- our expectations with respect to regulatory submissions, approvals and market launches of blood glucose test products by LifeScan, Inc.;
- our expectations with respect to the timing and amounts of revenues expected from LifeScan, Inc.;
- the progress of our contract research and development program with LifeScan, Inc.;
- the progress of our own research and development programs;
- our expectations with respect to corporate collaborations or strategic alliances with respect to our own products, including revenues expected from such collaborations;
- our expectations with respect to regulatory submissions and approvals of our own products;
- 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 development, manufacture and commercialization of in vitro diagnostic test devices for point-of-care use. In vitro diagnostic testing involves the testing outside of the body of a body fluid (e.g. blood or saliva) or tissue sample (biopsies or swabs). The blood test devices we are developing comprise a novel disposable test strip and a reusable meter. The devices are designed to be used by the patient or near to or at the site of the patient (at the "point-of-care") by non-patients to provide accurate and quick results to enable new treatment or an existing treatment to be immediately reviewed.

We have rights to an extensive patent portfolio comprising patent applications owned by our wholly owned Australian subsidiary, Universal Biosensors Pty Ltd, and a large number of patents and patent applications licensed to us by LifeScan, Inc. an affiliate of Johnson & Johnson ("LifeScan").

We are developing a number of electrochemical-cell based tests, including blood glucose tests (used in the management of diabetes) on behalf of LifeScan, a C-reactive protein test to assist in the diagnosis and management of inflammatory conditions, a prothrombin time test for monitoring the therapeutic range of the anticoagulant, warfarin, and 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).

We also intend to continue to develop additional immunoassay based point-of-care test devices by taking selected disease biomarkers currently measured in the central laboratory environment and creating tests using those biomarkers for the point-of-care setting.

We entered into a master services and supply agreement with LifeScan in October 2007 which contains the terms pursuant to which Universal Biosensors Pty Ltd agreed to provide certain services in the field of blood glucose monitoring to LifeScan and to act as a non-exclusive manufacturer of blood glucose test strips for LifeScan ("Master Services and Supply Agreement"). In February 2009, we announced that LifeScan had chosen not proceed with the registration of the original initial blood glucose test strips we had developed but instead wished to proceed with the development of an enhanced initial blood glucose test strip. We are in discussions with LifeScan with respect to the commercial terms for the development and manufacture of the enhanced initial blood glucose test strips and the resulting amendments required to the Master Services and Supply Agreement.

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 anticipated future manufacturing activities are undertaken in Melbourne, Australia, by Universal Biosensors Pty Ltd. Our shares of common stock in the form of CHESS Depositary Interests ("CDIs") were quoted on the Australian Securities Exchange ("ASX") on December 13, 2006. 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 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 2008, we have received contract research funding from LifeScan of A$13,077,964 pursuant to the Development and Research Agreement. The quantum 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, following which, the agreement automatically renews 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 (refer details below), 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. The scope of the program under the Development and Research Agreement was also expanded to include development work in connection with a blood glucose meter.

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 2008 we have spent A$13,003,248 relating to the acquisition of manufacturing and research and development equipment.

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 act as a non-exclusive manufacturer of an original version of the initial 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 agreement was amended to reflect certain definitional matters in the document. In February 2009, we announced that LifeScan had chosen not to proceed with the registration of the original initial blood glucose test strips but instead wished to proceed with the development of an enhanced initial blood glucose test strip. The enhanced initial blood glucose test strip is based on the same technology as the original product and would be manufactured using the same production processes and manufacturing equipment and infrastructure. We are in discussions with LifeScan with respect to the commercial terms for the development and manufacture of the enhanced initial blood glucose test strips and the resulting amendments to the Master Services and Supply Agreement. 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.

Since 2004, 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 2005, we have carried out research and development activities on a point-of-care prothrombin time blood test for monitoring the therapeutic range of the anticoagulant, warfarin. We have developed working prototypes of both of these tests and are targeting having a product available for launch in 2010. Since early 2008, we also started 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 conditions associated with thrombotic disease, particularly deep venous thrombosis (clots in the leg) and pulmonary embolism (clots in the lung). All these tests draw on the intellectual property licensed to us under the License Agreement in addition to intellectual property owned by Universal Biosensors Pty Ltd. 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 some of our products.

Our founding stockholder was The Principals Cornerstone Fund Pty Ltd, an Australian company which holds its shares on trust for Messrs Denver, Hanley, Kiefel and Dr Adam, all of whom are our directors. In mid 2002 we issued shares to Water Application and Systems Corporation worth A$1,753,156 in consideration of the acquisition of plant and equipment. Between incorporation and November 2006, we have secured investment from private and venture capital investors in Australia, the United States and a limited number of other jurisdictions totaling an aggregate of A$19,056,636. On December 5, 2006, we closed an initial public offer of our shares in Australia in which we raised A$18,000,000. At the same time, we closed a private placement of our shares in the United States in which we raised a further A$4,000,000. On December 13, 2006, we were admitted to the official list of ASX and our shares in the form of CHESS Depositary Interests, or CDIs, were quoted on the ASX. 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 2007, 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$280,000 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.

With the exception of the first year of our operations when we made a small profit of A$130,134, we have incurred net losses since our inception. We recognized a net loss of A$2,955,661, A$8,817,238 and A$11,995,886 in the years ended December 31, 2006, 2007 and 2008, respectively. Our accumulated losses from inception to December 31, 2008 are A$24,353,151. We expect to continue to incur losses as we continue the development of our point-of-care tests and expand our organization and commercial manufacturing

capability until we are able 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 development, manufacture and commercialization of in vitro diagnostic test devices for point-of-care use. Key aspects of our strategy include:

- finalizing negotiations with LifeScan with respect to amendments to the Master Services and Supply Agreement to reflect the change of product from the original initial blood glucose tests strips to an enhanced initial blood glucose test strip;
- completing product development, scale up and transfer into production of the enhanced initial blood glucose test strip for LifeScan;
- scale our manufacturing operations to meet potential demand for blood glucose test strips;
- continuing to provide services to LifeScan and manufacturing blood glucose test strips as required;
- continuing to undertake contract research and development work on behalf of LifeScan;
- continuing the development of our C-reactive protein test, prothrombin time test and D-dimer test and, if our development efforts are successful, seeking regulatory clearance for those tests. Our business strategy with respect to the commercialization of our C-reactive protein, prothrombin time and D-dimer tests is based in part upon entering into entering into collaborative arrangements or strategic alliances with other life sciences companies or other industry participants to complete the development and commercialization of those products and enable us to maintain our financial and operational capacity. We intend to develop the necessary commercial scale manufacturing capability to enable us to manufacture the test strip component for any tests we develop, either for ourselves, or on behalf of third parties. We propose to outsource the manufacture of the meters;
- seeking to leverage our intellectual property by developing additional immunoassays tests that use our platform of electrochemical cell technologies; and
- seeking to develop additional products in the field of blood glucose monitoring.

Plan of Operations for the Remainder of the Fiscal Year Ending December 2009

Our plan of operation over the remainder of the fiscal year ending December 2009 is to:

- finalize negotiations with LifeScan with respect to amendments to the Master Services and Supply Agreement to reflect the change of product;
- focus on completing product development and validation activities for the initial enhanced blood glucose test strip for LifeScan;
- continue to expand our commercial scale manufacturing capability;
- provide the necessary quality and regulatory infrastructure to support registration, launch and post-market activities of LifeScan;
- commence work on other blood glucose products and other research and development activities for LifeScan;
- continue research and development activities with respect to our C-reactive protein test, prothrombin time test and D-dimer test; and
- seek to identify and then negotiate collaborative arrangements with third parties with respect to one or more of our non-blood glucose programs.

As at March 25, 2009 we employed 80 full time employees.

Financial information about segments

We operate in one segment. Our principal activities are the research, development, manufacture and commercialization of in vitro diagnostic test devices for point-of-care use. We operate predominantly in one geographical area, being Australia. For details of our revenues, profit and loss and total assets for financial years ending December 31, 2004, 2005, 2006, 2007 and 2008, refer to "Item 6. Selected Financial Data".

Description of our business

We are a specialist medical diagnostics company focused on the development, manufacture and commercialization of in vitro diagnostic test devices for point-of-care use. The diagnostic blood tests we are developing comprise a novel disposable test strip and a reusable meter. The tests 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. Each of the tests we have developed, or are developing, utilize 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.

Novel technologies

The majority of current 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 are developing have a parallel and opposing configuration. The 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 or existing treatment to be immediately reviewed. 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

Amongst other things, in vitro diagnostic tests are currently used for:

- the measurement of risk factors or the presence of disease indicators which may permit early intervention;
- diagnosis, to help establish or help exclude the presence of, or help determine the severity of a condition in a patient or to monitor or detect the reoccurrence of a condition or disease; and
- ongoing disease management, to determine whether a prescribed medication is producing the intended physiological effect and to help select and adjust therapies and dosages of medications.

In vitro diagnostics tests are tests performed on samples removed from the human body. The samples may be body tissue such as biopsies or swabs, or fluids such as blood, urine and saliva. Traditionally, samples have been sent to a centralized pathology laboratory where analysis is performed by a trained laboratory professional. Pathology tests generally produce accurate results, however, the results may not be generated and returned quickly enough to enable the doctor to review and make a decision regarding the results at the time of the initial presentation of the patient. As a result of advances in technology, it has become possible for some testing to be performed, results to be generated for review and action to be taken at the "point-of-care", either by doctors, or in certain situations, by the patients themselves. Point-of-care testing is "real-time" diagnostic testing that is performed near to or at the site of the patient. 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. Our diagnostic blood 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 at a patient's home.

Point-of-care tests in development

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.

Point-of-Care Test	Development Stage	Next Anticipated Milestones
Blood glucose test	• Since 2002 contract research and development in the field of blood glucose monitoring for LifeScan • Since October 2007 we have undertaken, a number of tasks, relating to the development and manufacture of a blood glucose test strip for LifeScan • In February 2009, we announced that LifeScan had chosen not to proceed with the registration of the original initial blood glucose test strips but instead wished to proceed with the development of an enhanced initial blood glucose test strip.	• Finalize negotiations with LifeScan with respect to amendments to the Master Services and Supply Agreement to reflect the change of product; • Complete development of the enhanced initial blood glucose test • Decision to seek regulatory approval and launch at LifeScan's sole discretion
Immunoassay C-reactive protein test	• Development work undertaken since 2004 • Working prototype developed • A minimum of one additional year of development/ product validation work required	• Commence product validation in 2009 • Establish manufacturing process
Prothrombin time test	• Development work undertaken since early 2005 • Working prototype developed • A minimum of one additional year of development/ product validation work required	• Commence product validation in 2009 • Establish manufacturing process
D-dimer test	• Development work undertaken since early 2008 • A minimum of two additional years of development/ product validation work required	• Develop working prototype • Commence product validation in 2010 • Establish manufacturing process

Blood glucose test

Since April 2002, we have been undertaking contract research and development in the field of blood glucose monitoring for LifeScan. LifeScan has the exclusive rights to commercialization of any technology we develop in the area of blood glucose monitoring.

In October 2007 we entered into a Master Services and Supply Agreement with LifeScan, pursuant to which we agreed to undertake certain tasks and provide certain services for LifeScan with regard to a test for blood glucose monitoring, and pursuant to which Universal Biosensors Pty Ltd will act as a non-exclusive manufacturer of the original version of the initial blood glucose test strips 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 agreement was amended to reflect certain definitional matters in the document. In February 2009, we announced that LifeScan had chosen not to proceed with the registration of the original initial blood glucose test strips but instead wished to proceed with the development of an enhanced initial blood glucose test strip. The enhanced initial blood glucose test strip is based on the same technology as the original product and would be manufactured using the same production processes and manufacturing equipment and infrastructure. We are in discussions with LifeScan with respect to the commercial terms for the development and manufacture of the enhanced initial blood glucose test strips and the resulting amendments to the Master Services and Supply Agreement. The Master Services and Supply Agreement envisages that Universal Biosensors Pty Ltd will manufacture the original version of the initial blood glucose test strips in its Rowville facility on a non-exclusive basis, should that blood glucose product receive clearance to sell and be launched by LifeScan. We are seeking to negotiate comparable non-exclusive manufacturing rights with respect to the enhanced initial blood glucose test. LifeScan is likely at to decide at some point in the future to establish its own manufacturing operations or engage other third party manufacturers to manufacture the blood glucose products we develop for them. LifeScan is solely responsible for registration strategy and commercial efforts.

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.

Blood glucose monitoring is the largest segment within the in vitro diagnostic market. We estimate worldwide sales of blood glucose point-of-care tests to be $7.7 billion in 2005 ('The worldwide market for in vitro diagnostic tests' Kalorama Information, April 2006, 5th Edition., New York). We estimate that in 2005, the total prevalence of diabetes in the United States across all ages was approximately 20.8 million people or approximately 7% of the United States population (National Diabetes Information Clearinghouse http://diabetes.niddk.nih.gov/dm/pubs/statistics/#7). Of this total, an estimated 14.6 million people in the United States have actually been diagnosed with diabetes and an estimated 6.2 million people in the United States remain undiagnosed (National Diabetes Information Clearinghouse http://diabetes.niddk.nih.gov/dm/pubs/statistics/#7). The point-of-care market for blood glucose tests is made up of both hospital based testing and self-tests. LifeScan, a Johnson and Johnson Company, is one of the four companies that in aggregate account for over 80% of the world wide market for blood glucose tests.

Immunoassay for C-reactive protein test

Immunoassay testing is used to detect or quantify a specific substance utilizing an antibody-antigen reaction. Typically the substances being measured are molecules such as proteins, enzymes or hormones. By incorporating different antibodies specific to different molecules in any given immunoassay test, it is possible to build a wide variety of immunoassay tests. We believe our electrochemical cell technology is suitable for constructing a number of immunoassay tests.

We have developed a working prototype of an immunoassay point-of-care test to measure the amount of C-reactive protein in the blood which we have been developing since 2004. C-reactive protein is an established biomarker found in the blood that is routinely used in pathology laboratories for indication of inflammatory conditions. It is most prominently associated with infection and cardiovascular disease. Rather than being undertaken in a pathology laboratory, the C-reactive protein test we are developing would be undertaken in a doctor's setting with the results being interpreted by healthcare professionals.

If our development efforts continue to be successful, we expect to be in a position to commence formal validation phase of the C-reactive protein test in 2009, following which, we intend to establish the manufacturing processes for the test and commence the process of seeking regulatory clearance. We plan to seek partners to assist in the development

The C-reactive protein test draws on patents and patent applications licensed from LifeScan as well as know-how, patents and patent applications owned by Universal Biosensors Pty Ltd.

Prothrombin time test

Prothrombin time tests are a blood test widely used for monitoring the therapeutic range of the long-term anticoagulant, warfarin. Warfarin is a blood thinning medication commonly administered to patients with certain types of irregular heartbeats, patients who have had heart valve replacement surgery or people at risk of a stroke or cardiac event.

We have developed a working prototype of a point-of-care prothrombin time test which we have been developing since early 2005. If the development efforts continue to be successful, we expect to be in a position to commence the formal validation phase of the prothrombin time test in 2009, following which, we intend to establish the manufacturing processes for the test and commence the process of seeking regulatory clearance for the test. We plan to seek partners to assist in the development and commercialization of this test.

The prothrombin time test draws on patents and patent applications licensed from LifeScan as well as know-how, patents and patent applications owned by Universal Biosensors Pty Ltd.

D-dimer test

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).

Development work on this project commenced in early 2008 and we expect to develop a working prototype of a point-of-care D-dimer test in 2009. If the development efforts continue to be successful, we expect to be in a position to commence the formal validation phase of the D-dimer test in 2010 a process requiring at least two years, following which, we intend to establish the manufacturing processes for the test and commence the process of seeking regulatory clearance for the test. We plan to seek partners to assist in the development and commercialization of this test.

The D-dimer test draws on patents and patent applications licensed from LifeScan as well as know-how, patents and patent applications owned by Universal Biosensors Pty Ltd.

Additional immunoassay tests

We also intend to develop additional immunoassay based point-of-care test devices by taking selected disease biomarkers currently measured in the central laboratory environment and creating tests using those biomarkers for the point-of-care setting using our novel platform of electrochemical cell technologies. We propose to focus on the development of products which do not rely on the development of new medicines, treatments or biomarkers, but where existing therapies or practice can be enhanced significantly by simple and accurate diagnostic tools incorporating well known biomarkers.

We anticipate these tests will draw on patents and patent applications licensed from LifeScan as well as know-how, patents and patent applications owned by Universal Biosensors Pty Ltd.

Facilities

We occupied premises at 103 Ricketts Road, Mt Waverley in Melbourne, Australia from August 2002 until the expiry of the lease of those premises on September 6, 2007. Universal Biosensors Pty Ltd now 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 new premises in August 2007. The lease for the 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

We intend to manufacture the disposable test strips for each of our existing and future point-of-care tests using proprietary manufacturing equipment that we design but are built for us by specialist manufacturers. The starting materials for the strips are freely available from third party suppliers. With the exception of the blood

glucose test strips, we anticipate that initial packaging of our other test strips would be conducted in our facility in Corporate Avenue, Rowville, Melbourne.

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.

The Master Services and Supply Agreement provides that we will act as a non-exclusive manufacturer of the original version of the initial blood glucose test strips for LifeScan and that LifeScan will be 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. We are seeking to negotiate comparable manufacturing arrangements with respect to the enhanced initial blood glucose monitoring product. 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.

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 by non-professionals. 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 we seek 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 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 owned and licensed patents and patent applications.

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 research and development activities for LifeScan. Likewise, pursuant to the Master Services and Supply Agreement we have a limited license to intellectual property of LifeScan in the field of diabetes and blood glucose management generally 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, 2008.

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 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 in a range of jurisdictions within the Americas, Europe 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). 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). 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. This application is due for national stage entry in January of 2009.

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, along with associated PCT — PCT/IB2008/002849 and Taiwan counterparts. 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.

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. This patent relates to a method of transferring parametric information from a test strip based on color encoded fields.

Patent Family 7 — Patent Family Enhanced Immunoassay Sensor — Enhanced immunoassay sensor, United States of America Provisional patent application no. 61/129,688. This patent relates to a biosensor for detecting target analyte in a fluid sample based on electrochemical reactions.

Patent Family A — Electrochemical Cells. Patents under Patent Family A are currently either pending or granted in a range of jurisdictions within the Americas, Europe and Australasia. 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 either pending or granted in a range of jurisdictions within the Americas, Europe and Australasia. 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 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 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 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 E — Analytic Cell. Patents under Patent Family E are granted in a range of jurisdictions within the Americas, Europe and Australasia. This patent family relates to a device for the determination of ionic activities and/or concentrations in a solution containing ions and in particular an inexpensive means to facilitate the convenient measurement of pH. The last of the patents to expire within Patent Family E will expire on September 11, 2017.

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 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 either pending or granted in a range of jurisdictions within the Americas, Europe 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 either pending or granted in a range of jurisdictions within the Americas, Europe and Australasia. 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 granted in a range of jurisdictions within the Americas, Europe and Australasia. 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 June 26, 2023.

Patent Family J — Sensor with Improved Shelf Life. Patents under Patent Family J are currently either pending or granted in a range of jurisdictions within the Americas, Europe and Australasia. 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 September 19, 2020.

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 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 June 10, 2022.

Patent Family L — Method and Device for Sampling and Analyzing Interstitial Fluid and Whole Blood Samples. Patents under Patent Family L are currently either pending or granted in a range of jurisdictions within the Americas, Europe and Australasia. This patent family relates to a method and device for combining the sampling and analyzing of sub-dermal fluid samples, such as interstitial fluid or whole blood, in a device suitable for hospital bedside and home use. The last of the patents to expire within Patent Family L will expire on April 12, 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, Europe and Australasia. 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 May 13, 2024.

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 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 N2 — Antioxidant Sensor. Patents under Patent Family N2 are currently either pending or granted in a range of jurisdictions within the Americas, Europe and Australasia. This patent family relates to a device and method for measuring oxidant and antioxidant analytes in a fluid sample. The last of the patents to expire within Patent Family N2 will expire on July 13, 2021.

Patent Family N3 — Haemoglobin Sensor. Patents under Patent Family N3 are currently either pending or granted in a range of jurisdictions within the Americas, Europe and Australasia. This patent family relates to relates to a device and method for measuring haemoglobin in a fluid sample, such as whole blood. The last of the patents to expire within Patent Family N3 will expire on July 12, 2021.

Patent Family N4 — Immunosensor. Patents under Patent Family N4 are currently either pending or granted in a range of jurisdictions within the Americas, Europe 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 Australasia. 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 Australasia. 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 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 Australasia. 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 pending in a range of jurisdictions within the Americas, Europe and Australasia.

Patent Application T — Method and Apparatus for Rapid Electrochemical Analysis. This patent application relates to an improved method and apparatus for electrochemical analysis. The Unpublished 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. This patent application relates to methods and apparatus for determining analyte concentrations in a rapid and accurate manner. The unpublished United States Patent Application was filed on March 31, 2006.

Patent Application V — Systems and Methods for Discriminating Control Solution from a Physiological Sample. This patent application relates to systems and methods for discriminating between a control solution and a blood sample. The unpublished United States Patent Application was filed on March 31, 2006.

Patent Application W — Biosensor Apparatus and Methods of Use. The unpublished United States Patent Application was filed on November 21, 2005.

Patent Application X — Systems and Methods of Discriminating Control Solution from a Physiological Sample. The United States Provisional Patent Application was filed on September 28, 2007.

Patent Application Y — System and Method for Measuring Analyte in a Sample. The United States Provisional Patent Application was filed on January 17, 2008.

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 licensed patent applications. In the event that LifeScan elects not to proceed with the prosecution of a patent application, 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 licensed patents in all agreed jurisdictions. In the event LifeScan discontinues such maintenance payments, we may maintain the licensed patent solely at our own expense. In March 2009, we received notice from LifeScan that it intends to discontinue the prosecution and/ or maintenance of: (a) all the license patents and patent applications in a limited number of jurisdictions as to which we have advised LifeScan that we do not intend to pursue prosecution and/ or maintenance of any of the patents or patent applications in these limited jurisdictions; and (b) certain patents and patent applications listed in the notice. The determination as to whether we will assume the prosecution and maintenance of any such patents or patent applications in some or all of the relevant jurisdictions is still under consideration. We will prosecute and maintain such patents where appropriate to attempt to protect our rights in our proprietary technologies.

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

Our tests in development have not been approved for marketing or sale by any regulatory authorities and as such have not been sold in any jurisdiction. However, if approved for sale, we do not expect sales of the diagnostic tests in development to be materially impacted by seasonality.

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

We currently undertake research and development activities and only hold limited inventory. If LifeScan is successful in obtaining regulatory clearances for a blood glucose product, we will be required to satisfy our contractual obligations with respect to inventory and the supply of tests as agreed in the Master Services and Supply Agreement. The Master Services and Supply Agreement sets outs 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, 2008	2008	2007	2006
	A$	A$	A$	A$
Revenue from services	3,121,754	3,121,754	—	—
Research and development income	13,077,964	1,170,190	1,192,015	2,654,280
Interest income	4,599,033	2,542,060	1,440,102	443,769
Fee income	1,131,222	1,131,222	—	—
Total income	21,929,973	7,965,226	2,632,117	3,098,049
Income from LifeScan as a % of total income	79%	68%	45%	86%

We expect that we will receive in the order of A$1,443,418 under the Development and Research Agreement for the fiscal year ending December 31, 2009. 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 January 2008, LifeScan paid us a one-time fee of A$1,131,222 in connection with the Master Services and Supply Agreement. In February 2009 we received A$3,087,849 in connection with the provision by us to LifeScan of certain manufacturing support services. The Master Services and Supply Agreement provides that we may receive milestone payments and revenue in connection with the original initial blood glucose monitoring product. LifeScan has made the decision not to proceed with regulatory approval of this original initial blood glucose monitoring product. However, if we are successful at negotiating amendments to the Master Services and Supply Agreement and if a blood glucose monitoring test is launched to market and is successful and we manufacture blood glucose test strips for LifeScan, we will become increasingly dependent

on LifeScan for milestone payments 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 the non-glucose tests we are developing 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 Australian grant and A$280,000 under a grant from the State of Victoria, Australia. The Commonwealth of Australia and the State of Victoria may terminate their respective grant agreements 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

While our diagnostic tests are designed to be carried out at the point-of-care, most in vitro diagnostic tests are still carried out in hospitals and pathology laboratories, particularly in circumstances where a suitable technology does not exist for the tests to be undertaken at the point-of-care or where performing the tests or interpretation of the results is complicated and requires specialized healthcare personnel. For example, immunoassay testing still predominantly requires testing in a central pathology laboratory and interpretation of results by a healthcare professional. Our primary competitors with respect to our C-reactive protein test, prothrombin time test and D-dimer test are, and will likely remain, hospitals and pathology laboratories.

We will face competition from approved and marketed products as well as products in development, for both the central laboratory environment and for point-of-care settings. We expect our C-reactive protein test will compete primarily with pathology laboratories as testing for C-reactive protein in pathology laboratories is a well established practice and the results of any testing C-reactive protein testing must be interpreted by healthcare professionals. In pathology laboratories, automated testing for C-reactive protein is the most common modality, and all the major competitors in the sector provide reagents that run on automated analyzers. These companies include Dade Behring Holdings, Inc. (now a part of 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 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 also 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.

The majority of prothrombin time testing is conducted by pathology laboratories or specialist clinics and our prothrombin time test will compete with the tests used in these settings. In the self-test segment, two large, well established companies, Roche Holding Ltd and Thoratec Corporation (through its wholly owned subsidiary International Technidyne Corporation), have greater than 90% of world wide sales of prothrombin time patient self-testing. Both companies have significant resources they can bring to bear. Other smaller technology companies such as Hemosense, Inc. (now a part of Inverness Medical Innovations) are dedicated specifically to addressing this market. Furthermore, a number of large drug companies are actively developing new classes of oral anticoagulant, which may not need monitoring. Although it is unknown if they will be approved or favorably reimbursed, or perform as well as warfarin, they have the potential to significantly limit or render obsolete the current prothrombin time market, should they be approved.

We expect our D-dimer test will compete primarily with pathology laboratories as testing for D-dimer in pathology laboratories is a well established practice and the results of any D-dimer testing must be interpreted by healthcare professionals. In pathology laboratories, automated testing for D-dimer is the most common modality, and all the major competitors in the hemostasis segment of the in vitro diagnostics market provide reagents that run on automated analyzers. These companies include Dade Behring Holdings, Inc. (now a part of Siemens AG), Roche Holding Ltd, Instrumentation Laboratory, Diagnostica Stago and Biomerieux. 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 that our D-dimer 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 also expect our D-dimer test to compete with existing point-of-care technologies from competitors such as Biosite Diagnostics (now part of Inverness Medical Innovations).

Under the Master Services and Supply Agreement we agreed upon the terms pursuant to which we would be a non-exclusive manufacturer of the original initial blood glucose tests we developed for LifeScan. We are seeking to negotiate comparable non-exclusive manufacturing rights with respect to the enhanced initial blood glucose test. 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. There is a risk that our manufacturing costs may not be able to compete with the cost at which LifeScan or LifeScan's other contract manufacturers may be able to manufacture the blood glucose products which we develop. If we are not able to agree on suitable amendments to the Master Services and Supply Agreement, we will not generate revenue from the manufacture of initial blood glucose tests strips and some of the manufacturing equipment we have acquired may need to be redeployed to other programs.

Employees

At March 25, 2009 we had 80 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, manufacture and commercialization of in vitro diagnostic test devices for 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.

There is no guarantee that we will be able to successfully complete commercial negotiations for the amendment to our Master Services and Supply Agreement with LifeScan on acceptable terms or at all.

In February 2009, we announced that LifeScan had chosen not to proceed with the development of the initial blood glucose test strip that we develop but instead wished to proceed with the development of an enhanced blood glucose strip. We are in discussions with LifeScan with respect to the commercial terms for the development and manufacture of the enhanced blood glucose strip and the resulting amendments required to our Master Services and Supply Agreement with LifeScan. However, there is no guarantee that we will be able to successfully negotiate amendments to the Master Services and Supply Agreement, on acceptable terms or at all and the receipt and timing of any further revenues under the Master Services and Supply Agreement is uncertain. Although the existing Master Services and Supply Agreement provides a general framework within which we operate with LifeScan, failure to agree upon the commercial terms upon which we will develop and manufacture the enhanced initial blood glucose product will mean that we would not derive any revenues from any commercialization of that blood glucose test and, as a result, significant monies invested and management time spent with respect to both the original initial blood glucose test and the enhanced initial blood glucose tests may be rendered unproductive and worthless. In this event, we will need to revise our business plans and focus on the development of our own products. Any such failure may also be perceived negatively by investors and may have an adverse affect on our financial position, the value of our shares and the trading price of our securities.

Adverse economic conditions may harm our business.

Market and economic conditions have recently become more 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 the spending patterns of users of test strips we are developing and the financial condition of our commercial partner LifeScan. This may adversely impact on the demand for our products and services. The economic conditions may reduce the likelihood that LifeScan launches one of the products we develop for them and, if launched, may result in LifeScan, delaying or reducing the amount of product it purchases from us. We cannot accurately predict future levels of demand for the blood glucose tests we develop for LifeScan. 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.

LifeScan has the sole rights to commercialize the blood glucose products we develop with them.

Pursuant to the terms of our License Agreement with LifeScan, Inc., LifeScan has the sole rights to commercialize the blood glucose products which we develop with LifeScan. LifeScan controls the decision whether or not to launch the 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. If we are successful in negotiating amendments to the Master Services and Supply Agreement, decisions made by LifeScan with respect to the commercialization of the blood glucose products affect the

extent and timing of revenues to us under that agreement. LifeScan may choose not to launch 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. By way of example, we have previously undertaken work for LifeScan in connection with an original version of the initial glucose test strip which LifeScan has chosen not to commercialize. We are seeking to negotiate amendments to the Master Services and Supply Agree to reflect this change and are now developing an enhanced version of that test.

There is no guarantee that we will receive the inflows contemplated under the Master Services and Supply Agreement, in a timely fashion or at all.

In January 2008, LifeScan paid us a one-time fee of A$1,131,222 in connection with the Master Services and Supply Agreement. In February 2009, LifeScan paid us an additional A$3,087,849 under the Master Services and Supply Agreement for providing manufacturing process support services to LifeScan. The Master Services and Supply Agreement provides that we would receive a total of up to three milestones on the achievement of regulatory approval for the original version of the initial blood glucose test in three jurisdictions, services fees calculated with reference to the number of blood glucose strips sold by LifeScan and fees for the manufacture of blood glucose test strips by us. LifeScan controls the regulatory strategy with respect to the initial blood glucose test. LifeScan has decided not to seek regulatory approval for this original initial blood glucose test and the milestone payment is therefore unlikely to be forthcoming.

In the event that we are successful in negotiating amendments to the Master Services and Supply Agreement to reflect the change of product, if regulatory approval of the enhanced initial blood glucose monitoring product is not obtained in a timely fashion or at all, payment to us under the Master Services and Supply Agreement will be delayed or eliminated. Likewise, if regulatory approval is obtained but the launch is delayed or LifeScan chooses not to launch or chooses only to launch in a limited number of jurisdictions, our payments to us under the Master Services and Supply Agreement may be delayed, reduced or eliminated any of which would have a material adverse effect on us.

Our products and the blood glucose products we develop with LifeScan, even if approved by foreign regulatory agencies and launched may not be accepted by customers.

Success of our products and the products we develop with LifeScan are ultimately dependent on the market acceptance and level of sales of those products. Our ability to become profitable or maintain profitability in the future will be adversely affected if any of the products we develop with LifeScan, after receiving regulatory approval, fail to achieve or maintain market acceptance. If our products are not successful in the market place, our revenues from sales of those products will be reduced or eliminated. Likewise, if the blood glucose products we develop with LifeScan are launched but are not successful in the market place, our revenues from services fees and strip manufacturing fees 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.

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.

We have not yet manufactured commercial quantities of blood glucose tests strips or of any of our other products.

We currently operate manufacturing facilities in Melbourne, Australia. Although we have manufactured clinical trial quantities of blood glucose test strips for an initial product, we have not yet manufactured commercial quantities of any product. 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 or other problems that could seriously harm our business. We will be subject to ongoing inspections and regulation by regulatory authorities, including by the Australian Therapeutic Goods Administration ("TGA") and the Food and Drug Administration ("FDA").

We face the risk of product liability claims

We may be exposed to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of diagnostic tests. This may relate to our own products or the products which we developed with LifeScan. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation and the reputation of our commercial partners;
- costs of related litigation;
- management's attention 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; and
- the inability to commercialize our products.

We intend to seek appropriate product liability insurance. However, we may not be able to secure and 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. Any claim for damages against us could be substantial. If we are not able to obtain adequate coverage at a reasonable cost, the commercialization of our products may be delayed or severely compromised. We have liabilities 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 tests strips.

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

We may be exposed to product recalls and adverse public relations 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. In addition, in the event of any recall, corrective action or field action with respect to blood glucose products developed by us for LifeScan, to the extent such recall or action it is attributable to a breach by us of any of our warranties, representations, obligations or covenants contained in the Master Services and Supply Agreement or our negligence or wilful misconduct, we are 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 of the products we have developed could result in substantial and unexpected expenditures, which would reduce operating profit and cash flow. In addition, a product recall may divert significant management attention. Product recalls may damage the value of our or our commercial partners'

brands and lead to decreased demand for the products we have developed. Product recalls may also lead to increased scrutiny by regulatory agencies and increased litigation.

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

There is a risk that product development of the enhanced initial blood glucose test will be delayed or that development work and product validation will not be successful. The development of our C-reactive protein (and our immunoassay platform of tests generally), prothrombin time and D-dimer 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. We have undertaken in excess of four years of development work with respect to both our C-reactive protein test and our prothrombin time test and have developed a working prototype of both tests. We expect the development program for these tests to enter the validation phase in 2009 and are targeting market entry for these products in 2010. The validation phase comprises the largest body of work of a development program and technical failures are still possible. Work may need to be repeated or further development work may need to be done. Unforeseen costs and time delays may be encountered as a consequence. Even up to the point of regulatory filing issues may arise, and there is no guarantee that work will complete sufficient to support a regulatory filing. We commenced work on our D-dimer test in 2008. We still need to undertake a significant amount of technical risk reduction and product development of this test. Each 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 our initial blood glucose products is well advanced, there remains a degree of development risk with those products. Additionally, we may agree to develop new products with LifeScan under our Master Services and Supply Agreement. 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 of the relevant product. As a result, significant monies invested and management time may be rendered unproductive and worthless.

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. Specifically in relation to the blood glucose products we develop, LifeScan is responsible for determining the commercialization strategy and is responsible for obtaining all necessary regulatory clearances. Even if we are successful in negotiating amendments to the Master Services and Supply Agreement to reflect the change of product, if LifeScan is unable to obtain the necessary clearances to sell or if the clearances are delayed, revoked or subject to unacceptable conditions, we would not receive payments under the Master Services and Supply Agreement which would have a material adverse effect on us. With respect to our own point-of-care tests, if we are unable to obtain the necessary clearances to sell or if the clearances are delayed, revoked or subject to unacceptable conditions, we may not be in a position to commercialize our products, 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 our products or the products we develop for LifeScan, ourselves 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 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.

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, 100% 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.

Prior to December 31, 2007, we did not hedge the effect of currency fluctuations on our overseas expenditures. 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 loses from un-hedged currency fluctuations, which could be significant.

Increases in our costs to manufacturing products for LifeScan may decrease our revenues 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 original initial blood glucose test strip we have developed for LifeScan. The commercial arrangement for the enhanced initial product and other products we develop with LifeScan may likewise include a cap on the amount we can charge for the manufacture of strips. Our net income will decrease if our manufacturing costs increase or are in excess of what we have anticipated. In the event we are successful in negotiating amendments to the Master Services and Supply Agreement, 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 and Services and Supply Agreement provides a mechanism whereby the issue can be referred to a 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.

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

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. Additionally, we may need to undertake clinical trials for market acceptance purposes. 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. Any unanticipated costs or delays in our clinical trial could cause us to expend substantial additional funds or 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 indication or that marketing authorization may not be granted in the future. If we 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.

There is a risk that we will not be able to enter into collaborative arrangements or strategic alliances with respect to our products. To the extent we are able to enter into collaborative arrangements or strategic alliances, we will be exposed to risks related to those collaborations and alliances.

Our business strategy with respect to the commercialization of our C-reactive protein, prothrombin time and D-dimer tests is based in part upon entering into collaborative arrangements or strategic alliances with other life sciences companies or other industry participants to complete the development and commercialization of those products and enable us to maintain our financial and operational capacity. To date, all of our revenue has been generated through our collaboration with LifeScan. With respect to our C-reactive protein, prothrombin time and D-dimer tests, there is a risk we may not be able to enter into additional such 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 commercialization efforts or liquidate some or all of our assets. As a result, significant monies invested and management time may be rendered unproductive and worthless.

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 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.

The failure to secure adequate supplies of the materials required to manufacture our products and the products we develop with LifeScan could compromise the commercialization of our products and our manufacture of blood glucose products for LifeScan.

In common with most major manufacturers in our industry, certain components of our products and the products we have developed with LifeScan come from preferred suppliers. These are established companies and we expect to have reliable supply. 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.

We currently have limited manufacturing capacity for meters and outsource some development and manufacturing activities which place us at risk of lengthy and costly delays of bringing our products to market.

We currently outsource some development and manufacturing activities with respect to the meters for our 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. 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 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.

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 manufacture 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 is limited and we may not be able to negotiate agreements with manufacturers on commercially reasonable terms, the complex nature of the meters, which may require a significant learning curve for the manufacturer, and the FDA must 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 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 experience significant fluctuations in our operating results.

We may experience significant fluctuations in our operating results for the foreseeable future. These fluctuations are due to a number of factors, many of which are outside of our control, and may result in volatility of our stock price. Future operating results will depend on many factors, including:

- our ability to finalize negotiations with LifeScan with respect to amendments to the Master Services and Supply Agreement to reflect the change of product focus from the original initial blood glucose test strips to an enhanced initial blood glucose test strip;
- the decision of LifeScan to seek regulatory approval and to launch the enhanced initial blood glucose product and future products we develop for them;
- if launched, the market acceptance of the enhanced initial blood glucose product we develop with LifeScan;
- the timing of receipt from LifeScan of any milestone payment;
- our ability to manufacture sufficient quality and quantity of the enhanced initial blood glucose products for LifeScan;
- LifeScan deciding to launch the enhanced initial blood glucose product and the number of blood glucose products ordered from us by LifeScan and the extent to which LifeScan manufactures or utilizes other third party manufacturers to manufacture blood glucose products;
- our manufacturing costs;
- achievement and timing of research and development milestones;
- cost and timing of clinical trials and regulatory approvals for our products;
- the timing of the introduction and market acceptance of our products;

- marketing and other expenses;
- manufacturing or supply disruptions;
- the timing of the introduction and market acceptance of new products by us or competing companies;
- the timing and magnitude of certain research and development expenses; and
- general market conditions including without limitation changes in foreign currency and inflation.

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 our 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.

We do not currently have any 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. To date, we do not have, and may never have, any products that generate revenues. In addition, none of the products we have developed for LifeScan have received regulatory approval and therefore we have not received any milestone payments from LifeScan payable on achievement of regulatory approval and have not received any revenue for manufacturing blood glucose strips for LifeScan. To date, we have funded our operations through the issue of shares, from payments received under the Development and Research Agreement, an initial one-time payment from LifeScan in January 2008 of A$1,131,222 and a payment in February 2009 of A$3,087,849 under the Master Services and Supply Agreement and from government and state grants received by Universal Biosensors Pty Ltd.

With the exception of the first year of our operations when we made a small profit of A$130,134, we have incurred net losses since our inception. We recognized a net loss of A$2,955,661, A$8,817,238 and A$11,995,886 in the years ended December 31, 2006, 2007 and 2008, respectively. Our accumulated losses from inception to December 31, 2008 are A$24,353,151. 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:

- our ability to finalize negotiations with LifeScan with respect to amendments to the Master Services and Supply Agreement to reflect the change of product focus from the original initial blood glucose tests strips to an enhanced initial blood glucose test strip;
- our ability to complete product development and validation activities for the enhanced initial blood glucose test strips;
- our ability to perform the required services under the Master Services and Supply Agreement;
- the successful registration by LifeScan of blood glucose products we develop in the major target markets;
- LifeScan determining to launch the enhanced initial blood glucose product and future blood glucose products we develop for them;

- successful market acceptance and the success of sales and marketing efforts of the blood glucose products we develop with LifeScan;
- our ability to manufacture a sufficient quantity and quality of blood glucose test strips;
- 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;
- 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 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;
- our ability to enter into collaborative, licensing and other arrangements that we may establish and the terms and conditions of any such arrangements;
- the timing and success 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;
- our capacity to manufacture the necessary quality and quantities of our products;
- development of the C-reactive protein and prothrombin time tests markets which may not occur as we expect;
- successful market acceptance and the success of sales and marketing efforts of our products 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, developing, marketing and selling 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.

Because of the numerous risks and uncertainties associated with the development, manufacture, sales and marketing of point-of-care test, we may experience larger than expected future losses and may never become profitable. If we fail to become and remain profitable, or if we are unable to fund our continuing losses, the holders of our shares could lose all or part of their investment.

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. However, the Development and Research Agreement may be terminated either for cause or with nine months notice prior to the end of each rolling one year period. If terminated, we would lose a source of income.

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 is targeted at both the existing and emerging point-of-care testing market. We cannot be sure that this market will grow as we anticipate. Such growth will require continued support and demand from payers, patients and health care professionals and the endorsement by professional bodies that influence the practice of medicine. With respect to our own products, future 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, our business anticipated growth will be adversely affected and our results will suffer.

The degree of market acceptance of any of our approved products will depend on a variety of factors, including:

- timing of market introduction and the number and clinical profile of competitive products;
- our ability to secure the support of key clinicians and physicians for our 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 our 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 results will be adversely affected.

The use of C-reactive protein as a marker for inflammatory conditions is not yet widely accepted. 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 performance of our point-of-care tests may not be perceived as being comparable with established laboratory methods, which may limit the market acceptance of our product.

The majority of C-reactive protein, prothrombin time and D-dimer testing has, and continues to be, performed by large hospitals or commercial pathology laboratories. Healthcare professionals who are responsible for managing patients with an inflammatory disease or patients who are on warfarin therapy have experience with, and confidence in, the results generated by these hospitals and pathology laboratories. 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.

LifeScan may undertake more of its own manufacturing of the blood glucose products which we have developed or may use other contract manufacturers.

Under the Master Services and Supply Agreement, we agreed to terms pursuant to which we would have been a non- exclusive manufacturer of the original initial blood glucose tests we developed for LifeScan. We are seeking to negotiate comparable non-exclusive manufacturing rights with respect to the enhanced initial blood glucose test and may seek rights to negotiate any future blood glucose products we develop 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. There is a risk that our manufacturing costs may not be able to compete with the cost at which LifeScan or LifeScan's other contract manufacturers may be able to manufacture the blood glucose products which we develop. 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.

We operate in a highly competitive market and face competition from large, well-established medical device manufacturers with significant resources. If we fail to compete effectively, our business will suffer.

The market for point-of-care C-reactive protein testing, prothrombin time testing and blood glucose testing is intensely competitive, 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, our products may become less useful or obsolete and our operating results will suffer. Because our products have long development and government approval cycles, we must anticipate changes in the market place and the direction of technological innovation and customer demands. We may be unable to accurately anticipate changes in our markets and the direction of technological innovation and the demands of our customers, our competitors may develop improved technologies or the market place may conclude that our products are obsolete. Any developments adversely affecting the markets for our products 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 our products, or if more effective technologies are introduced, our business will suffer.

Our 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 will face competition from approved and marketed products as well as products in development. There can be no assurances given in respect of our ability to compete in the competitive markets in which we operate.

For our C-reactive protein test, prothrombin time test and other point-of-care tests that we develop, we will need to compete with testing undertaken in laboratories which are a well established practice. In pathology laboratories, all the major competitors in the sector provide reagents that run on automated analyzers. Companies providing a C-reactive protein reagent to run on automated analyzers include Dade Behring Holdings, Inc. (now a part of 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. Companies providing a prothrombin time test reagent to run on automated analyzers include Dade Behring Holdings, Inc. (now a part of Siemens AG), Roche Holding Ltd and Diagnostica Stago. To compete against established practice, we will need to show that our C-reactive protein and prothrombin time tests are an effective and time and cost saving alternative. We also expect our C-reactive protein and prothrombin time tests to compete with existing point-of-care technologies from competitors such as Inverness Medical Innovations, Orion Corporation, Axis-Shield plc and International Technidyne. Even if we can show competitive product advantages, customers may be resistant to changing their supplier.

With regard to prothrombin time testing, a number of large drug companies are actively developing a new class of oral anticoagulant (direct thrombin inhibitors), which may not need monitoring. Although it is unknown if they will be approved or favorably reimbursed, or perform as well as warfarin, or whether they will need some form of monitoring, they have the potential to significantly limit the current prothrombin time market.

With regard to D-dimer testing a number of companies provide reagents which run on automated analyzers. These companies include Dade Behring Holdings, Inc. (now a part of Siemens AG), Roche Holding Ltd, Biomerieux, Instrumentation Laboratory and Diagnostica Stago. We also expect our D-dimer product to compete with existing point-of-care technologies from competitors such as Inverness Medical Innovations. Even if we can show competitive product advantages, customers may be resistant to changing their supplier.

Additionally, these and other 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 in development. All of these companies are larger than we and 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.

We may not be able to compete effectively against these companies or their products and, if we fail to do so, our business will be harmed. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are more effective, are more convenient, are less expensive, that reach the market sooner than our products or that are otherwise preferred over our products. Developments by our competitors may render our C-reactive protein and prothrombin time tests and any other future products we may 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 our products obtain regulatory clearances, but do not compete effectively in the marketplace, our business will suffer.

If our competitors or LifeScan's competitors are able to develop and market products that are preferred over the products we develop, our commercial opportunity may be significantly reduced or eliminated.

We face competition with respect to our products and LifeScan faces competition with respect to blood glucose products we develop for them, from established life sciences and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. We are seeking to develop and market products that will compete with other products that currently exist or are being developed or may be developed in the future.

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 our products 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.

Many of our competitors currently 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.

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. 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. 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.

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 25, 2009, the closing price per share of our shares ranged from a low of A$0.41 during February 2009 to a high of A$1.78 during the fourth quarter of the 2007 fiscal year and was A$0.53 on March 25, 2009. We may experience a material decline in the market price of our shares, 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. These factors include:

- failure to finalize the amendments required to the Master Services and Supply Agreement to reflect the change of product;
- failures or delays with our development programs;
- failures or delays in LifeScan launching blood glucose products we develop with them;
- unforeseen safety issues or adverse side effects resulting from the commercial use of any of the products we develop or are involved in developing;
- regulatory actions in respect of any of our products, any of the products we are involved in developing with LifeScan or the products of any of our competitors;
- failure or delay of any of our products or any of the products we have developed with LifeScan obtaining regulatory authorizations in our key markets or limitations on the indications or other conditions on any regulatory authorizations given;
- failure of any of our products or the products we have developed with LifeScan (if approved and launched) to achieve commercial success;
- announcements of the introduction of new products by us or our competitors;
- announcements by regulatory authorities in relation to our products or the products we develop for LifeScan;

- market conditions, including market conditions in the medical diagnostic and life sciences and biotechnology sectors;
- increases in our costs or decreases in our revenues due to unfavorable movements in foreign currency exchange rates;
- developments or litigation concerning patents, licenses and other intellectual property rights;
- litigation or public concern about the safety of our potential products;
- changes in recommendations or earnings estimates by securities analysts;
- actual and anticipated fluctuations in our quarterly operating results;
- deviations in our operating results from the estimates of securities analysts;
- rumors relating to us or our competitors;
- additions or departures of key personnel; and
- developments concerning current or future strategic alliances or acquisitions.

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 2009, 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.

Because our shares are relatively illiquid, a single stockholder 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, Kiefel 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, Kiefel and Dr Adam are directors, holds approximately 9% of our shares. Messrs Denver, Hanley, Kiefel and Dr Adam's interest in the issued shares (excluding options) of PFM Cornerstone Ltd are approximately 2%, 3%, 5% and 2% respectively. Mr. Andrew Jane is one of our directors and a partner 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. Legal title is held by CHESS 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 an acquisition of us, 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.*

We occupied premises at 103 Ricketts Road, Mt Waverley in Melbourne, Australia from August 2002 until the expiration of the lease of those premises on September 6, 2007. Universal Biosensors Pty Ltd now 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 new 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 intend to manufacture the disposable test strips for each of our existing and future point-of-care tests using our own custom manufacturing equipment. Our manufacturing equipment is based on pilot manufacturing equipment developed and tested by our scientists and engineers. We expended approximately A$4,813,073, A$9,058,265 and A$9,594,920 in the years ended December 31, 2006, 2007 and 2008, respectively in relation to the acquisition of manufacturing equipment and upgrading our manufacturing facility. In the period December 31, 2008 to March 25, 2009, we have committed an additional A$3,000,000 to the acquisition of additional manufacturing equipment.

Depending on the specific point-of-care test and 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. We expect that with minor modifications, the manufacturing equipment we already have would be suitable for the commercial manufacture of the strips for all of the tests currently being developed by us and, given the nature of the technologies, is likely to be able to be used for any future tests that we may develop.

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. *SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.*

No matters were submitted to a vote of our stockholders during the fourth quarter of our fiscal year ended December 31, 2008.

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. The main difference between holding CDIs and holding the underlying securities (in this case our shares) is that a holder of CDIs has beneficial ownership of the equivalent number of our shares instead of legal title. Legal title is held by CHESS Depositary Nominees Pty Ltd, or CDN, and the shares are registered in the name of CDN and held by CDN on behalf of and for the benefit of the holders of CDIs. CDN is a wholly owned subsidiary of ASX.

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

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 since December 13, 2006, the date on which the our CDIs were quoted thereon.

	High A$	Low A$
Fiscal Year 2006		
Fourth Quarter (December 13, 2006 to December 31, 2006)	A$1.45	A$0.81
Fiscal Year 2007		
First Quarter	A$1.74	A$1.00
Second Quarter	A$1.55	A$0.96
Third Quarter	A$1.52	A$1.12
Fourth Quarter	A$1.78	A$1.18
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

Security details

As of March 25, 2009, there were 156,976,936 shares of our common stock issued and outstanding and 6,527,284 employee options over an equivalent number of shares of common stock (4,498,899 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.

Holders

Currently, CDN holds all of our shares on behalf of and for the benefit of the holders of CDIs. Set out below is the number of our registered holders of CDIs at specific dates:

Date	Total Number of Registered Holders	Number of Holders that are United States Residents
At March 25, 2009	1,114	10

Dividends

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

Securities authorized for issuance under equity compensation plans

Set out below are details of our Employee Option Plan as at December 31, 2008.

Equity Compensation Plan Information

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining for Future Issuance
Equity compensation plans approved by security holders	6,373,284	A$0.66	(1)
Equity compensation plans not approved by security holders	—	—	(1)
Total	6,373,284	A$0.66	

(1) The number of employee options able to be granted is limited to the amount permitted to be granted at law, the ASX Listing Rules and by the limits on our authorized share capital in our certificate of incorporation. The Listing Rules of ASX generally prohibit companies whose securities are quoted on the ASX from issuing securities exceeding 15% of issued share capital in any 12 month period, without stockholder approval.

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

During 2008, with the exception of employee stock options exercised, there were no other equity securities sold by us.

The table below sets forth the number of employee stock options exercised and the number of shares issued in the period from January 1, 2008 to December 31, 2008. We issued these shares in reliance upon exemptions from registration under Regulation S under the Securities Act of 1933, as amended.

Period Ending	Number of Options Exercised and Corresponding Number of Shares Issued	Option Exercise Price	Proceeds Received
May, 2008	18,124	A$0.35	$5,047

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.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

There were no repurchases of equity securities in 2008.

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, 2006, 2007 and 2008 and the period from inception to December 31, 2008 has been derived from our consolidated audited financial statements, included elsewhere herein. The selected financial data for the fiscal years ended December 31, 2004 and 2005 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, 2008	Years Ended December 31,				
	A$	2008	2007	2006	2005	2004
	A$	A$	A$	A$	A$	A$
Revenue						
Revenue from products	$ —	$ —	$ —	$ —	$ —	$ —
Revenue from services	3,121,754	3,121,754	—	—	—	—
Total revenue from ordinary activities	3,121,754	3,121,754	—	—	—	—
Costs of revenues						
Cost of goods sold	—	—	—	—	—	—
Cost of services	3,121,754	3,121,754	—	—	—	—
Total costs of revenues	3,121,754	3,121,754	—	—	—	—
Gross profit	—	—	—	—	—	—
Operating expenses						
Research and development (1 and 2)	28,916,019	11,585,258	7,157,216	3,466,604	2,086,824	2,127,078
General and administrative(3)	14,362,764	5,510,127	4,226,757	2,511,182	922,088	534,709
Total operating expenses	43,278,783	17,095,385	11,383,973	5,977,786	3,008,912	2,661,787
Research and development income	13,077,964	1,170,190	1,192,015	2,654,280	2,757,817	2,372,128
Loss from operations	(30,200,819)	(15,925,195)	(10,191,958)	(3,323,506)	(251,095)	(289,659)
Other income/(expense)						
Interest income	4,599,033	2,542,060	1,440,102	443,769	128,282	30,197
Interest expense	(9,489)	(9,489)	—	—		—
Fee income	1,131,222	1,131,222	—	—		
Other	144,696	265,310	(210,382)	87,076	(6,147)	90,793
Total other income/(expense)	5,865,462	3,929,103	1,229,720	530,845	122,135	120,990
Net loss before tax	(24,335,357)	(11,996,092)	(8,962,238)	(2,792,661)	(128,960)	(168,669)
Income tax benefit/(expense)	(17,794)	206	145,000	(163,000)	—	—
Net loss	$(24,353,151)	$(11,995,886)	$ (8,817,238)	$(2,955,661)	$ (128,960)	$ (168,669)
Basic and diluted net loss per share	$ (0.35)	$ (0.08)	$ (0.07)	$ (0.06)	$ —	$ —
Average weighted number of shares outstanding during the period	70,523,954	156,970,679	129,637,286	49,408,822	43,573,580	43,533,269

Notes:

1. Net of research grant income in these amounts	$2,366,063	$300,613	$872,513	$578,653	$614,284	$—
2. Includes non-cash compensation expense (research and development)	$1,148,752	$661,497	$339,882	$147,373	$ —	$—
3. Includes non-cash compensation expense (general and administrative)	$ 851,138	$299,611	$277,833	$273,694	$ —	$—

	Years Ended December 31,				
	2008	2007	2006	2005	2004
	A$	A$	A$	A$	A$
Balance Sheet Data:					
Cash and cash equivalents	28,334,864	41,958,285	30,184,756	4,434,274	4,140,496
Total assets	52,505,321	63,512,160	37,879,601	6,203,277	5,888,264
Long-term debt	—	—	—	—	—
Convertible preference shares(1)	—	—	—	3,000,000	3,000,000
Total stockholders' (deficit) equity	48,703,230	59,749,624	35,281,927	5,683,519	5,555,338

(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 development, manufacture and commercialization of in vitro diagnostic test devices for point-of-care use. In vitro diagnostic testing involves the testing outside of the body of a body fluid (e.g. blood or saliva) or tissue sample (biopsies or swabs). The diagnostic blood test devices we are developing comprise a novel disposable test strip and a reusable meter. The devices are designed to be used near to or at the site of 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, an affiliate of Johnson & Johnson.

We are developing an immunoassay point-of-care test to measure the amount of C-reactive protein in the blood. A C-reactive protein test may be used to assist in the diagnosis and management of inflammatory conditions. We are also developing a prothrombin time test for monitoring the therapeutic range of the

anticoagulant, warfarin and have also started 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.

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 in connection with the Development and Research Agreement, an initial payment under the Master Services and Supply Agreement received in January 2008 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 act as a non-exclusive manufacturer of an original version of the initial 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. In February 2009, we announced that LifeScan had chosen not to proceed with the registration of the original initial blood glucose test strips but instead wished to proceed with the development of an enhanced initial blood glucose test strip. The enhanced initial blood glucose test strip is based on the same technology as the original product and would be manufactured using the same production processes and manufacturing equipment and infrastructure. We are in discussions with LifeScan with respect to the commercial terms for the development and manufacture of the enhanced initial blood glucose test strips and the consequent amendments to the Master Services and Supply Agreement. 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.

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 receive a license to such intellectual property outside of the LifeScan field of diabetes and blood glucose management generally. The scope of the program under the Development and Research Agreement was also expanded to include development work in connection with a blood glucose meter.

In consideration of undertaking the development and research, LifeScan makes quarterly payments to us. From April 2002 to December 31, 2008, we have received aggregate contract research funding from LifeScan of A$13,077,964. We received A$2,654,280, A$1,192,015 and A$1,170,190 in 2006, 2007 and 2008, respectively. The Development and Research Agreement automatically renews for successive one year periods 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. 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 A$578,653, A$872,513 and A$300,613 in the fiscal years ended December 31, 2006, 2007, 2008 and A$2,366,063 from inception to December 31, 2008, 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 Nil, A$130,000 and A$150,000 in the fiscal years ended December 31, 2006, 2007, 2008 and A$280,000 from inception to December 31, 2008, 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 Statement of Financial Accounting Standards No. 123(R), Accounting for Stock-Based Compensation (“SFAS 123(R)”).

Each of the inputs to the Trinomial Lattice model which is the equivalent of the Black-Scholes pricing model is discussed below.

Share price at valuation date

We have applied the Trinomial Lattice model which is the equivalent of the Black-Scholes pricing model in order to value our options.

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 us around the respective valuation dates of the options, as these prices are most indicative of the fair value of our 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.

Date of Capital Raising	Value per Preferred Stock (Post Stock Split Described Elsewhere in This Form 10-K)
	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 in 2007 was determined using the closing price of our common stock trading in the form of CDIs on the 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 us 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 Rule 6.22 of 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:

	Pre Rights Offering		Post Rights Offering	
Grant Date of Option	Exercise Price	Fair Value of Option	Exercise Price	Fair Value of Option
	A$	A$	A$	A$
December 2003	0.39	0.11	0.30	0.11
January 2006	0.45	0.30	0.35	0.27
March 2007	1.25	0.78	1.18	0.79
September 2007	1.27	0.77	1.20	0.78
October 2007	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 the ASX on December 13, 2006 with an initial offering price of A$0.50. The share price at valuation date was as follows:

Option Grant Date	Share Price	Volatility
	A$	
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%

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

Time to expiry

All options granted under our share option plan have a 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 Expenditures

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.

Property, Plant and Equipment

Property, plant and equipment are recorded at acquisition cost, less accumulated depreciation and amortization. Depreciation and amortization are calculated on a straight-line basis over the estimated useful lives of the related assets, which are generally three to ten years. Amortization of leasehold improvements is computed using the straight-line method over the shorter of the remaining lease term or the estimated useful life of the related assets. Maintenance and repairs are charged to operations as incurred and include minor corrections and normal services and does not include items of capital nature.

We receive 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 we do not control the monies until the relevant expenditure has been incurred. Grants due to us under the grant agreement are recorded as "Currents Assets" on the balance sheet.

Income Taxes

We apply Statement of Financial Accounting Standards No. 109 — Accounting for Income Taxes (SFAS 109) 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 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.

Asset Retirement Obligations

Asset retirement obligations ("ARO") are legal obligations associated with the retirement and removal of long-lived assets. 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, we capitalize 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. We derecognize 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.

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. Impairment, if any, is measured as the amount by which the carrying amount of the assets exceeds its fair value. Impairment, if any, is assessed using discounted cash flows.

Results for the Year Ended December 31, 2008

Gross Profit on Services Performed

Under the terms of our arrangement with LifeScan, we have 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 Income

We receive research and development revenue 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. Revenue is recognized when services have been performed, the amount of the payment can be reliably measured and collectability is reasonably assured. The recognition of revenue is not based on the completion of any milestones, or on a percentage of completion basis. We recognize revenue for accounting purposes ratably over the annual grant period.

The revenue 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 revenue to a specific expenditure but to a specified period of research. The annual research and development revenue 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.

Research and development income for the fiscal years ended December 31, 2008, 2007 and 2006 were primarily derived from LifeScan under the Development and Research Agreement and totaled A$1,170,190, A$1,192,015 and A$2,654,280, respectively. We expect that we will receive approximately A$1,443,418 under the Development and Research Agreement for the fiscal year ending December 31, 2009.

Research and Development Expenses

Our operating expenses to date have substantially been 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. 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 years ended December 31, 2006, 2007, 2008 and for period from inception to December 31, 2008 are as follows:

	Period from Inception to December 31, 2008	Years Ended December 31,		
		2008	2007	2006
	A$	A$	A$	A$
Research and development expenses	31,282,082	11,885,871	8,029,729	4,045,257
Research grants received recognized against related research and development expenses	(2,366,063)	(300,613)	(872,513)	(578,653)
Research and development expenses as reported	28,916,019	11,585,258	7,157,216	3,466,604

These expenses are related to developing our electrochemical cell platform technologies and producing and testing strips. 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 (refer section on "Gross Profit on Services Performed"). We expect that our expenses will increase significantly during 2009 as we expand our research and development programs and expand our organization and develop a commercial manufacturing capability.

We have not reported our internal historical research and development costs or our personnel and personnel-related costs on a project-by-project basis. Our programs share a substantial amount of our common fixed costs such as facilities, depreciation, utilities and maintenance. Accordingly, we do not track our research and development costs by individual research and development program.

In addition, we expect research and development expenditures to grow as we advance our development programs and explore other commercial opportunities our technology platform can be applied to. 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 if appropriate 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.

As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development programs or when and to what extent we will receive cash inflows from the commercialization and sale of products. Our inability to complete our research and development programs in a timely manner or our failure to enter into collaborative agreements, when appropriate, could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to seek additional, external sources of financing from time to time in order to continue with our strategy. Our inability to raise additional capital on terms reasonably acceptable to us would jeopardize the future success of our business.

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$2,511,182, A$4,226,757 and A$5,510,127 in 2006, 2007 and 2008, 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 Statement No. 123(R), “Share Based Payment”, or SFAS 123(R). The impact of the change in accounting policy applied prospectively resulted in the stock option expense being A$421,067, A$617,715 , A$961,108 and A$1,999,890 for the years ended December 31, 2006, 2007, 2008 and for the period from inception to December 31, 2008.

The following table represents information relating to stock options outstanding under the plans:

Exercise Price A$		Options Outstanding		
		Shares	Weighted Average Remaining Life in Years	Options Exercisable Shares
2006	0.30	1,808,751	7.00	1,772,503
	0.35	2,011,736	9.00	532,838
2007	0.30	1,594,890	6.00	1,594,890
	0.35	1,743,505	8.00	975,058
	1.18	845,000	9.20	281,657
	1.20	663,000	9.70	—
	1.13	100,000	9.80	—
2008	0.30	1,594,890	5.00	1,594,890
	0.35	1,725,394	7.00	1,551,394
	1.18	837,000	8.20	557,890
	1.20	663,000	8.70	220,996
	1.13	—	—	—
	0.89	1,199,000	9.20	399,651
	0.70	354,000	9.60	—

Comparison of the Years Ended December 31, 2008 and 2007

Gross Profit on Services Performed

Under the terms of our arrangement with LifeScan, during 2008 we have 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.

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 to date have substantially been 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$872,513 and A$300,613 received for the R&D Start Grant Program for 2007 and 2008, 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.

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. Our aggregate expenses (cost of services and operating expenses) have increased significantly during 2008 compared to the 2007 financial year. Subject to agreement on amendments to the Master Services and Supply Agreement, these expenses are expected to continue to increase significantly throughout the balance of 2009 as we expand our research and development programs; expand our organization; and work on our commercial manufacturing capability for the enhanced initial blood glucose test strip. We currently have 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. While the C-reactive protein, D-dimer and the prothrombin time test still have a high degree of technical development risk, if the research and development efforts progress as anticipated, we expect to be in a position to commence the formal validation phase in 2009 for C-reactive protein and prothrombin time test and 2010 for D-dimer, a process requiring approximately one year, following which, we will commence the process of seeking regulatory clearance for the tests. Our business strategy with respect to the commercialization of our C-reactive protein, prothrombin time and D-dimer tests is based in part upon entering into entering into collaborative arrangements or strategic alliances with other life sciences companies or other industry participants to complete the development and commercialization of those products and enable us to maintain our financial and operational capacity.

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 having our shares registered with the United States Securities Exchange. 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.

Research and development income

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

Interest income

Interest income increased from A$1,440,102 in 2007 to A$2,542,060 in 2008. 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.

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 from A$8,817,238 in 2007 to A$11,995,886 in 2008 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.

Basic and diluted net loss per share

	2008	2007
	A$	A$
Net loss	(11,995,886)	(8,817,238)
Weighted average number of ordinary shares used as denominator in calculating basic and diluted net loss per share	156,970,679	129,637,286
Basic and diluted net loss per share	(0.08)	(0.07)

The potentially dilutive options issued under our Employee Option Plan were not considered in the computation of diluted net loss per share because they would be anti-dilutive given our loss making position in this and previous years.

Comparison of the Years Ended December 31, 2007 and 2006

Research and development income

Our research and development income for 2006 and 2007 was A2,654,280 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$7,157,216 in 2007 from A$3,466,604 in 2006. 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$578,653 and A$872,513 received for the R&D Start Grant Program for 2006 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.

Research and development expenses are related to developing our electrochemical cell platform technologies and pilot production. Our expenses have significantly increased and are expected to continue to increase significantly in 2008 as we expand our research and development programs and expand our organization and commercial manufacturing capability.

General and administrative expenses

General and administrative expenses increased to A$4,226,757 in 2007 from A$2,511,182 in 2006. General and administrative expenses 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 facility costs not otherwise included in research and development expenses, insurance expense, consultancy fees and professional fees for legal 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 having our shares registered with the United States Securities Exchange. 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.

Fair value of stock options issued to employees

As of January 1, 2006, we adopted Statement No. 123(R), "Share Based Payment", or SFAS 123(R). The impact of the change in accounting policy is an increase in non-cash expenses of A$421,067 in 2006. The non-cash compensation expense increased to A$617,715 as a result of options granted to employees in 2007.

Interest and other income

Interest and other income increased from A$443,769 in 2006 to A$1,440,102 in 2007. The increase in interest income is attributable to the greater level of funds invested during the year and increased returns on the funds invested. We commenced the 2007 financial year with A$30,184,756 in cash. The cash and bank balance at the end of the 2007 financial year was A$41,958,285. The increase in cash and bank balance during the financial year is as a result of the renounceable rights issue in November and December 2007 in which A$34,246,043 was raised.

Income tax expense

Income tax expense during the 2007 year relates to the reversal of provision for income tax.

Net loss

Net loss increased from A$2,955,661 in 2006 to A$8,817,238 in 2007 as a result of increased activity during the 2007 financial year thus resulting in increased research and development expenses and general and administrative expenses.

Basic and diluted net loss per share

	2007	2006
	A$	A$
Net loss	(8,817,238)	(2,955,661)
Weighted average number of ordinary shares used as denominator in calculating basic and diluted net loss per share	129,637,286	49,408,822
Basic and diluted net loss per share	(0.07)	(0.06)

The increase in basic and diluted net loss per share during the 2007 year is primarily due to increased losses sustained during the year.

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, an initial one time payment 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, 2008, we had received aggregate net cash proceeds from the following: (a) A$32,518,792 from the renounceable rights issue; (b) A$37,082,855 from the issuance of equity securities other than those issued under the renounceable rights offer; (c) A$13,077,964 from LifeScan under our Development and Research Agreement; (d) A$3,121,754 from LifeScan as revenue from services performed; (e) A$2,646,063 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 and (g) A$4,599,033 from interest on investments. As of December 31, 2008, we had A$28,334,864 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, 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.

For the year ended December 31, 2006, we used net cash of A$1,399,735 for operating activities. This consisted of a net loss for the period of A$2,955,661, which included A$360,711 of non-cash depreciation and amortization, and non-cash stock option expense of A$421,067. Net cash used in investing activities during the year ended December 31, 2006 was A$4,813,073, which included the purchase of plant and equipment reflecting the commencement of the expansion of our manufacturing capabilities. Net cash provided by financing activities during the year ended December 31, 2006 was A$32,267,358 resulting from the issue and

sale of our preferred stock which raised A$12,624,795 and A$19,642,563 raised by way of a private placement of our shares to United States accredited investors and by way of an initial public offering of our shares in Australia.

As at December 31, 2008, we had cash and cash equivalents of A$28,334,864 as compared to A$41,958,285 as of December 31, 2007. The decrease in cash and cash equivalents balance is as a result of our outgoings for our ongoing operations including capital expenditure outlay. The decrease has been partially offset by revenues received from LifeScan for provision of certain services.

In October 2007, we entered into a Master Services and Supply Agreement with LifeScan. In January 2008 we received an initial one time payment of A$1,131,222. In February 2009 we received A$3,087,849 in connection with the provision by us to LifeScan of certain manufacturing support services. The receipt and timing of any further revenue under the Master Services and Supply Agreement is uncertain.

Since May 2008, we have also been receiving payments from LifeScan for services related to production development and scale up. Payments received for services performed to date are A$3,121,754. Services provided to LifeScan under this arrangement ceased in September 2008.

We are in discussions with LifeScan with respect to the commercial terms for the development and manufacture of the enhanced initial blood glucose test strips and the resulting amendments to the Master Services and Supply Agreement. 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 we are not successful in negotiating amendments to the Master Services and Supply Agreement to reflect the change of initial product, or if at any time LifeScan indicates that it will not proceed with commercialization of the initial blood glucose test covered by the Master Services and Supply Agreement, or if the product does not obtain regulatory approval, we will use the installed manufacturing equipment for the immunoassay and prothrombin time tests we are developing, contingent on those tests reaching the point of manufacture. To reach that point, development efforts will need to continue to be successful. If development efforts continue to be successful and we are able to enter into a strategic partnership to support the development and commercialization of the tests, we expect to be in a position to commence formal validation of the C-reactive protein test and the prothrombin time test in 2009 and 2010 for D-dimer test, following which, we will seek regulatory clearance for these tests. As appropriate, we will likely seek partners to assist in the development, sales and distribution of these tests. We also intend to develop additional immunoassay based point-of-care test devices by taking selected disease biomarkers currently measured in the central laboratory environment and creating tests using those biomarkers for the point-of-care setting using our novel platform of electrochemical cell technologies.

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, will allow the Group to perform under the Master Services and Supply Agreement and to progress the Group's other development programs. In the event we are not successful in negotiating appropriate amendments to the Master Services and Supply Agreement, 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 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 commercialization activities.

Operating Capital and Capital Expenditure Requirements

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 commercialization 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 2009 to be in the range of A$5,000,000 to A$6,000,000 for the purchase of equipment to support our activities under the Master Services and Supply Agreement, capacity expansion, final product validation activities, for ongoing development of our existing products, and for other ongoing research and development activities. We have also funded the majority of the fit out cost of our new facilities at Corporate Avenue from our existing cash. Our capital expenditure in connection with the fit out in 2008 was A$1,829,923. Our future funding requirements will depend on many factors, including, but not limited to:

- expenses we incur in manufacturing, developing, marketing and selling products;
- whether we are successful in negotiating appropriate amendments to the Master Services and Supply Agreement to reflect the change of product from the original initial blood glucose monitoring product to the enhanced initial blood glucose monitoring product;
- the timing and amount of receipts of revenue from LifeScan under the Master Services and Supply Agreement;
- any need to scale 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;
- changes to our operations to enable us to perform services required under the Master Services and Supply Agreement;
- the success of our research and development efforts, and whether or not additional funds are required to support these;
- the rate of progress and cost of our product development activities;
- the timing and amount of revenue generated by sales of our point-of-care tests;
- costs and timing of regulatory approvals;
- 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, 2008, the future minimum lease payments under non-cancelable operating leases (with initial or remaining lease terms in excess of one year) are:

	A$
Less than 1 year	500,120
1 — 3 years	1,052,583
3 — 5 years	1,122,195
More than 5 years	144,703
Total minimum lease payments	2,819,601

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, 2008 were as follows:

		Payments Due by Period			
	Total	Less than 1 Year	1 3 Years	3 5 Years	More than 5 Years
	A$	A$	A$	A$	A$
Long-Term Debt Obligations	—	—	—	—	—
Asset Retirement Obligations(1)	1,699,133	—	—	—	1,699,133
Operating Lease Obligations(2)	2,819,601	500,120	1,052,583	1,122,195	144,703
Purchase Obligations	—	—	—	—	—
Other Long-Term Liabilities on Balance Sheet under GAAP(3)	197,897	—	—	—	197,897
Total	4,716,631	500,120	1,052,583	1,122,195	2,041,733

(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 long service leave owing to the employees.

Segments

We operate in one segment. Our principal activities are the research, development, manufacture and commercialization of in vitro diagnostic test devices for point-of-care use. We operate predominantly in one geographical area, 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. It is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. We do not expect the adoption of SFAS No. 161 to have a material impact on our financial statements.

EITF Issue 07-01: "Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property." This issue is effective for financial statements issued for fiscal years beginning after December 15, 2008. This issue addresses the income statement classification of payments made between parties in a collaborative arrangement. The adoption of EITF 07-01 is not expected to have a significant impact on the Company's results of operations, cash flows or financial position.

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

Our exposure to market risk is limited 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 Australian dollars 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 decrease. 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.

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

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

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:

	Years 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	—
Total revenue from ordinary activities	—	1,240,801	1,880,953	—
Costs of revenues				
Cost of goods sold	—	—	—	—
Cost of services	—	1,240,801	1,880,953	—
Total costs of revenues	—	1,240,801	1,880,953	—
Gross profit	—	—	—	—
Operating expenses				
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 expenses	3,329,642	3,498,006	2,538,868	7,728,869
Research and development income	279,298	274,213	259,740	356,939
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	$ (1,158,339)	$ (2,601,046)	$ (1,330,448)	$ (6,906,053)
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

	Years Ended December 31, 2007			
	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	—	—	—	—
Total revenue from ordinary activities	—	—	—	—
Costs of revenues				
Cost of goods sold	—	—	—	—
Cost of services	—	—	—	—
Total costs of revenues	—	—	—	—
Gross profit	—	—	—	—
Operating expenses				
Research and development (1 and 2)	1,396,617	1,665,381	1,804,762	2,290,456
General and administrative(3)	766,629	1,110,907	843,238	1,505,983
Total operating expenses	2,163,246	2,776,288	2,648,000	3,796,439
Research and development income	317,981	300,591	294,377	279,066
Loss from operations	(1,845,265)	(2,475,697)	(2,353,623)	(3,517,373)
Other income/(expense)				
Interest income	391,231	359,724	249,995	439,152
Interest expense	—	—	—	—
Other	(118,445)	(162,676)	62,210	8,529
Total other income/(expense)	272,786	197,048	312,205	447,681
Net loss before tax	(1,572,479)	(2,278,649)	(2,041,418)	(3,069,692)
Income tax benefit/(expense)	—	—	—	145,000
Net loss	$ (1,572,479)	$ (2,278,649)	$ (2,041,418)	$ (2,924,692)
Basic and diluted net loss per share	$ (0.01)	$ (0.02)	$ (0.02)	$ (0.02)
Average weighted number of shares used to compute per share data	128,072,553	128,086,971	128,157,992	134,276,878

Notes:

1. Net of research grant income in these amounts	$ 190,442	$ 209,433	$ 240,263	$ 232,375
2. Includes non-cash compensation expense (research and development)	$ 24,506	$ 20,176	$ 122,211	$ 172,989
3. Includes non-cash compensation expense (general and administrative)	$ 33,491	$ 58,137	$ 44,798	$ 141,407

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

None.

ITEM 9A. *CONTROLS AND PROCEDURES*

Evaluation of Disclosure Controls and Procedures. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-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, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective such that the information required to be disclosed by us in reports filed under the Securities Exchange Act of 1934 is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding disclosure. A controls system cannot provide absolute assurance, however, that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Changes in Internal Control Over Financial Reporting. During the most recent quarter ended December 31, 2008, 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, 2008. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission 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, 2008, 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.

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 2009 (the "2009 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 2009 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.universalbiosensors.com. We intend to satisfy any disclosure requirement under

item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of the Code of Ethics for our Chief Executive Officer and Chief Financial Officer, by posting such information on our website at www.universalbiosensors.com

The information required by this item regarding any material changes to the procedures by which security holders may recommend nominees to our Board of Directors is incorporated by reference to the 2009 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 2009 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 2009 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 2009 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 2009 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 2009 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 2009 Proxy Statement under the caption "Independent Public Accountants — Audit Fees."

PART IV

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

(a)(1) Financial Statements

Index to Financial Statements

(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 Managing Director

Date: March 30, 2009

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:

Signature	Title	Date
/s/ Mark Morrisson Mark Morrisson	Chief Executive Officer and Managing Director (Principal Executive Officer)	March 30, 2009
/s/ Salesh Balak Salesh Balak	Chief Financial Officer (Principal Financial Officer)	March 30, 2009
/s/ Andrew Denver Andrew Denver	Director	March 30, 2009
/s/ Denis Hanley Denis Hanley	Director	March 30, 2009
/s/ Andy Jane Andy Jane	Director	March 30, 2009
/s/ Jane Wilson Jane Wilson	Director	March 30, 2009
/s/ Colin Adam Colin Adam	Director	March 30, 2009
/s/ Charles Kiefel Charles Kiefel	Director	March 30, 2009

Consolidated Financial Statements and Schedules

UNIVERSAL BIOSENSORS, INC.
(A Development Stage Enterprise)

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Contents

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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, 2008 and December 31, 2007, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2008 and cumulatively, for the period from September 14, 2001 (date of inception) to December 31, 2008 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.

As discussed in Note 3, effective from October 1, 2008, the Company changed it's reporting currency from U.S. Dollars to Australian Dollars.

PricewaterhouseCoopers

March 30, 2009 Sydney

UNIVERSAL BIOSENSORS, INC.
(A Development Stage Enterprise)

CONSOLIDATED BALANCE SHEETS

	December 31, 2008	December 31, 2007
	A$	A$
ASSETS		
Current assets:		
Cash and cash equivalents	28,334,864	41,958,285
Short-term investments (held-to-maturity)	—	3,123,501
Inventories, net	—	486,633
Accrued income	118,305	79,811
Accounts receivables	31,657	471,348
Prepayments	3,730,246	139,871
Other current assets	535,000	843,733
Total current assets	32,750,072	47,103,182
Property, plant and equipment	23,522,706	17,981,202
Less accumulated depreciation	(3,767,457)	(1,572,221)
Property, plant and equipment — net	19,755,249	16,408,981
Total assets	52,505,321	63,512,163
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	630,977	811,896
Income taxes payable	—	18,000
Accrued expenses	838,697	996,753
Employee entitlements provision	435,387	267,774
Total current liabilities	1,905,061	2,094,423
Non-current liabilities:		
Asset retirement obligations	1,699,133	1,566,892
Employee entitlements provision	197,897	101,224
Total non-current liabilities	1,897,030	1,668,116
Total liabilities	3,802,091	3,762,539
Stockholders' equity:		
Preferred stock, $0.01 par value. Authorized 1,000,000 shares; issued and outstanding nil in 2008 (2007: nil) Common stock, $0.0001 par value. Authorized 300,000,000 shares; issued and outstanding 156,976,936 shares in 2008 (2007: 156,958,812)	15,698	15,696
Additional paid-in capital	73,338,995	72,389,505
Accumulated deficit	(12,357,265)	(3,540,027)
Current year loss	(11,995,886)	(8,817,238)
Accumulated other comprehensive income	(298,312)	(298,312)
Total stockholders' equity	48,703,230	59,749,624
Total liabilities and stockholders' equity	52,505,321	63,512,163

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, 2008	Years Ended December 31,		
		2008	2007	2006
	A$	A$	A$	A$
Revenue				
Revenue from products	$ —	$ —	$ —	$ —
Revenue from services	3,121,754	3,121,754	—	—
Total revenue from ordinary activities	3,121,754	3,121,754	—	—
Costs of revenues				
Cost of goods sold	—	—	—	—
Cost of services	3,121,754	3,121,754	—	—
Total costs of revenues	3,121,754	3,121,754	—	—
Gross profit	—	—	—	—
Operating expenses				
Research and development (1 and 2)	28,916,019	11,585,258	7,157,216	3,466,604
General and administrative(3)	14,362,764	5,510,127	4,226,757	2,511,182
Total operating expenses	43,278,783	17,095,385	11,383,973	5,977,786
Research and development income	13,077,964	1,170,190	1,192,015	2,654,280
Loss from operations	(30,200,819)	(15,925,195)	(10,191,958)	(3,323,506)
Other income/(expense)				
Interest income	4,599,033	2,542,060	1,440,102	443,769
Interest expense	(9,489)	(9,489)	—	—
Fee income	1,131,222	1,131,222	—	—
Other	144,696	265,310	(210,382)	87,076
Total other income/(expense)	5,865,462	3,929,103	1,229,720	530,845
Net loss before tax	(24,335,357)	(11,996,092)	(8,962,238)	(2,792,661)
Income tax benefit/(expense)	(17,794)	206	145,000	(163,000)
Net loss	$(24,353,151)	$ (11,995,886)	$ (8,817,238)	$ (2,955,661)
Basic and diluted net loss per share	$ (0.35)	$ (0.08)	$ (0.07)	$ (0.06)
Average weighted number of shares outstanding during the period	70,523,954	156,970,679	129,637,286	49,408,822

Notes:

1. Net of research grant income in these amounts	$ 2,366,063	$ 300,613	$ 872,513	$ 578,653
2. Includes non-cash compensation expense (research and development)	$ 1,148,752	$ 661,497	$ 339,882	$ 147,373
3. Includes non-cash compensation expense (general and administrative)	$ 851,138	$ 299,611	$ 277,833	$ 273,694

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	Shares	Amount				
		A$		A$	A$	A$	A$	A$
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	—	—	—	—	—	—	(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	—	—	—	—	—	—	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	—	—	—	—	—	—	(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	—	—	—	—	—	—	—	—
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	—	—	—	—	—	—	—	—
Total Comprehensive Income								(11,995,886)
Exercise of stock options issued to employees	—	—	18,124	2	5,045	—	—	5,047
Stock option expense	—	—	—	—	961,108	—	—	961,108
Balances at December 31, 2008	—	—	156,976,936	15,698	73,338,995	(24,353,151)	(298,312)	48,703,230

Note

Common stock has a par value of U.S. $0.0001.

All share and per share amounts from inception to December 31, 2006 presented have been retroactively adjusted to give effect to the stock split. 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, 2008	Years Ended December 31,		
		2008	2007	2006
		A$	A$	A$
Cash flows from operating activities:				
Net loss	(24,353,151)	(11,995,886)	(8,817,238)	(2,955,661)
Adjustments to reconcile net loss to net cash used in operating activities:				
Net exchange difference	1,102,572	—	983,991	171,623
Depreciation and impairment of plant & equipment	4,281,283	2,266,847	708,699	360,711
Share based payments expense	1,999,890	961,108	617,715	421,067
Loss on fixed assets disposal	150,685	34,207	116,478	—
Change in assets and liabilities:				
Inventory	—	486,633	(486,633)	—
Accounts receivables	(938,985)	439,691	(931,864)	(380,768)
Prepaid expenses and other current assets	191,728	191,728	—	—
Accrued income	(108,855)	(38,494)	31,786	(202,448)
Income tax payable	—	(18,000)	(145,000)	163,000
Employee entitlements	633,284	264,286	5,835	217,257
Accounts payable and accrued expenses	1,492,532	267,494	146,957	805,484
Net cash used in operating activities	(15,549,017)	(7,140,386)	(7,769,274)	(1,399,735)
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	(3,616,235)	(3,616,235)	—	—
Purchases of property, plant and equipment	(20,743,898)	(5,978,685)	(9,058,265)	(4,813,073)
Net cash used in investing activities	(24,360,133)	(6,471,419)	(12,181,766)	(4,813,073)
Cash flows from financing activities:				
Gross proceeds from share issue	73,517,472	—	34,246,043	34,623,314
Transaction costs on share issue	(4,099,870)	(16,663)	(1,727,251)	(2,355,956)
Proceeds from stock options exercised	184,045	5,047	148,428	—
Net cash provided by/(used in) financing activities	69,601,647	(11,616)	32,667,220	32,267,358
Net increase/(decrease) in cash and cash equivalents	29,692,497	(13,623,421)	12,716,180	26,054,550
Cash and cash equivalent at beginning of period	—	41,958,285	30,184,756	4,434,274
Effect of exchange rate fluctuations on the balances of cash held in foreign currencies	(1,357,633)	—	(942,651)	(304,068)
Cash and cash equivalents at end of period	28,334,864	28,334,864	41,958,285	30,184,756

See accompanying notes to the financial statements

UNIVERSAL BIOSENSORS, INC.
(A Development Stage Enterprise)

Notes to Consolidated Financial Statements
(for the years ended December 31, 2006, 2007 and 2008 and for the period from inception (September 14, 2001) to December 31, 2008)

(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 Depositary 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 development, manufacture and commercialization of a range of in vitro diagnostic tests for point-of-care use. In vitro diagnostic testing involves the testing of a body fluid or tissue sample outside the body. The Company's diagnostic tests comprise a novel disposable test strip and a reusable meter and are small, portable and easy-to-use.

Universal Biosensors has rights to an extensive patent portfolio comprising 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. ("LifeScan"), an affiliate of Johnson & Johnson Corporation.

The Group has a range of point-of-care blood tests in development including an immunoassay point-of-care test to measure the amount of C-reactive protein in the blood which may be used to assist in the diagnosis and management of inflammatory conditions and a prothrombin time test which may be used for monitoring the therapeutic range of the anticoagulant, warfarin. The Group has developed a working prototype of the immunoassay C-reactive protein test and the prothrombin time test. The Group has also started work on a 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 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). Universal Biosensors also intends to develop additional immunoassay based point-of-care test devices by taking selected disease biomarkers currently measured in the central laboratory environment and creating tests using those biomarkers for the point-of-care setting using our novel platform of electrochemical cell technologies. Universal Biosensors proposes to focus on the development of products which do not rely on the discovery of new medicines, treatments or biomarkers, but instead proposes to focus on areas where existing therapies or practice can be enhanced significantly by simple and accurate diagnostic tools incorporating well known biomarkers.

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 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. In February 2009, Universal Biosensors announced that LifeScan had chosen not to proceed with the registration of the original initial blood glucose test strips but instead wished to proceed with the development of an enhanced initial blood glucose test strip. The enhanced initial blood glucose test strip is based on the same technology as the original product and would be manufactured using the same production processes and manufacturing equipment and infrastructure. Universal Biosensors are in discussions with LifeScan with respect to the commercial terms for

the development and manufacture of the enhanced initial blood glucose test strips and the resulting amendments to the Master Services and Supply Agreement. The Master Services and Supply Agreement is structured as an umbrella agreement which enables LifeScan and Universal Biosensors 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.

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").

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 its planned commercial manufacturing operations have not yet commenced.

(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 ("A$") unless otherwise stated.

The Company's financial statements have been prepared assuming the Company will continue as a going concern. Other than a small profit in the Company's first year of operations, the Company has sustained operating losses since inception. The Company expects to continue to incur losses as it continues the development of its point-of-care tests and expands the organization and commercial manufacturing capability until the Company is able 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.

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.

There are no open derivative instruments as at December 31, 2008.

Cash flow hedges

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

Where a derivative financial instrument is designated as a hedge of the variability in cash flows of a recognized asset or liability, or a highly probable forecast transaction, the effective part of any gain or loss on the derivative financial instrument is recognized directly in equity. When the forecast transaction subsequently

results in the recognition of a non-financial asset or non-financial liability, the associated cumulative gain or loss is removed from equity and included in the initial cost or other carrying amount of the non-financial asset or liability. If a hedge of a forecast transaction subsequently results in the recognition of a financial asset or a financial liability, then the associated gains and losses that were recognized directly in equity are reclassified into the income statement in the same period or periods during which the asset acquired or liability assumed affects the income statement.

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

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

Inventory

Raw materials are stated at the lower of cost and net realizable value. Costs of purchased inventory are determined after deducting rebates and discounts.

Receivables

Receivables are recognized initially at fair value and subsequently measured at amortized cost, less provision for doubtful debts. Receivables are due for settlement no more than 45 days from the receipt of the invoice by the customer.

Collectibility of receivables is reviewed on an ongoing basis. Debts which are known to be uncollectible are written off. A provision for doubtful receivables is established when there is objective evidence that the Group will not be able to collect all amounts due according to the original terms of receivables. The amount of the provision is the difference between the asset's carrying amount and the present value of estimated future cash flows, discounted at the original effective interest rate. Cash flows relating to short-term receivables are not discounted if the effect of discounting is immaterial. The amount of the provision is recognized in the income statement.

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 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.

Research and Development

Research and development expenses consists 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, 2006, 2007, 2008 and for period from inception to December 31, 2008 are as follows:

	Period from Inception to December 31, 2008	Years Ended December 31,		
		2008	2007	2006
	A$	A$	A$	A$
Research and development expenses	31,282,082	11,885,871	8,029,729	4,045,257
Research grants received recognized against related research and development expenses	(2,366,063)	(300,613)	(872,513)	(578,653)
Research and development expenses as reported	28,916,019	11,585,258	7,157,216	3,466,604

Income Taxes

The Company applies Statement of Financial Accounting Standards No. 109 — Accounting for Income Taxes (SFAS 109) which establishes financial accounting and reporting standards for the effects of income taxes that result from a company's activities during the current and preceding years. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or

settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

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

The Company adopted 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 2007 financial year have been lodged. Internationally, consolidated income tax returns up to the 2007 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. SFAS No. 143 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,	
	2008 A$	2007 A$
Movement in ARO		
Opening balance at January 1	1,566,892	—
New obligations	—	1,525,550
Accretion expense	132,241	41,342
Ending balance at December 31	1,699,133	1,566,892

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. Impairment, if any, is measured as the amount by which the carrying amount of the assets exceeds its fair value. Impairment, if any, is assessed using 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.

Revenue Recognition

Revenue from services

We provide certain services to LifeScan. We recognize revenue from these services as we perform the services.

Research and development revenue

On April 1, 2002, the Company and LifeScan entered into a License Agreement, pursuant to which LifeScan granted to the Company a worldwide, royalty free, exclusive license, with a limited right to sub-license, to make, have made, use, sell under and exploit in any way a range of key patents, patent applications and know-how owned by LifeScan, relating to electrochemical sensor technologies in all fields in the area of diabetes and blood glucose management generally ("LifeScan Fields"), 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 key patents, patent applications and know-how owned by LifeScan in all fields including in the fields of the Company's own point-of-care tests. At the time of execution of the Master Services and Supply Agreement in October 2007, the License Agreement was amended to grant the Company a license to certain new patents outside of such field of use.

LifeScan has assumed responsibility for the cost of maintaining the licensed patents and patent applications. In the event that LifeScan elects not to proceed with the prosecution of any patent application, the Company may assume responsibility for those patents. Pursuant to the License Agreement, if the Company receives a lump sum, actual or minimum royalties payment from any sub-licence, 50% of such lump sum or royalties is payable to LifeScan.

Also in 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. At the time of

execution of the Master Services and Supply Agreement in October 2007, the Development and Research Agreement was amended to conform the intellectual property provisions in the Master Services and Supply Agreement such that LifeScan would own 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 scope of the program under the Development and Research Agreement was also expanded to include development work in connection with a blood glucose meter.

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. Revenue 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 is paying the Company US$250,000 per quarter under the Development and Research Agreement.

The revenue derived from the Development and Research Agreement is recognized over the period in which the agreed upon research services are completed. The Company recognizes revenue for accounting purposes ratably over the annual grant period. Under the Development and Research Agreement, the Company is not matching the revenue to a specific expenditure but to a specified period of research. The annual research and development revenue received from LifeScan is agreed 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.

The Company considers the income received under the Development and Research Agreement not to be indicative of its core operating activities or revenue producing goals of the Company, and as such account for this income as "other operating income" per SEC Regulation S-X Article 5-03. The Company is of the view that presenting the income from the Development and Research Agreement as top line revenue with estimated costs that do not include all fixed charges on a full "absorption" basis would not provide the reader of the financial statements with a true indication of future operating margins.

Revenue 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

Under the terms of the Master Services and Supply Agreement, in January 2008 the Company received an initial non-refundable fee of A$1,131,222 in consideration for the grant of certain rights to LifeScan. The Company recorded the fee income as revenue upon receipt. This revenue is recorded under the caption "Other income" in the consolidated statements of operations as it is not indicative of the core operating activities or revenue producing goals of the Company.

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 Australian Dollars 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 Australian Dollars (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 year ended December 31, 2008. 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 US dollars. This was based on the facts that the denomination of a significant proportion of transactions and the major source of finance were in US dollars.

In 2006, the Company expanded significantly its Australian based research activities. All of the Company's directors became and continue to be resident in Australia. All 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$87,076, (A$210,382), A$265,310 and A$145,734 for each of the years ended December 31, 2006, 2007 and 2008 and the period from inception to December 31, 2008, respectively.

Group companies

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.

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 product development 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 Group's leases for the years ended December 31, 2006, 2007 and 2008 are considered operating leases. The costs of operating leases are charged to the statement of operations on a straight-line basis over the lease term.

Stock-based Compensation

Prior to January 1, 2006, the Company applied 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 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 ESOP). Results for periods before January 1, 2006 have not been restated to reflect, and do not include the impact of, FASB Statement No. 123(R), "Share Based

Payment", or SFAS 123(R). The following table illustrates the effect on net income if the fair-value-based method had been applied to all outstanding and unvested awards in each period.

	Year Ended December 31, 2005
	A$
Net loss, as reported	(128,960)
Add stock-based employee compensation expense included in reported net income, net of tax	—
Deduct total stock-based employee compensation expense determined under fair-value-based method for all awards	(45,913)
Pro forma net loss	(174,873)

As of January 1, 2006, the Company adopted SFAS 123(R), 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 SFAS 123(R) 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 SFAS 123 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 the equivalent of the Black-Scholes valuation model, which is consistent with valuation techniques previously utilized for options in footnote disclosures required under SFAS 123, as amended by 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 SFAS 123(R). There were no transitional adjustments on adoption of SFAS 123(R).

The application of SFAS 123(R) had the following effect on reported amounts for the year ended December 31, 2006, 2007 and 2008 relative to amounts that would have been reported under previous accounting:

	Under Previous Accounting	2006 SFAS 123(R) Adjustments	As Reported
	A$	A$	A$
Net loss - 2006	(2,534,594)	(421,067)	(2,955,661)
Net loss - 2007	(8,199,523)	(617,715)	(8,817,238)
Net loss - 2008	(11,034,778)	(961,108)	(11,995,886)

Pension Costs

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

Net Loss per Share and Anti-dilutive Securities

Basic and diluted net loss per share is presented in conformity with Statement of Financial Accounting Standards No. 128 — Earnings Per Share ("SFAS 128"). Basic and diluted net loss per share has been computed using the weighted-average number of common shares outstanding during the period. All periods present in these financial statements have been retroactively adjusted to give effect to the stock split in December 2006 (note 11). The potentially dilutive options issued under the Universal Biosensors Employee Option Plan and the convertible preference shares (see note 12) were not considered in the computation of diluted net loss per share because they would be anti-dilutive given the Group's loss making position in this and previous years.

Total Comprehensive Income

The Company follows Statement of Financial Accounting Standard ("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 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. It is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. We do not expect the adoption of SFAS No. 161 to have a material impact on our financial statements.

EITF Issue 07-01: "Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property." This issue is effective for financial statements issued for fiscal years beginning after December 15, 2008. This issue addresses the income statement classification of payments made between parties in a collaborative arrangement. The adoption of EITF 07-01 is not expected to have a significant impact on the Company's results of operations, cash flows or financial position.

(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 April 1, 2007 for an initial period of seven years and five months, with two options to renew the lease for successive five-year periods. The Group'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, 2008 are:

	A$
2009	500,120
2010	517,366
2011	535,217
2012	555,188
2013	567,007
2014 and thereafter	144,703
Total minimum lease payments	2,819,601

Rent expense was A$195,832, A$482,805, A$514,984 and A$1,818,554 for the fiscal years ended December 31, 2006, 2007 and 2008 and for the period from inception to December 31, 2008, respectively.

Government research grants

Universal Biosensors Pty Ltd has 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 has been 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 A$262,119 (2007: A$894,849) were received during 2008 and income of A$300,613 (2007: A$872,513, 2006: A$578,653, and period from inception to December 31, 2008: A$2,366,063) was recognized with A$118,305 recorded as accrued income at December 31, 2008 (2007: A$79,811).

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, 2008 was A$130,000 (2007: A$150,000, 2006: Nil and period from inception to December 31, 2008: A$280,000). 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.

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 loss before income taxes is as follows:

	Period from Inception to December 31, 2008		Years Ended December 31,					
			2008		2007		2006	
	$	%	$	%	$	%	$	%
Loss before income taxes	(24,335,357)		(11,996,092)		(8,962,238)		(2,792,661)	
Computed by applying income tax rate of home jurisdiction	(7,300,607)	30	(3,598,828)	30	(2,688,671)	30	(837,798)	30
Research & development incentive	(2,620,297)	11	(702,124)	6	(983,029)	11	(571,193)	20
Disallowed expenses/(income):								
Share based payment	599,967	(3)	288,332	(3)	185,315	(2)	111,839	(4)
Other	233,340	(1)	2,600	(0)	20,157	(0)	153,483	(5)
Change in valuation allowance	9,326,223	(38)	4,010,020	(33)	3,484,228	(39)	1,306,669	(47)
Adjustment in respect of current income tax of prior years	(220,832)	1	(206)	0	(163,000)	2	—	—
Income tax expense/(benefit)	17,794	(0)	(206)	0	(145,000)	2	163,000	(6)

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

	As of December 31,	
	2008	2007
Deferred tax assets:		
Operating loss carry forwards	9,320,465	5,353,416
Unamortized capital raising cost	650,355	402,151
Depreciation and amortization	62,699	67,467
Asset retirement obligations	109,228	35,587
Employee entitlements	189,985	110,699
Other accruals	268,388	111,208
Total deferred tax assets	10,601,120	6,080,529
Valuation allowance for deferred tax assets	(10,601,120)	(6,080,529)
Net deferred tax asset	—	—

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

At December 31, 2008 the Company has A$31,068,217 (A$17,844,721 at December 31, 2007) 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.

(6) 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) and includes all directors. 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 2006, 2007 and 2008 were 2,066,108, 1,608,000 and 1,553,000, respectively.

In accordance with SFAS 123(R), the fair value of the option grants was estimated on the date of each grant using the Trinomial Lattice model which is the equivalent of the Black-Scholes option pricing model. The assumptions for these grants were:

	Grant Date					
	Aug-08	Mar-08	Oct-07	Sep-07	Mar-07	2006
Exercise Price (A$)	$ 0.70	$ 0.89	$ 1.13	$ 1.20	$ 1.18	$ 0.35
Share Price at Grant Date (A$)	$ 0.71	$ 0.91	$ 1.19	$ 1.21	$ 1.21	$ 0.45
Volatility	71%	76%	76%	72%	74%	55%
Expected Life	10 years	10 years	10 years	10 years	10 years	10 years
Risk Free Interest Rate	5.85%	5.87%	6.13%	5.99%	5.86%	4.40%
Fair Value of Option (A$)	$ 0.45	$ 0.59	$ 0.78	$ 0.78	$ 0.79	$ 0.27

Each of the inputs to the Trinomial Lattice model which is the equivalent of the Black-Scholes pricing model is discussed below.

Share price at valuation date

We have applied the Trinomial Lattice model which is the equivalent of the Black-Scholes pricing model in order to value our options.

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.

Date of Capital Raising	Value per Preferred Stock A$ (Post Stock Split Described in Note 11)
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:

	Pre Rights Offering		Post Rights Offering	
Grant Date of Option	Exercise Price	Fair Value of Option	Exercise Price	Fair Value of Option
	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:

Option Grant Date	Share Price A$	Volatility
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%

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

Time to expiry

All options granted under our share option plan have a 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 period indicated is as follows:

	Number of Shares	Weighted Average Exercise Price A$
Balance at January 1, 2006	1,844,997	0.30
Granted	2,066,108	0.35
Exercised	—	—
Forfeited	(90,618)	0.33
Expired	—	—
Balance at December 31, 2006	3,820,487	0.33
Granted	1,608,000	1.19
Exercised	(420,474)	0.32
Forfeited	(61,618)	0.35
Expired	—	—
Balance at December 31, 2007	4,946,395	0.61
Granted	1,553,000	0.85
Exercised	(18,124)	0.35
Forfeited	(107,987)	1.13
Expired	—	—
Balance at December 31, 2008	6,373,284	0.66

At December 31, 2008, the number of options exercisable was 4,324,821 (2007: 2,851,605 and 2006: 2,305,341).

The following table represents information relating to stock options outstanding under the plans as of December 31, 2008, 2007 and 2006:

	Exercise Price	Options Outstanding		Options Exercisable
		Shares	Weighted Average Remaining Life in Years	Shares
	A$			
2006	$0.30	1,808,751	7.00	1,772,503
	$0.35	2,011,736	9.00	532,838
2007	$0.30	1,594,890	6.00	1,594,890
	$0.35	1,743,505	8.00	975,058
	$1.18	845,000	9.20	281,657
	$1.20	663,000	9.70	—
	$1.13	100,000	9.80	—
2008	$0.30	1,594,890	5.00	1,594,890
	$0.35	1,725,394	7.00	1,551,394
	$1.18	837,000	8.20	557,980
	$1.20	663,000	8.70	220,996
	$1.13	—	—	—
	$0.89	1,199,000	9.20	399,651
	$0.70	354,000	9.60	—

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.

Period Ending	Number of Options Exercised and Corresponding Number of Shares Issued	Option Exercise Price	Proceeds Received
		A$	A$
2007	213,865	0.39	71,047
2007	206,609	0.45	77,381
2008	18,124	0.35	5,047
Total	438,598		153,475

(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 significant 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 Group 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.

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 act as a non-exclusive manufacturer of an original version of the initial blood glucose test strips we developed for LifeScan. In February 2009, Universal Biosensors announced that LifeScan had chosen not to proceed with the registration of the original initial blood glucose test strip but instead wished to proceed with the development of an enhanced initial blood glucose test strip. Universal Biosensors are in discussions with LifeScan with respect to the commercial terms for the development and manufacture of the enhanced initial blood glucose test strips and the resulting amendments to the Master Services and Supply Agreement. The Master Services and Supply Agreement is structured as an umbrella agreement which enables LifeScan and Universal Biosensors 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.

There is no guarantee that we will be able to successfully negotiate amendments to the Master Services and Supply Agreement to reflect the change to the product, on acceptable terms or at all. If we fail to agree upon the commercial terms upon which we will develop and manufacture the enhanced initial blood glucose test strip, we would not derive any revenues from any commercialization of that blood glucose test, which would have a material adverse effect on our business and financial condition.

(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.

The following transactions occurred with LifeScan:

	As of December, 31	
	2008	2007
	A$	A$
Current Receivables Reimbursement of expenses	31,919	464,341
Sale of Goods and Services Revenue from services	3,121,754	—
Purchases of Goods and Services Support services provided by LifeScan	1,064,736	—

Other transactions with LifeScan are detailed as follows:

- the Company received research and development revenue of A$1,170,190 in 2008 (2007: A$1,192,015) under the Development and Research Agreement with LifeScan
- the Company received an initial non-refundable fee of A$1,131,222 in 2008 (2007: Nil) 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 (2007: Nil) for certain expenditure incurred on behalf of LifeScan

Denis Hanley, Andrew Denver, Colin Adam and Charles Kiefel 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.

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.

(9) Property, Plant and Equipment

	As of December, 31	
	2008	2007
	A$	A$
Plant and equipment	13,003,248	3,826,919
Leasehold improvements	8,123,925	6,294,002
Capital work in process	2,395,533	7,860,281
	23,522,706	17,981,202
Accumulated depreciation	(3,767,457)	(1,572,221)
Property, plant & equipment, net	19,755,249	16,408,981

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, 2006, 2007 and 2008 was A$205,978, A$300,213 and 1,501,516, respectively.

The Company receives Victorian government grants under certain research agreements to purchase plant and equipment. Plant and equipment is presented net of the government grant of A$130,000 for the year ended December 31, 2008 (2007: A$150,000). 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$360,711, A$708,699, A$2,266,847 and A$4,281,283 for the fiscal years ended December 31, 2006, 2007 and 2008 and for the period from inception to December 31, 2008, respectively.

The movement in accumulated depreciation for the 2007 and 2008 financial year is agreed to depreciation expense as follows:

	As of December, 31	
	2008	2007
	A$	A$
Movement in accumulated depreciation	2,195,236	264,572
Accumulated depreciation of fixed assets disposed	71,611	444,127
Depreciation expense for the financial year	2,266,847	708,699

(10) Accrued Expenses

Accrued expenses consist of the following:

	As of December, 31	
	2008	2007
	A$	A$
Legal, tax and accounting fees	346,000	588,980
Salary and related on-costs	460,761	248,861
Other	31,936	158,912
	838,697	996,753

(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.

Holders of common stock are generally entitled to one vote per share held on all matters submitted to a vote of the holders of common stock. At any meeting of the shareholders, the presence, in person or by proxy, of the majority of the outstanding stock entitled to vote shall constitute a quorum. Except where a greater percentage is required by the Company's Amended and Restated Certificate of Incorporation or By-laws, the affirmative vote of the holders of a majority of the shares of common stock then represented at the meeting and entitled to vote at the meeting shall be sufficient to pass a resolution. Holders of common stock are not entitled to cumulative voting rights with respect to the election of directors, and the common stock does not have pre-emptive rights.

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

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

(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 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

As required by Australian law, 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$295,288, A$507,270, A$587,885 and A$1,774,182 for the fiscal years ended December 31, 2006, 2007 and 2008, and the period from inception to December 31, 2008, respectively.

(14) Net Loss per Share

Basic net loss per ordinary share was computed by dividing the net 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 and the convertible preference shares on issue during the current and prior periods are considered to be potential ordinary shares for the purpose of calculating diluted net loss per share. However, all these were not included in the calculation of diluted net loss per share as the effect of including them is anti-dilutive.

	Period from Inception to December 31, 2008	Year Ended December 31,		
		2008	2007	2006
Weighted average number of ordinary shares used as denominator in calculating basic and diluted net loss per share	70,523,954	156,970,679	129,637,286	49,408,822

(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 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, 2008.

(16) Segments

The Company operates in one segment. The principal activities of the Company are the research, development, manufacture and commercialization of a range of in vitro diagnostic tests for point-of-care use.

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 December 11, 2008, the Company entered into an additional services addendum to provide manufacturing process support to LifeScan. In February 2009, the Company received A$3,087,849 milestone payment under the manufacturing process support addendum.

On February 16, 2009, the Company announced that LifeScan had chosen not to proceed with the registration of the original initial blood glucose test strips but instead wished to proceed with the development of an enhanced initial blood glucose test strip. The Company is in discussions with LifeScan with respect to the commercial terms for the development and manufacture of the enhanced initial blood glucose test strips and the resulting amendments to the Master Services and Supply Agreement.

On February 17, 2009, the Company granted 154,000 options to its new employees under the Company's Employee Option Plan.

With the exception of the above, there has not arisen in the interval between the end of the financial year and 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.

UNIVERSAL BIOSENSORS, INC.
(A Development Stage Enterprise)

Schedule ii — Valuation and Qualifying Accounts
(for the years ended December 31, 2006, 2007 and 2008 and for the period from inception (September 14, 2001) to December 31, 2008)

	Balance at Beginning of Period	Additions		Deductions	Balance at End of Period
		Charged to Costs and Expenses	Charged to Other Accounts		
	A$	A$	A$	A$	A$
Year ended December 31, 2004					
Deferred income tax valuation allowance	148,589	122,515	52,422	—	323,526
Year ended December 31, 2005					
Deferred income tax valuation allowance	323,526	166,602	3,633	—	493,761
Year ended December 31, 2006					
Deferred income tax valuation allowance	493,761	1,306,669	291,987	—	2,092,417
Year ended December 31, 2007					
Deferred income tax valuation allowance	2,092,417	3,484,228	503,884	—	6,080,529
Year ended December 31, 2008					
Deferred income tax valuation allowance	6,080,529	4,010,020	510,571	—	10,601,120
Period from inception to December 31, 2008					
Deferred income tax valuation allowance	—	9,326,223	1,274,897	—	10,601,120

INDEX TO EXHIBITS

Exhibit Number	Description	Location
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 filed 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. October 2007 amendment incorporated by reference to our Form 10-Q filed on November 14, 2007 as Exhibit 10.3.
10.3	Form of indemnity agreement entered into with directors of us, our chief financial officer and company secretary	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.3.
10.4	Lease of premises 1 Corporate Avenue, Rowville Victoria Australia by and between Universal Biosensors Pty Ltd and Heyram Properties Pty Ltd.	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.5.
10.5	AusIndustry, R&D Start Program Agreement, effective February 25, 2005 (particular and general conditions).	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.6.
10.6	Employee Option Plan	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.7
10.7	Employment agreement between Universal Biosensors Pty Ltd and Mr 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

Exhibit Number	Description	Location
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 July 1, 2006	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.13
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 incorporated by reference to our Quarterly Report on Form 10-Q filed on November 14, 2007 as Exhibit 10.1.)	Filed herewith
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.)	Filed herewith
14.0	Code of Ethics	Incorporated by reference to our Annual Report on Form 10-K filed on March 28, 2008 as Exhibit 14.0
21.0	List of Subsidiaries	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 21.00
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

Exhibit Number	Description	Location
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

ASX ADDITIONAL INFORMATION

Additional information required by ASX Limited and not shown elsewhere in this report is as follows. The information is current as at April 1, 2009.

(a) Distribution of equity securities

The Company's shares of common stock are traded on the Australian Securities Exchange in the form of CHESS Depositary Interests, or 'CDIs'. CHESS Depositary Nominees Pty Ltd, or 'CDN', holds legal title in the Company's shares of common stock on behalf of holders of CDIs.

As at April 1, 2009 there were:

- 156,976,936 CDIs held by 1,114 individual shareholders. CDIs are exchangeable, at the option of the holder, into shares of common stock at a ratio of 1:1. Holders of CDIs have the right to direct CDN, how it should vote the underlying shares of common stock represented by CDIs at shareholder meetings. Holders of CDIs are entitled to the economic benefits of the underlying shares of common stocks, such as dividends as though they were the holders of the shares; and
- 6,527,284 options over shares of common stock held by 76 individual option holders.

Holding ranges	CDIs	Options over shares of common stock
1 – 1,000	76	0
1,001 – 5,000	214	0
5,001 – 10,000	179	2
10,001 – 100,000	529	66
100,001 – and over	116	8
	1,114	76

There are 47 holders of CDIs with a less than marketable parcel.

(b) Holders of CDIs holding greater than 5%

	Beneficial interests in shares of common stock	
Name	Number	Percentage
The Principals Cornerstone Fund Pty Limited*	22,651,074	14.430
Johnson & Johnson Development Corporation	18,231,729	11.614
CM Capital Investments Pty Ltd	14,121,272	8.996
PFM Cornerstone Limited	13,476,406	8.585
Kaasim Pty Ltd	8,582,636	5.467

* 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	14.430
2.	Johnson & Johnson Development Corporation	18,231,729	11.614
3.	CM Capital Investments Pty Ltd (CM Capital Venture No.3)	14,121,272	8.996
4.	PFM Cornerstone Limited	13,476,406	8.585
5.	Kaasim Pty Ltd	8,582,636	5.467
6.	National Nominees Limited	5,512,167	3.511
7.	CM Capital Investments (CM Capital 3A)	3,508,112	2.235
8.	Equity Trustees Limited	3,309,778	2.108
9.	Mr. Alastair Hodges	3,048,416	1.942
10.	Mr. Densi Michael Hanley	2,313,230	1.474
11.	Litster & Associates Pty Ltd	2,284,335	1.455
12.	Mr. Garry Chambers	1,750,755	1.115
13.	Sayers Investments (ACT) Pty Ltd	1,664,445	1.060
14.	Megreg Holdings Pty Ltd	1,619,992	1.032
15.	Mr. Thomas William Beck and Mrs Lynne Carol Beck	1,525,804	0.972
16.	Mr. Joseph James Pagliaro & Mrs. Michelle Mary Pagliaro	1,420,367	0.905
17.	Mr. Ronald Chatelier	1,367,085	0.871
18.	Mrs. Elizabeth Jane Wilson	1,300,000	0.828
19.	Citicorp Nominees Pty Limited	1,294,320	0.825
20.	Mr. Andrew Denver & Mrs. Linda Denver	1,181,812	0.753
		110,163,735	70.178
		156,976,936	

(d) Restricted Securities

27,189,052 shares and 960,560 options over shares were released from mandatory escrow on 13 December 2008. There are no securities subject to mandatory escrow.

Corporate Directory

Board of Directors

Mr Mark Morrisson (CEO)
Mr Andrew Denver (Chairman)
Dr Colin Adam
Mr Denis Hanley
Mr Andy Jane
Mr Charles Kiefel
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, United 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

Universal Biosensors