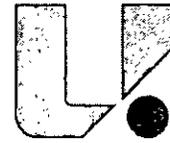


# Annual Report

Universal Biosensors, Inc.  
Annual Report for the Year Ended December 31, 2007



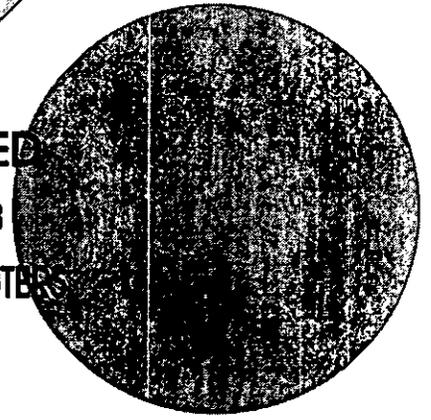
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## Chairman's Letter



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, 2007.

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

At the time of the initial public offering of our shares on the Australian Securities Exchange ('ASX'), we indicated that a major goal for 2007 was the entry into of a supply agreement with LifeScan, Inc. ('LifeScan') for the development and supply of a blood glucose product which we had been working on and to which we had committed significant resources. In October 2007, I was pleased to report that the Master Services and Supply Agreement was signed with LifeScan. This is a broad agreement that allows our good relationship to continue to grow and develop for a number of additional activities both for the current product and for future potential projects.

The funding we received through our successful renounceable rights issue which closed late in 2007 will allow the Company to complete the development of the initial blood glucose sensor strip and accelerate the establishment of our manufacturing capability. In addition, the funding will enable us to add a second development project to our dry immunoassay development program which, with our prothrombin time test, means we will have three active programs in the pipeline after the initial blood glucose test.

Notable during the year was our ability to attract highly capable new talent to the Company and to see the rapid development and growth of our existing team. We have a world class group of scientists, engineers, and quality, regulatory and operating professionals, who are the essential ingredient to the success of the Company.

The Company's goal of providing important tools for the management of chronic disease and thereby improving the lives of patients living with the disease requires robust products capable of being used effectively close to the patient. The Company possesses unique capabilities and expertise to bring these products to market and these capabilities continue to be enhanced.

It is pleasing to see the growth and development of the Company as it transitions from a research and development focused entity to one that is preparing to serve the needs of patients.

On your behalf and on behalf of the Board, I would like to thank the employees and service providers for their efforts and achievements during the year. The Company has made significant advances, however, the most important ones still remain.

Yours faithfully

Andrew Denver  
Chairman



## CEO Report



Throughout 2007 we made significant advances in establishing our commercial manufacturing capability as well as continuing with the research and development of novel point-of-care tests. The first two certifications of our Quality Management System were achieved, we moved into our purpose designed manufacturing facility, installed high volume manufacturing equipment for the initial blood glucose sensor strip, entered into a Master Services and Supply Agreement with LifeScan, Inc. and successfully raised A\$34.2 million through a renounceable rights issue.

### **Master Services and Supply Agreement**

On October 29, 2007, we entered into a master services and supply agreement with LifeScan, Inc. which contains the terms under which our subsidiary Universal Biosensors Pty Ltd will provide certain services to LifeScan and will act as a non exclusive manufacturer of an initial blood glucose sensor strip to LifeScan ('Master Services and Supply Agreement'). LifeScan, an affiliate of Johnson & Johnson, is one of the world's leading manufacturers of blood glucose monitoring systems for home and hospital use.

The Master Services and Supply Agreement positions us not just as a product developer, but also as a manufacturer of the initial blood glucose sensor strips and allows us to earn revenue in three different ways – through the successful achievement of specified milestones, through the manufacturing of the initial blood glucose sensor strips and through service fees once strips are sold in the market place.

The Master Services and Supply Agreement represents an expansion of our existing relationship with LifeScan and is the third agreement entered into between LifeScan and Universal Biosensors since 2002. The other key agreements include our Development and Research Agreement under which we provide continued product development services and the Licence Agreement under which we receive a license to certain key patents.

### **Initial glucose sensor strip for patient self-testing of blood glucose**

In January 2007 we started to fit out our new building in Rowville, Melbourne, which is now the headquarters of our manufacturing, research and development activities. We moved to the new building in Rowville in August at around the same time as our custom built high volume manufacturing equipment was installed. This followed on from the first two certifications of our Quality Management System in the first half of the year. These certifications are a prerequisite for companies wishing to design, develop and supply product into the heavily regulated global medical device and diagnostics marketplace.

The initial glucose sensor strip we are developing in conjunction with LifeScan and the associated meter components of the blood glucose product are well advanced in the validation stage of product development.

### **Capital Raising**

In the final quarter of 2007, we successfully completed a renounceable rights offering which raised AS\$34.2 million before capital raising expenses. These funds are being used for working capital, to upgrade our manufacturing capacity and to undertake further product development.

### **Personnel**

We continued to add strength and experience to our team throughout 2007. Dr Adrian Oates was appointed as our Vice-President of Quality and Regulatory Affairs, Dr David Hartley as Quality Manager and Robert Hamilton was

appointed as Production Manager. Garry Chambers our Head of Engineering expanded his responsibilities and was promoted to Vice President of Operations. In addition to our senior level appointments, we also added significant talent across other areas of the organization.

#### Product Pipeline

We currently have two non glucose development programs, including a program to develop immunoassay based tests (with the first such immunoassay test being a test for C-reactive protein) and a prothrombin time test. We made good progress with both these development programs in 2007. If the development efforts continue to be successful for each of these tests, we expect to be in a position to commence the formal validation phase in 2009, a process requiring approximately one year, following which, we will commence the process of seeking regulatory clearance for the test.

C-reactive protein is a molecule which when found in elevated level in the blood acts as a marker which indicates inflammation. Although this molecule was first described in the 1930's, it has remained poorly understood until the last few years. Today the role and measurement of C-reactive protein is being investigated in hundreds of studies, driven by the understanding that inflammation plays a key role in a number of important chronic conditions that affect millions of patients, including cardiovascular disease, cancer and certain respiratory diseases. Good tests for C-reactive protein exist in the laboratory, but not at point-of-care which is where many of the patients and healthcare providers who manage these conditions would prefer to be making their decisions, in real time. A key enabler for our C-reactive protein product opportunity is the ability to construct a 'dry' immunoassay with assay performance that allows comparability to benchmark laboratory tests with ease of use similar to that of existing blood glucose tests. The work we are doing with C-reactive protein is supported by an AusIndustry START grant.

Our other non-glucose program is the development of a prothrombin time test. This test is designed to be used to monitor the therapeutic window of the Coumadin (warfarin) family of drugs. As the population ages, more individuals are likely to be prescribed with Coumadin medication. The prothrombin time strip and meter program continues to advance well and we anticipate adding resources to this program in 2008.

Additionally, we are continually in discussions with LifeScan with respect to future potential development programs in the area of diabetes and blood glucose management generally.

#### The Year Ahead

In the year ahead we will continue to prepare for the manufacture of the initial blood glucose sensor strips for market, and continue to scale our business for high volume manufacturing. The medical devices and diagnostics industry is a global business with global suppliers and supply chains and we will continue to build the infrastructure necessary to support these activities. We are excited about the possibilities for the products under development and we will expand our resources to ensure they are advanced appropriately.

We look forward to another successful year continuing to build on our significant achievements to date.



**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, 2007

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**  
*(State or other jurisdiction of  
incorporation or organization)*

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

**Universal Biosensors, Inc.**  
**1 Corporate Avenue,**  
**Rowville, 3178, Victoria**  
**Australia**  
*(Address of principal  
executive offices)*

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

**Not Applicable**  
*(Zip Code)*

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

<u>Title of Each Class</u>	<u>Name of Each Exchange on Which Registered</u>
None	Not applicable

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

*Title of each class*

**Shares of common stock, par value \$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, and 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 Ruler 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 \$46,787,041 as of June 30, 2007.

The number of shares outstanding of each of the registrant's classes of common stock as of March 18, 2008:

<u>Title of Class</u>	<u>Number of Shares</u>
Common Stock, \$.0001 par value	156,958,812

**DOCUMENTS INCORPORATED BY REFERENCE:**

Certain information contained in the registrant's definitive Proxy Statement for the 2008 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," "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 "\$", "U.S.\$" or "dollars" and dollar amounts are references to United States dollars. References to "A\$" are references to Australian 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.;
- our expectations with respect to regulatory submissions and approvals of the blood glucose test;
- our expectations with respect to the timing and amounts of revenues expected under our master services and supply agreement with 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 regulatory submissions and approvals of our own products candidates;
- our expectations with respect to additional corporate collaborations, including revenues expected from such collaborations;
- 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), a C-reactive protein test to assist in the diagnosis and management of inflammatory conditions and a prothrombin time test for monitoring the therapeutic range of the anticoagulant, warfarin.

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 will undertake certain tasks and provide certain services to LifeScan with regard to tests for blood glucose monitoring. We will act as a non exclusive manufacturer of blood glucose test strips for LifeScan in accordance with a master services and supply agreement entered into with LifeScan in October 2007. We also continue to provide contract research and development services to LifeScan in the area of development of blood glucose tests for diabetics.

#### 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](http://www.universalbiosensors.com). The information contained in, or that can be accessed through, our web site is not part of this Form 10-K.

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 scope of the fields of diabetes and blood glucose management generally being the fields in which LifeScan have exclusive rights to the relevant patents; 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 2007, we have received contract research funding from LifeScan of approximately \$8,652,807 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 us gives 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 \$1,000,000 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. The new facilities have been fitted out to a large extent but we intend to complete some additional works to increase our manufacturing capacity.

During 2006, we ordered the construction of large scale custom designed manufacturing equipment which was delivered in the first half of 2007. From September 2001 to December 2007 we have spent approximately \$9,445,987 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 will provide certain services in the field of blood glucose monitoring to LifeScan and will act as a non exclusive manufacturer of blood glucose test strips for LifeScan. Additionally, we will continue to provide contract research and development services to LifeScan in the field of blood glucose monitoring pursuant to a Development & Research Agreement.

In addition to carrying out research and development activities for LifeScan, 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. Both 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 founding stockholder was The Principals Cornerstone Fund Pty Ltd, an Australian company which holds 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 \$1,000,000 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 approximately \$14,309,509. On December 5, 2006, we closed an initial public offer of our shares in Australia in which we raised approximately \$14,243,400 (equivalent to 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 approximately \$3,165,200 (equivalent to 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 approximately \$29,653,913 (equivalent to A\$34,246,034). Between April 2002 to December 2007, in addition to the funding from LifeScan, Universal Biosensors Pty Ltd has also received grant monies of \$1,636,542 through an Australian Commonwealth Government R&D Start Grant which is reflected as a reduction of our costs and \$132,240 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 \$110,670, we have incurred net losses since our inception. We recognized a net loss of \$36,966, \$2,219,039 and \$7,372,049 in the years ended December 31, 2005, 2006 and 2007, respectively. Our accumulated losses from inception to December 31, 2007 are \$9,759,926. 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:

- completing product development, scale up and transfer into production of a blood glucose test. As part of this program we intend to complete the fit out of our building in Rowville for manufacturing of the sensor strip component of the blood glucose test;
- continuing to provide services to LifeScan under the Master Services and Supply Agreement with regard to tests for blood glucose monitoring and, if the initial blood glucose product receives regulatory approval and is launched by LifeScan, act as a non exclusive manufacturer of blood glucose test strips for LifeScan;
- completing the development of our C-reactive protein test and the prothrombin time test and, if development is successful, seeking regulatory clearance for those tests. If we are successful in obtaining regulatory clearance for our C-reactive protein test and the prothrombin time test, we intend to sell those tests using specialist distributors in Europe, the United States and elsewhere internationally. We intend to manufacture the sensor strip component of both products in our Melbourne facility;
- seeking to leverage our intellectual property by developing additional immunoassays tests that use our platform of electrochemical cell technologies;
- if appropriate, we may seek commercial partners to assist in the development or sales and distribution of our existing and future tests. We intend to develop the necessary commercial scale manufacturing capability to enable us to manufacture the sensor component for any tests we develop, either for ourselves, or on behalf of third parties;
- continuing to undertake contract research and development work on behalf of LifeScan; and
- seeking to develop additional products for application in diabetes or blood glucose testing.

## **Plan of Operations for the Remainder of the Fiscal Year Ending December 2008**

Our plan of operation over the remainder of the fiscal year ending December 2008 is to:

- continue product validation activities in relation to the blood glucose test pursuant to the Master Services and Supply Agreement;
- continue to expand our commercial scale manufacturing capability and capacity for manufacturing blood glucose test strips;
- continue to build the necessary quality and regulatory infrastructure to support registration, launch and post-market activities of LifeScan;
- modify our Rowville building to enable us to increase our manufacturing capacity;
- commence work on other blood glucose products;
- continue research and development activities pursuant to the Development and Research Agreement;
- continue activities pursuant to the Licence Agreement;
- continue research and development activities with respect to our C-reactive protein test and prothrombin time test; and
- commence research and development work on other immunoassays.

As at March 18, 2008 we employed 51 full time employees. As we increase our manufacturing capability and accelerate our research and development activities, we expect that we will need to increase the number of our employees by at least 20 full time employees in the remainder of the fiscal year ending December 2008.

### **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, 2003, 2004, 2005, 2006 and 2007, 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 test devices we are developing comprise a novel disposable test strip and a reusable meter. The test devices 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 in a sample of blood when the analyte is reacted with the chemistry contained on the strip 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 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.

<u>Point-of-Care Test</u>	<u>Development Stage</u>	<u>Next Anticipated Milestones</u>
Blood glucose test	<ul style="list-style-type: none"><li>• Since October 2007 we have undertaken, and are undertaking a number of tasks for LifeScan, relating to the development and manufacture of a blood glucose test, pursuant to the Master Services and Supply Agreement</li><li>• We also continue to undertake development and research activities pursuant to the Development and Research Agreement</li></ul>	<ul style="list-style-type: none"><li>• Establish manufacturing</li><li>• Subsequent milestones at LifeScan's sole discretion including all decisions on launch if any</li></ul>
Immunoassay C-reactive protein test	<ul style="list-style-type: none"><li>• Development work undertaken since 2004</li><li>• Working prototype developed</li><li>• A minimum of two additional years of development/product validation work required</li></ul>	<ul style="list-style-type: none"><li>• Commence product validation in 2009</li><li>• Establish manufacturing process</li></ul>
Prothrombin time test	<ul style="list-style-type: none"><li>• Development work undertaken since early 2005</li><li>• Working prototype developed</li><li>• A minimum of two additional years of development/product validation work required</li></ul>	<ul style="list-style-type: none"><li>• Commence product validation in 2009</li><li>• Establish manufacturing process</li></ul>

### ***Blood glucose test***

Since April 2002, we have been undertaking contract research and development of a blood glucose test and associated technologies, for LifeScan. LifeScan has the exclusive rights to commercialization of the blood glucose test. We expect that we will continue to undertake research and development for LifeScan in the area of blood glucose management generally.

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 blood glucose test strips for LifeScan. The Master Services and Supply Agreement envisages that Universal Biosensors will manufacture the blood glucose test strips in its Rowville facility on a non exclusive basis, should the blood glucose product receive clearance to sell and be launched by LifeScan. LifeScan is solely responsible for registration strategy and commercial efforts. We are a non exclusive manufacturer for LifeScan and LifeScan may at some point in the future decide to establish its own manufacturing operations or engage other third party manufacturers.

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 in the blood. Typically the substances being measured are molecules such as proteins, enzymes or hormones. By incorporating different antibodies specific to different molecules in an 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 the 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 a process requiring at least one year, following which, we will commence the process of seeking regulatory clearance for this test. If appropriate, we may seek partners to assist in the development of this test. We intend selling the C-reactive protein test using specialist distributors in Europe, the United States and internationally.

### ***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 a process requiring at least one year, following which, we will commence the process of seeking regulatory clearance for the test. If appropriate, we may seek partners to assist in the development of this test. We currently intend selling the prothrombin time test using specialist distributors in Europe, the United States and elsewhere internationally.

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.

#### *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.

#### *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 are currently upgrading the capacity of this facility at an estimated cost of approximately \$1,800,000.

#### *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 and have built for us. The starting materials for the strips are freely available from third party suppliers. Initial packaging of the test strips would be conducted in our facility in Corporate Avenue Rowville, Melbourne.

The raw materials for the blood glucose test strips comprises films and separators for constructing the strips, and chemicals. We obtain the webs 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 strip is an enzyme which we currently source from one supplier. We expect to have a reliable supply of the enzyme.

With respect to the blood glucose product, under the Master Services and Supply Agreement we are a non exclusive manufacturer of the blood glucose test strips for LifeScan and LifeScan will be responsible for the blood glucose test meters and the control solution used to confirm accurate operation of the meters. With respect to the meters for our own products, we intend to outsource to contractors, the manufacture of the reusable meters and the control solution used to confirm accurate operation of the meters. We believe that outsourcing the manufacture of the meters and the control solution for our products will minimize the capital investment required by us yet maintain quality standards, help control costs and take advantage of the expertise such third parties have in the design and production of meters and control solutions.

#### *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; the conduct of trials which show the suitability for use of the product by non-professionals and demonstration of an appropriate quality management system. Assessment of the technical file and the quality management system usually takes place during an on-site inspection. There is no common international regulatory body and we would be required to be inspected by regulators from several of the 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 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, 2007.

*Patent Family 1 — Electrochemical Detection Method.* Patents under Patent Family 1 are currently pending in a range of jurisdictions within the Americas, Europe and Australasia. Patent Family 1 relates to an electrochemical detection method for detecting agglutination.

*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 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 2 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 June 19, 2016.

*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 20, 2018.

*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 currently either pending or 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 March 16, 2019.

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

*Patent Family 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 March 26, 2021.

*Patent Family M — Method of Preventing Short Sampling of a Capillary or Wicking Fill Device.* Patents under Patent Family M 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 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 March 26, 2021.

*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 July 6, 2021.

*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 12, 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 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 October 1, 2022.

*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 December 16, 2022.

*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.

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. We are in the process of scaling up our commercial scale manufacturing capability to enable us to undertake the manufacture of test strips. As part of this process, we will establish practices with respect to working capital items. If LifeScan is successful in obtaining regulatory clearances for the 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 out the circumstances under which LifeScan may return defective products.

#### *Dependence on single customer.*

We currently receive a significant portion of our income from LifeScan pursuant to the Development and Research Agreement. Between April 2002 and December 2007, we have received contract research funding from LifeScan of approximately \$8,652,807. We recognized income under the Development and Research Agreement of \$2,086,013, \$2,000,000 and \$999,981 in the fiscal years ending December 31, 2005, 2006 and 2007 respectively. Income from the Development and Research Agreement represented 92%, 84% and 45% of our income for the fiscal years ending December 31, 2005, 2006 and 2007, respectively. We expect that we will receive in the order of \$1,000,000 under the Development and Research Agreement for the fiscal year ending December 31, 2008. 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 us 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 agreement is otherwise terminated in accordance with its terms.

In January 2008, LifeScan paid us a one-time fee of \$1,000,000 in connection with the Master Services and Supply Agreement. We may receive a total of up to three milestone amounts upon the achievement of regulatory approval of the initial blood glucose monitoring product in three specified jurisdictions. If the blood glucose 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 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 \$1,636,542 under the Commonwealth of Australian grant and \$132,240 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 and our prothrombin time 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 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, they have the potential to significantly limit or render obsolete the current prothrombin time market, should they be approved.

### *Employees*

At March 18, 2008 we had 51 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) 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.*

***LifeScan have the sole rights to commercialize the blood glucose tests we have been involved in developing.***

LifeScan have the sole rights to commercialize the blood glucose tests we have been involved in developing. We recently entered into a Master Services and Supply Agreement with LifeScan, Inc. which contains the terms pursuant to which Universal Biosensors Pty Ltd will undertake certain tasks and provide certain services 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 blood glucose test strips for LifeScan. LifeScan control the decision whether or not to launch the blood glucose test and, if launched, the timing of such launch, the jurisdictions in which the product will be launched and the nature of any such launch. Decisions made by LifeScan with respect to the commercialization of the blood glucose test affect the extent and timing of revenues to us under the Master Services and Supply Agreement. LifeScan may choose not to launch the blood glucose product, may choose to launch the product in a limited number of jurisdictions, may delay the launch of the blood glucose test, or its sales and marketing efforts to commercialize the blood glucose tests may not be successful, all of which would have a material adverse effect on our business and financial position.

***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 \$1,000,000 in connection with the Master Services and Supply Agreement. We may receive a total of up to three further milestone amounts upon the achievement of regulatory approval of the initial blood glucose monitoring product in three specified 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 blood glucose test and is responsible for regulatory filings. If regulatory approval is not obtained in a timely fashion, the payment of the milestones under the Master Services and Supply Agreement will be delayed. Any delay in obtaining regulatory approval and launching the blood glucose tests will also result in a delay in the receipt of any services fees and manufacturing fees payable to us which would have a material adverse effect on us. If regulatory approval is not achieved in one or more of the specified jurisdictions, we will not receive the milestone payment which corresponds to the achievement of regulatory approval in those relevant jurisdiction(s).

The service fee payable by LifeScan to Universal Biosensors is calculated by reference to the number of strips sold by LifeScan. If regulatory approval is not obtained or if LifeScan determines not to launch the blood glucose test, Universal Biosensors will not receive any services fees notwithstanding that it would have undertaken services for LifeScan pursuant to the Master Services and Supply Agreement. Likewise, if regulatory approval is not obtained or if the product is not launched, Universal Biosensors will not manufacture test strips for LifeScan and will therefore not receive any fees for the manufacture of the blood glucose tests strips. Even if regulatory approval is obtained by LifeScan and LifeScan launch the blood glucose test, the number of blood glucose tests strips ordered from us may be low or we may not be able to manufacture adequate quantities of the blood glucose test strips due to factors within or outside of our control. In each of these circumstances our inflows will be reduced or eliminated which would have a material adverse effect on us.

***The new blood glucose test may not be successful.***

If the blood glucose test is launched, our revenues from services fees and, to a large extent strip manufacturing fees, are dependent on the market acceptance and level of sales of the blood glucose test achieved by LifeScan. If the blood glucose test is not successful in the market place, our revenues will be reduced or eliminated which would have a material adverse effect on us.

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

The Master Services and Supply Agreement imposes a number of material obligations on us. If the Master Services and Supply Agreement with LifeScan were terminated as a result of either party defaulting on its material obligations, either party becoming insolvent or as a result of other factors outlined in the 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 but have not yet manufactured commercial quantities of 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 may be subject to ongoing inspections and regulation of regulatory authorities, including by the Australian Therapeutic Goods Administration and the Food and Drug Administration.

***Universal Biosensors faces the risk of product liability claims and product recall costs.***

We may be exposed to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of diagnostic tests. We intend to seek product liability insurance, however, adequate product liability insurance may not be available on commercially acceptable terms. Product liability claims may damage our reputation and, if insurance proves inadequate, the product liability claims may harm our business. Defending a suit, regardless of its merit, could be costly and could divert management attention. We have liabilities to LifeScan and indemnify LifeScan under the Master Services and Supply Agreement with respect to 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. In addition, in the event of any recall, corrective action or field action, and the cause or basis of such recall or action to the extent 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.

***There is a significant degree of technical risk associated with the development of our C-reactive protein test and prothrombin time tests.***

The development of our C-reactive protein test and our prothrombin time test and any new diagnostic test devices 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 three 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. However, we still need to undertake at least one further year of product development with respect to the tests and then undertake product validation. Both 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.

***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 test, LifeScan is responsible for obtaining necessary regulatory clearances. If LifeScan are unable to obtain the necessary clearances to sell or if the clearances are delayed, revoked or subject to unacceptable conditions we would not receive milestones or service fees 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 require the recall of 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.

***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:

- the timing of receipt by LifeScan of regulatory approval for the blood glucose test and the receipt of any applicable milestone payments;
- the timing of the introduction and market acceptance of the blood glucose test by LifeScan;
- our ability to manufacture sufficient quality and quantity of blood glucose tests strips for LifeScan;
- the extent to which LifeScan manufactures or utilizes other third party manufacturers to manufacture the blood glucose test strips;
- 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; and
- the timing and magnitude of certain research and development expenses.

***Our clinical trials for our C-reactive protein and prothrombin time tests could take longer to complete and cost more than we anticipate which may result in our development plans being significantly delayed.***

We will need to conduct clinical studies for regulatory submission and market acceptance purposes. These studies are costly, time consuming and unpredictable. Any unanticipated costs or delays in our clinical studies

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.

***We currently have very limited marketing and sales capability in relation to our non-blood glucose related products.***

We intend to commercialize our non-blood glucose related products upon receipt of regulatory approval. Prior to market launch we would need to acquire the ability to manage and support the specialist distributors we seek to recruit, and we may not be able to attract, and retain experienced personnel. Even if we acquire expert capability, our sales and marketing efforts may not be successful.

***We are dependent on a single supplier for certain raw materials.***

In common with most major manufacturers in our industry, certain components of our products 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. The key chemical in the blood glucose test strip is an enzyme which we currently source from one preferred supplier. The supplier is an established company and we expect to have a reliable supply of the enzyme and the technology is transferrable to another company if required. 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.

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

If any of our products after receiving regulatory approval fail to achieve or maintain market acceptance, our ability to become profitable or maintain profitability in the future will be adversely affected. We believe that market acceptance will depend on our ability to provide and maintain evidence of safety, efficacy and cost effectiveness. In addition, market acceptance depends on the effectiveness of our marketing strategy, and the ability of our products to be preferred by customers over the offerings of our competitors.

***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 or our prothrombin time test or any future tests we intend to develop. The termination of the License Agreement would have a material adverse effect on us.

***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. 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 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 \$110,670, we have incurred losses in each year since our inception. We incurred losses of approximately \$36,966, \$2,219,039 and \$7,372,049 in the fiscal years ended December 31, 2005, 2006 and 2007, respectively. Our accumulated losses from inception to December 31, 2007 are \$9,759,926. 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 scale our manufacturing operations to meet demand for blood glucose strips under the Master Services and Supply Agreement and for our point-of-care tests;
- the level of additional cost we may incur related to the fit out of our manufacturing facility in Melbourne, Australia and the acquisition of additional manufacturing equipment;
- our ability to perform the required services under the Master Services and Supply Agreement;
- the successful registration by LifeScan of the initial blood glucose test in the major target markets, including the markets in which we are entitled to milestone payments upon registration;
- LifeScan determining to launch the initial blood glucose test;
- successful market acceptance and the success of sales and marketing efforts of the initial blood glucose test by LifeScan;
- our ability to manufacture a sufficient quantity and quality of initial 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;
- 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 test and prothrombin time test and future point-of-care tests;
- the timing and successful registration of our products and our ability to maintain regulatory clearances, pass regular audits and respond to any issues that are raised by regulators from time to time;
- the ability of our products to be preferred over the products of our competitors;
- our capacity to manufacture the necessary quality and quantities of our products;
- successful market acceptance and the success of sales and marketing efforts of our products and the revenue generated by sales of products;
- the emergence of competing technological developments;
- our research and development efforts may take longer than we anticipate;
- the rate of progress and cost of our product development activities;
- expenses we incur in manufacturing, developing, marketing and selling products;
- 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.

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. 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 a significant source of income.***

We undertake contract research and development activities for LifeScan pursuant to a Development and Research Agreement. The Development and Research Agreement is expected to remain an ongoing source of income for us in the short to medium term. 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 significant source of income.

***We are likely to 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, significant additional capital would 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.

***Currency fluctuations may expose us to increased costs.***

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 Biosensor 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. Appreciation of United States dollars reporting currency against Australian dollars could result in increased expenses as it is calculated using the average exchange rate during the year.

Our business could otherwise be affected by fluctuations in foreign exchange rates causing increased costs. 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 and revenues in other jurisdictions. Prior to December 31, 2007, we did not hedge the effect of currency fluctuations on our overseas expenditures. We managed our currency risks by settling foreign currency payables within a short period of time upon recognition of a foreign currency liability. We have plans to hedge the effect of currency fluctuations commencing in the first half of 2008.

***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 and prothrombin time testing has, and continues to be, performed by large hospitals or commercial pathology laboratories. Healthcare professionals responsible for managing patients with an inflammatory disease or 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.

***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. 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.

***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. 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 is 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 testing market.

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 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 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. 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.

We may also be forced to bring an infringement action if we 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.

***Our shares have been publicly traded on the ASX in the form of CHESSE Depository Interests, or CDIs, since December 2006 and have a limited trading history. We expect that the price of our common stock will fluctuate substantially.***

Our shares of common stock in the form of CDIs were quoted on the ASX and began trading on December 13, 2006.

As a result, we have a limited trading history. We expect that the price of our common stock in the form of CDIs will fluctuate substantially. The price at which our shares in the form of CDIs will trade on the ASX will be influenced by a large number of factors including some which are specific to us and our operations, some which may affect the quoted medical diagnostic sector or quoted companies generally, and many which are outside our control.

***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, resales 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 will be 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 and related regulations implemented by the SEC, have substantially increased legal and financial compliance costs. We expect that our efforts to comply with applicable laws and regulations, including the Securities Exchange Act of 1934 as amended ("Exchange Act") and the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley Act"), will involve significant, and potentially increasing, costs. In particular, we will be evaluating our internal controls systems to allow management to report on, and our independent auditors to attest to, our internal controls. We will be performing the system and process evaluation and testing (and any necessary remediation) required to comply with the management certification and auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. If we are not able to implement the requirements of Section 404 in a timely manner or 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 have 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 8% 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%, 2% 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 CHESSE Depository Nominees Pty Ltd ("CDN") and the shares are registered in the name of CDN and held by CDN on behalf of and for the benefit of CDI Holders. CDN is a wholly owned subsidiary of ASX. CDI holders will be entitled to all the economic benefits of the shares underlying their CDIs, such as dividends (if any), bonus issues or rights issues 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.

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

The liability of certain Australian independent registered public accounting firms, such as Pricewaterhouse Coopers Australia ("PwC Australia"), with respect to claims arising out of their audit reports on companies' financial statements, is subject to the limitations set forth in the Professional Standards Act 1994 of New South Wales, Australia (the "Professional Standards Act") and the accountants scheme adopted by CPA Australia and 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"). As a result, the Professional Standards Act and the NSW Accountants Scheme 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 its professional services for us, including, without limitation, its audits of our financial statements, to the lesser of ten times the reasonable charge for the service by PwC Australia that gave rise to the claim and A\$20 million. The limit does not apply to claims for breach of trust, fraud or dishonesty.

These limitations may limit recovery upon the enforcement in Australian courts of any judgment under U.S. law 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.

## **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 are currently upgrading the capacity of this facility at an estimated cost of approximately \$1,800,000. 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. During 2006, we ordered the construction of large scale custom designed manufacturing equipment. The delivery of the manufacturing equipment took place in the first half of 2007. Our manufacturing equipment is based on pilot manufacturing equipment developed and tested by our scientists and engineers. The key manufacturing equipment includes Strip Manufacturing Machines. We expended approximately \$70,000, \$4,475,000 and \$1,993,974 in the years ended December 31, 2005, 2006 and 2007, respectively in relation to the acquisition of manufacturing equipment. In the period December 31, 2007 to March 25, 2008, we have committed an additional approximately \$4,300,000 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 would be suitable for the commercial manufacture of the strips for the three 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 may be developed.

## **ITEM 3. LEGAL PROCEEDINGS.**

So far as we are aware, there are no legal or arbitration proceedings, active or threatened against, or being brought by, 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, 2007.

## **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 CHESSE Depository Interests, or CDIs, under the ASX trading code "UBI". The Clearing House Electronic Subregister System, or "CHESSE", 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. CHESSE 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 CHESSE. 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 CHESSE Depository Nominees Pty Ltd, or CDN, and the shares are registered in the name of CDN and held by CDN on behalf of and for the benefit of the holders of CDIs. CDN is a wholly owned subsidiary of ASX.

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

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

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

The following tables sets forth, for the periods indicated, the highest and lowest market prices in Australian dollars for our CDIs reported on the ASX since December 13, 2006, the date on which the our CDIs were quoted thereon.

	<u>High A\$</u>	<u>Low A\$</u>
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

#### Security details

As of March 18, 2008, there were 156,958,812 shares of our common stock issued and outstanding and 4,946,395 employee options over an equivalent number of shares of common stock (3,047,341 of which were exercisable or exercisable within 60 days thereafter). All of our issued and outstanding shares of common stock are fully paid.

In connection with the initial public offering of our shares in Australia and quotation of our shares in the form of CDIs on the ASX, certain of our stockholders have entered into lock up agreements with ASX restricting their ability to dispose of their common stock. 27,189,052 of our shares are subject to escrow until December 12, 2008. Likewise, our Managing Director has entered into a lock up agreement with ASX restricting his ability to dispose of 960,560 of his shares that may be granted on exercise of his employee options until December 12, 2008.

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 at least six months but less than one year may sell so long as the public information requirements of Rule 144 are, and, after one year, is entitled to sell the shares without having to comply with the manner of sale, public information, volume limitation or 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:

<u>Date</u>	<u>Total Number of Registered Holders</u>	<u>Number of Holders that are United States Residents</u>
At March 18, 2008.....	1,009	11

### Dividends

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

### Securities authorized for issuance under equity compensation plans

Set out below are details of our Employee Option Plan as at December 31, 2007.

<u>Plan Category</u>	<u>Equity Compensation Plan Information</u>		
	<u>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</u>	<u>Weighted Average Exercise Price of Outstanding Options, Warrants and Rights</u>	<u>Number of Securities Remaining for Future Issuance</u>
Equity compensation plans approved by security holders .....	4,946,395	\$0.55	(1)
Equity compensation plans not approved by security holders .....	—	—	(1)
Total .....	4,946,395	\$0.55	(1)

- (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 prohibits 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

#### *Renounceable Rights Issue*

On December 4, 2007, we closed a renounceable rights issue of new shares of common stock to raise an aggregate total of approximately \$29,653,913 at an issue price of \$1.10 (equivalent to A\$1.20) per share. The renounceable rights issue was underwritten by Wilson HTM Corporate Finance Ltd, an underwriter based in Brisbane, Australia ("Underwriter"). We paid the Underwriter a management fee of approximately \$532,543 (equivalent to A\$599,306) and an underwriting commission of approximately \$912,931 (equivalent to

A\$1,027,381) in connection with the renounceable rights issue. In addition, we reimbursed the Underwriter for certain of their outgoings, costs and expenses incurred in connection with the renounceable rights issue. We raised approximately \$28,130,694 net of fees and commissions paid to the Underwriter in our renounceable rights issue in Australia.

In an agreement with the Underwriters, a company called PFM Cornerstone Limited sub-underwrote 12.5 million new shares in the rights offer. The Underwriters paid a sub-underwriting fee of approximately \$396,720 (equivalent to A\$450,000) to PFM Cornerstone Limited. Dr Adam and Messrs Hanley, Denver and Kiefel are directors of us and are also directors of, and have equity interests in, PFM Cornerstone Limited, a company which holds approximately 8% 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%, 2% and 2% respectively.

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

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

The table below sets forth the number of employee stock options exercised and the number of shares issued in the period from January 1, 2007 to December 31, 2007. We issued these shares in reliance upon exemptions from registration under Regulation S under the Securities Act of 1933, as amended.

<u>Period Ending</u>	<u>Number of Options Exercised and Corresponding Number of Shares Issued</u>	<u>Option Exercise Price</u>	<u>Proceeds Received</u>
January, 2007 . . . . .	79,745	\$0.29	\$ 23,425
April, 2007 . . . . .	7,250	\$0.33	\$ 2,400
July, 2007 . . . . .	28,998	\$0.33	\$ 9,600
August, 2007 . . . . .	10,874	\$0.33	\$ 3,588
August, 2007 . . . . .	79,745	\$0.29	\$ 23,442
November, 2007 . . . . .	36,248	\$0.29	\$ 10,512
November, 2007 . . . . .	18,124	\$0.29	\$ 5,256
November, 2007 . . . . .	<u>159,487</u>	\$0.33	<u>\$ 52,631</u>
Total . . . . .	<u>420,471</u>		<u>\$130,854</u>

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

There were no repurchases of equity securities in 2007.

**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, 2005, 2006 and 2007 and the period from inception to December 31, 2007 has been derived from our consolidated audited financial statements, included elsewhere herein. The selected financial data for the fiscal years ended December 31, 2003 and 2004 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 U.S. dollars (except as otherwise noted).

	Period from Inception (September 14, 2001) to December 31, 2007	Years Ended December 31,				
		2007	2006	2005	2004	2003
		US\$	US\$	US\$	US\$	US\$
Revenue . . . . .	—	—	—	—	—	—
Cost of goods sold . . . . .	—	—	—	—	—	—
Gross profit . . . . .	—	—	—	—	—	—
<b>Operating expenses:</b>						
Research and development (1 and 2) . . . . .	13,263,072	6,004,189	2,576,434	1,591,829	1,567,933	1,008,967
General and administrative(3) . . . . .	7,089,944	3,697,584	1,887,642	703,036	395,246	288,570
Total operating expenses . . . . .	20,353,016	9,701,773	4,464,076	2,294,865	1,963,179	1,297,537
Research and development income . . . . .	8,652,807	999,981	2,000,000	2,086,013	1,816,813	1,000,000
Loss from operations . . . . .	(11,700,209)	(8,701,792)	(2,464,076)	(208,852)	(146,366)	(297,537)
Interest and other income . . . . .	1,934,486	1,208,102	367,858	171,886	89,944	73,539
Net loss before tax . . . . .	(9,765,723)	(7,493,690)	(2,096,218)	(36,966)	(56,422)	(223,998)
Income tax (expense)/income . . . . .	5,797	121,641	(122,821)	—	—	37,878
Net loss . . . . .	(9,759,926)	(7,372,049)	(2,219,039)	(36,966)	(56,422)	(186,120)
Basic and diluted net loss per share . . . . .	US\$(0.17)	US\$(0.06)	US\$(0.04)	US\$0.00	US\$0.00	US\$0.00
Number of shares used to compute per share data . . . . .	56,761,670	129,637,286	49,408,822	45,573,580	43,533,269	43,533,269

Notes:

	US\$	US\$	US\$	US\$	US\$	US\$
(1) Net of research grant income in these amounts . . . . .	1,636,542	731,951	436,015	468,576	—	—
(2) Includes non-cash compensation expense (R&D) . . . . .	391,590	285,127	106,463	—	—	—
(3) Includes non-cash compensation expense (General & Administrative) . . . . .	430,791	233,074	197,717	—	—	—

	Year Ended December 31,				
	2007	2006	2005	2004	2003
	US\$	US\$	US\$	US\$	US\$
<b>Balance Sheet Data:</b>					
Cash and cash equivalents . . . . .	\$36,990,423	\$23,885,198	\$3,253,426	\$3,225,446	\$3,197,621
Total assets . . . . .	55,992,321	30,051,095	4,551,345	4,583,843	4,502,992
Long-term debt . . . . .	—	—	—	—	—
Convertible preference shares(1) . . .	—	—	3,000,000	3,000,000	3,000,000
Total stockholders' (deficit) equity . .	52,675,265	27,914,725	4,167,079	4,327,608	4,406,521

(1) Convertible preference shares were converted to shares of common stock immediately prior to the issue of shares under 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. We have carried out in excess of three years of research and development on a point-of-care immunoassay blood test for C-reactive protein and a point-of-care prothrombin time blood test for monitoring the therapeutic range of warfarin and have developed working prototypes of both tests. In 2002, we entered into a Development and Research Agreement with LifeScan pursuant to which we undertake contract research and development in the area of diabetes management and the development of a blood glucose test for diabetics. At the same time in 2002, we also entered into a License Agreement with LifeScan pursuant to which LifeScan granted us a license to use certain intellectual property in connection with our point-of-care test devices. In 2007 we entered into a Master Services and Supply agreement with LifeScan which contains the terms pursuant to which we will provide certain services to LifeScan and will act as a non exclusive manufacturer of certain blood glucose test strips to LifeScan.

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 and an initial payment under the Master Services and Supply Agreement received in January 2008 and government and state grants.

*Master Services and Supply Agreement with LifeScan*

On October 29, 2007, we along with Universal Biosensors Pty Ltd entered into a master services and supply agreement with LifeScan which contains the terms pursuant to which Universal Biosensors Pty Ltd will provide certain services to LifeScan and will act as a non exclusive manufacturer of certain initial blood glucose test strips to LifeScan. We have agreed to guarantee the obligations of Universal Biosensors Pty Ltd under the Master Services and Supply Agreement.

LifeScan will have control over the commercialization of the blood glucose test strips (which are not currently approved for marketing and sale), including sole discretion to decide where and how to market and sell the test strips. After an initial costing phase, LifeScan will pay Universal Biosensors Pty Ltd an annually agreed transfer price per test strip manufactured and supplied by Universal Biosensors Pty Ltd, with such transfer price not to exceed a maximum amount specified in the Master Services and Supply Agreement.

Pursuant to the terms of the Master Services and Supply Agreement, Universal Biosensors Pty Ltd will provide a range of services to LifeScan, including continued development activities with respect to the initial test strips and services in support of the regulatory approval of the blood glucose monitoring product and the manufacture of the initial blood glucose tests strips. In January 2008, LifeScan paid Universal Biosensors Pty Ltd a one-time fee of \$1,000,000 in connection with the services, and will pay Universal Biosensors Pty Ltd a total of up to three milestone amounts upon the achievement of regulatory approval of the initial blood glucose monitoring product in three specified jurisdictions. In addition, Universal Biosensors Pty Ltd will receive a quarterly service fee which will be calculated with reference to the number of relevant products sold by LifeScan irrespective of who manufactures such products. The service fee is capable of being paid out as a lump sum fee in certain circumstances. We will also be paid a fee in connection with blood glucose tests strips manufactured by us.

Universal Biosensors Pty Ltd assigns to LifeScan all intellectual property in the test strips, in the manufacturing process for the test strips and with respect to certain other work Universal Biosensors Pty Ltd has undertaken in connection with the LifeScan product. LifeScan grants Universal Biosensors Pty Ltd a license to use such intellectual property outside of the defined LifeScan field of diabetes and blood glucose management generally ("LifeScan Field").

The Master Services and Supply Agreement will continue until it is terminated in accordance with its terms. The Master Services and Supply Agreement may be terminated for material breach by the other party if that breach is not remedied after notice requiring it to do so. LifeScan may terminate the Master Services and Supply Agreement if either we or Universal Biosensors Pty Ltd undergoes an insolvency event, under certain circumstances for a change of control of Universal Biosensors Pty Ltd or us or if LifeScan is unable to obtain regulatory approval for relevant products. LifeScan may also terminate the Master Services and Supply Agreement under certain circumstances after payment of a lump sum fee calculated in accordance with the Master Services and Supply Agreement. Universal Biosensors Pty Ltd may also terminate with two years notice in certain limited circumstances.

#### ***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, 2007, we have received aggregate contract research funding from LifeScan of \$8,652,807. We received \$2,086,013, \$2,000,000 and \$999,981 in 2005, 2006 and 2007, 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 and prothrombin times 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 approximately \$1,782,829 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 December 31, 2008. 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 Australia 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 \$468,576, \$436,015 and \$731,951 in the fiscal years ended December 31, 2005, 2006, 2007 and \$1,636,542 from inception to December 31, 2007, 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 approximately \$440,000 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. To date only one grant payment of \$132,240 in October 2007 has been received under this grant.

***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.

***(a) 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 Black-Scholes pricing model is discussed below.

***Share price at valuation date***

We have applied 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 2004 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.

<u>Date of Capital Raising</u>	<u>Value per Preferred Stock U.S.\$ (Post Stock Split Described Elsewhere in this Form 10-K)</u>
December 2003 . . . . .	0.29
June 2006 . . . . .	0.33
August 2006 . . . . .	0.33

Based on these valuation points, we applied an assumed per share price of \$0.29 with respect to the options we granted in 2004 and \$0.33 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 either \$0.06 or \$0.07 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:

<u>Grant Date of Option</u>	<u>Pre Rights Offering</u>		<u>Post Rights Offering</u>	
	<u>Exercise Price</u>	<u>Fair Value of Option</u>	<u>Exercise Price</u>	<u>Fair Value of Option</u>
December 2003 . . . . .	\$0.29	\$0.08	\$0.22	\$0.08
January 2006 . . . . .	\$0.33	\$0.22	\$0.26	\$0.20
March 2007 . . . . .	\$1.01	\$0.63	\$0.95	\$0.64
September 2007 . . . . .	\$1.08	\$0.66	\$1.02	\$0.66
October 2007 . . . . .	\$1.11	\$0.71	\$1.04	\$0.72

***Volatility***

With respect to the options granted in 2004 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 2004 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 in 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 \$0.40. The share price at valuation date was as follows:

<u>Option Grant Date</u>	<u>Share Price</u>	<u>Volatility</u>
March 22, 2007 . . . . .	\$0.98	74%
September 19, 2007 . . . . .	\$1.04	72%
October 29, 2007 . . . . .	\$1.10	76%

Consequently, the high level of volatility on our shares was the key driver for the volatility increasing from 55% at December 31, 2006 to 74%, 72% and 76% at March, September and October, 2007, respectively.

***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.

***(b) Research and Development Expenditures***

Research and development expenses consist of costs incurred to further our research and development activities and include salaries and related employee benefits, costs associated with building prototypes

including meter development, regulatory activities, research-related overhead expenses, 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 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 are recorded as accrued income and included in "Current Assets".

*(c) 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.

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.

*(d) 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.

***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, 2007, 2006 and 2005 were primarily derived from LifeScan under the Development and Research Agreement and totaled \$999,981, \$2,000,000 and \$2,086,013, respectively. We expect that we will receive approximately \$1,000,000 under the Development and Research Agreement for the fiscal year ending December 31, 2008. The 2008 payment anticipated is in line with what was received in the fiscal year ended December 31, 2007 but less than in the fiscal years ended December 31, 2006 and 2005 as the blood glucose test has reached the product validation stage and research and development activities to be funded by LifeScan are expected to be reduced during the fiscal year ending December 31, 2008.

**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 the R&D Start Grant Program, are expensed as incurred. Research and development expenses include:

- consultant and employee related expenses, which include salary and benefits;
- 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, 2005, 2006, 2007 and for period from inception to December 31, 2007 are as follows:

	Years Ended December 31,			Period from
	2005	2006	2007	Inception to
	U.S.\$	U.S.\$	U.S.\$	Year Ended
Research and development expenses . . . . .	2,060,405	3,012,449	6,736,140	14,889,614
Research grants received recognized against related research and development expenses . .	<u>(468,576)</u>	<u>(436,015)</u>	<u>(731,951)</u>	<u>(1,636,542)</u>
Research and development expenses as reported . . . . .	<u>1,591,829</u>	<u>2,576,434</u>	<u>6,004,189</u>	<u>13,263,072</u>

These expenses are related to developing our electrochemical cell platform technologies and diagnostic test pilot manufacturing production. We expect that our expenses will increase significantly during 2008 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 they will be completed and commercialized. The timing and cost of any program is dependent upon achieving technical objectives, which are inherently uncertain and, both the C-reactive protein and prothrombin time tests still have a high degree of technical risk. 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 for personnel in executive, finance, accounting, information technology and human resources functions. Other general and administrative expenses include patent related costs, facility costs not otherwise included in research and development expenses, consultancy fees and professional fees for legal and accounting services.

General and administrative expenses were, \$703,036, \$1,887,642 and \$3,697,584 in 2005, 2006 and 2007, respectively. We expect that our general and administrative expenses will increase as we expand our legal and accounting staff and 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 \$0, \$304,180, \$518,201 and \$822,381 for the years ended December 31, 2005, 2006, 2007 and for the period from inception to December 31, 2007.

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

	Exercise Price	Options Outstanding		Options Exercisable Shares
		Shares	Weighted Average Remaining Life in Years	
2004	\$0.22	2,076,982	9.0	663,329
2005	\$0.22	1,844,997	8.0	1,207,042
2006	\$0.26	2,011,736	9.0	532,838
2007	\$0.22	1,808,751	7.0	1,772,503
	\$1.04	100,000	9.8	—
	\$1.02	663,000	9.7	—
	\$0.95	845,000	9.2	281,657
	\$0.26	1,743,505	8.0	975,058
	\$0.22	1,594,890	6.0	1,594,890

## *Comparison of the Years Ended December 31, 2007 and 2006*

### *Research and development income*

Our research and development income for 2006 and 2007 was \$2,000,000 and \$999,981, respectively recognized pursuant to the Development and Research Agreement.

### *Research and development expenses*

Research and development expenses increased to \$6,004,189 in 2007 from \$2,576,434 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 \$436,015 and \$731,951 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;
- 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 \$3,697,584 in 2007 from \$1,887,642 in 2006. General and administrative expenses consist principally of salaries and related costs 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 becoming and United States domestic filer. We expect that our general and administrative expenses will increase as we expand our legal and accounting staff and 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 \$304,180 in 2006. The non-cash compensation expense increased to \$518,201 as a result of options granted to employees in 2007.

### *Interest and other income*

Interest and other income increased from \$367,858 in 2006 to \$1,208,102 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 2006 financial year with \$23,885,198 in cash. The cash and bank balance at the end of the 2007 financial year was \$39,744,102. 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 approximately \$29,653,913 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 \$2,219,039 in 2006 to \$7,372,049 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*

	<u>2006</u>	<u>2007</u>
Net loss .....	\$ 2,219,039	\$ 7,372,049
Weighted average number of ordinary shares used as denominator in calculating basic and diluted net loss per share .....	49,408,822	129,637,286
Basic and diluted net loss per share .....	\$ (0.04)	\$ (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.

*Comparison of the Years Ended December 31, 2006 and 2005*

*Research and development income*

Our research and development income for 2005 and 2006 was \$2,086,013 and \$2,000,000, respectively recognized pursuant to the Development and Research Agreement.

*Research and development expenses*

Research and development expenses increased to \$2,576,434 in 2006 from \$1,591,829 in 2005. The increase was due primarily to increased tenancy costs at our leased premises and related operating expenses, as well as increased staffing and other personnel related costs to support our research and development program. We expect that research and development expenses for pilot manufacturing and stability testing of our point-of-care tests will continue to increase in 2007. Included in the research and development expenses are Australian research grants of \$468,576 and \$436,015 received for the R&D Start Grant Program for 2005 and 2006, respectively.

*General and administrative expenses*

General and administrative expenses increased to \$1,887,642 in 2006 from \$703,036 in 2005. 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 becoming and United States domestic filer. We expect that our general and administrative expenses will increase as we expand our legal and accounting staff and 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 \$304,180. Prior to January 1, 2006, we 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, we complied with the disclosure only provisions of FASB Statement No. 123, “Accounting for Stock-Based Compensation”, or SFAS 123 hence no compensation charge was required.

*Interest and other income*

Interest and other income increased from \$171,886 in 2005 to \$367,858 in 2006. The increase in interest income is attributable to the greater level of funds invested during the year. We commenced the 2006 financial year with \$3,253,426 in cash. The cash and bank balance at the end of the 2006 financial year was \$23,885,198. The increase in cash and bank balance during the financial year is as a result of private placements in mid 2006 in which \$9,990,000 was raised and a private placement of our shares to United States accredited investors in December 2006 in which approximately \$3,165,200 (equivalent to A\$4,000,000) raised and an initial public offering of our shares in Australia in December 2006 in which approximately \$14,243,400 (equivalent to A\$18,000,000) was raised.

*Income tax expense*

Income tax expense during the 2006 year relates to the reversal of research and development credits.

*Net loss*

Net loss increased from \$36,966 in 2005 to \$2,219,039 in 2006 as a result of increased activity during the 2006 financial year thus resulting in increased research and development expenses and general and administrative expenses.

*Basic and diluted net loss per share*

	<u>2005</u>	<u>2006</u>
Net loss . . . . .	\$ 36,966	\$ 2,219,039
Weighted average number of ordinary shares used as denominator in calculating basic and diluted net loss per share . . . . .	43,573,580	49,408,822
Basic and diluted net loss per share . . . . .	\$ 0.00	\$ (0.04 )

The increase in basic and diluted net loss per share during the 2006 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, an initial one off payment under the Master Services and Supply Agreement and research grants and interest on investments. Through to December 31, 2007, we had received aggregate net cash proceeds from the following: (a) \$28,130,694 from the renounceable rights issue; (b) \$29,983,522 from the issuance of equity securities other than those issued under the renounceable rights offer; (c) \$8,652,807 from LifeScan under our Development and Research Agreement; (d) \$1,768,782 as contributions from government and state grants; and (e) \$1,934,486 from interest on investments. As of December 31, 2007, we had \$36,990,423 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, 2007, we used net cash of \$6,553,834 for operating activities. This consisted of a net loss for the period of \$7,372,049, which included \$594,527 of non-cash depreciation and amortization, and non-cash stock option expense of \$518,201. Net cash used in investing activities during the year ended December 31, 2007 was \$10,497,094, which included purchase of plant and equipment of \$7,743,415 reflecting the commencement of the expansion of our manufacturing capabilities and leasehold improvements to the Rowville premises and \$2,753,679 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 \$28,261,548 resulting from the renounceable rights offer which raised \$28,130,694 and \$130,854 raised by way of employees exercising their options.

For the year ended December 31, 2006, we used net cash of \$1,538,471 for operating activities. This consisted of a net loss for the period of \$2,219,039, which included \$231,613 of non-cash depreciation and amortization, and non-cash stock option expense of \$304,180. Net cash used in investing activities during the year ended December 31, 2006 was \$3,377,721, 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 \$25,533,159 resulting from the issue and sale of our preferred stock which raised \$9,990,000 and \$15,543,159 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.

For the year ended December 31, 2005, net cash provided by operating activities was \$207,570. This consisted of a net loss for the period of \$36,966, which included \$228,103 of non-cash depreciation and amortization. Net cash used in investing activities during the year ended December 31, 2005 was \$214,682, which included purchases of plant and equipment. Net cash provided by financing activities during the year ended December 31, 2005 was \$23,429 resulting from the exercise of options issued to employees.

As at December 31, 2007, we had cash and cash equivalents of \$36,990,423 as compared to \$23,885,198 as of December 31, 2006. This increase was due to the proceeds received from the renounceable rights issue we completed in December 2007. The increase was partially offset as a result of our ongoing operations including capital expenditure outlay.

In October 2007, we entered into a Master Services and Supply Agreement with LifeScan. In January 2008 we received an initial one off payment of \$1,000,000. The receipt and timing of any further revenue under the Master Services and Supply Agreement is uncertain.

If at any time LifeScan indicates that it will not proceed with commercialization of the 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 it is 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, we expect to be in a position to commence formal validation of the C- reactive protein test and the prothrombin time test in 2009, following which, we will seek regulatory clearance for these tests. We intend to sell our C-reactive protein and prothrombin time tests using specialist distributors in Europe, the US and internationally. 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. If appropriate, we may seek commercial partners to assist in the development or sales and distribution of its existing and future tests.

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 the proceeds of the renounceable rights issue, together with our cash, cash equivalents and short-term marketable securities balances, 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 do not receive the milestone payments as described under the Master Services and Supply Agreement and we are not able to generate revenue for the manufacturing and supply of the blood glucose test in 2008, we believe that our current cash and cash equivalents will be sufficient to fund our ongoing operations until the end of 2009. In order to achieve our objectives, we will likely require additional funding. 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 renounceable rights issue has resulted in dilution to our stockholders. 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 2008 to be in the range of \$6,000,000 to \$8,000,000 for the purchase of equipment to support our activities, such as mobilization to meet our obligations 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 is likely to total approximately \$1,800,000. Our future funding requirements will depend on many factors, including, but not limited to:

- expenses we incur in manufacturing, developing, marketing and selling products;
- 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;
- whether the timing and amount of receipts of revenue from LifeScan under the Master Services and Supply Agreement through: (i) milestone payments upon the achievement of regulatory milestones; (ii) services fees calculated with reference to blood glucose tests strips sold by LifeScan; and (iii) income from the manufacture of blood glucose tests strips by Universal Biosensors for LifeScan is sufficient to offset our costs in total or in part;
- 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 1, 2007, the future minimum lease payments under non-cancelable operating leases (with initial or remaining lease terms in excess of one year) are:

	U.S.\$
Less than 1 year . . . . .	440,905
1 - 3 years . . . . .	927,957
3 - 5 years . . . . .	994,013
More than 5 years . . . . .	<u>647,937</u>
Total minimum lease payments . . . . .	<u>3,010,812</u>

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

### Contractual Obligations

Our future contractual obligations primarily for future rental payment obligations on the current office and manufacturing space, including financing costs, at December 31, 2007 were as follows:

	Payments Due By Period				
	Total	Less than 1	1 - 3 Years	3 - 5 Years	More than 5
	U.S.\$	Year	U.S.\$	U.S.\$	Years
Long-Term Debt Obligations . . . . .	—	—	—	—	—
Asset Retirement Obligations(1) . . .	1,381,372	—	—	—	1,381,372
Operating Lease Obligations(2) . . .	3,010,812	440,905	927,957	994,013	647,937
Purchase Obligations . . . . .	—	—	—	—	—
Other Long-Term Liabilities on					
Balance Sheet under GAAP(3) . .	89,239	—	—	—	89,239
Total . . . . .	4,481,423	440,905	927,957	994,013	2,118,548

- (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.
- (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 February 2007, the Financial Accounting Standards Board ("FASB") issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities ("SFAS 159"). SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities using different measurement techniques. SFAS 159 requires additional disclosures related to the fair value measurements included in the entity's financial statements. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2007. Accordingly, we will adopt SFAS 159 in fiscal year 2008. We are currently evaluating the impact of SFAS 159 on the consolidated financial statements.

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, "Fair Value Measurements" ("SFAS 157"). SFAS 157 defines fair value as used in numerous accounting pronouncements, establishes a framework for measuring fair value in generally accepted accounting principles (GAAP) and

expands disclosure related to the use of fair value measures in financial statements. SFAS No. 157 does not expand the use of fair value measures in financial statements, but standardizes its definition and guidance in GAAP. The Standard emphasizes that fair value is a market-based measurement and not an entity-specific measurement based on an exchange transaction in which the entity sells an asset or transfers a liability (exit price). SFAS 157 establishes a fair value hierarchy from observable market data as the highest level to fair value based on an entity's own fair value assumptions as the lowest level. The Statement is to be effective for our financial statements issued in 2008; however, earlier application is encouraged. We believe that SFAS 157 will not have a material impact on our consolidated financial statements.

#### 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.

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

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

#### Supplementary Financial Information

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

	Year Ended December 31, 2007			
	Quarter Ended March 31	Quarter Ended June 30	Quarter Ended September 30	Quarter Ended December 31
Revenue	\$ —	\$ —	\$ —	\$ —
Cost of goods sold	—	—	—	—
Gross profit	—	—	—	—
<b>Operating expenses:</b>				
Research and development(1 and 2)	1,098,020	1,376,993	1,523,030	2,006,146
General and administrative(3)	638,093	1,071,943	666,754	1,320,794
Total operating expenses	1,736,113	2,448,936	2,189,784	3,326,940
Research and development income	249,997	249,995	249,996	249,993
Loss from operations	(1,486,116)	(2,198,941)	(1,939,788)	(3,076,947)
Interest and other income	307,586	299,411	215,284	385,821
Net loss before tax	(1,178,530)	(1,899,530)	(1,724,504)	(2,691,126)
Income tax (expense)/income	—	—	—	121,641
Net loss	\$ (1,178,530)	\$ (1,899,530)	\$ (1,724,504)	\$ (2,569,485)
Basic and diluted net loss per share	\$ (0.01)	\$ (0.01)	\$ (0.01)	\$ (0.02)
Number of shares used to compute per share data	128,072,553	128,086,971	128,191,651	134,276,878

Notes:

(1) Net of research grant income in these amounts . . . .	149,726	173,493	202,654	206,078
(2) Includes non-cash compensation expense (R&D) . . .	19,267	16,849	100,987	148,024
(3) Includes non-cash compensation expense (General & Administrative) . . . . .	26,331	47,732	38,011	121,000

	Year Ended December 31, 2006			
	Quarter Ended March 31	Quarter Ended June 30	Quarter Ended September 30	Quarter Ended December 31
<b>Revenue</b> . . . . .	\$ —	\$ —	\$ —	\$ —
Cost of goods sold . . . . .	—	—	—	—
Gross profit . . . . .	—	—	—	—
<b>Operating expenses:</b>				
Research and development(1 and 2) . . . . .	507,471	589,996	753,150	725,817
General and administrative(3) . . . . .	137,600	572,904	338,767	838,371
Total operating expenses . . . . .	645,071	1,162,900	1,091,917	1,564,188
Research and development income . . . . .	500,000	500,000	500,000	500,000
Loss from operations . . . . .	(145,071)	(662,900)	(591,917)	(1,064,188)
Interest and other income . . . . .	26,275	28,817	93,609	219,157
Net loss before tax . . . . .	(118,796)	(634,083)	(498,308)	(845,031)
Income tax (expense)/income . . . . .	—	(54,168)	(67,756)	(897)
Net loss . . . . .	\$ (118,796)	\$ (688,251)	\$ (566,064)	\$ (845,928)
Basic and diluted net loss per share . . . . .	\$ (0.00)	\$ (0.02)	\$ (0.01)	\$ (0.01)
Number of shares used to compute per share data . . . . .	43,613,014	43,613,014	43,613,014	56,906,135

Notes:

(1) Net of research grant income in these amounts . . . . .	137,813	102,321	81,920	113,961
(2) Includes non-cash compensation expense (R&D) . . . . .	38,927	29,306	20,300	17,930
(3) Includes non-cash compensation expense (General & Administrative) . . . . .	72,294	54,424	37,700	33,299

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

Not Applicable

**ITEM 9A. CONTROLS AND PROCEDURES**

We maintain disclosure controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized, and reported within the required time periods and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Principal Accounting Officer, as appropriate, to allow for timely decisions regarding required disclosure. The effectiveness of any system of disclosure controls and procedures is subject to certain limitations, including the exercise of judgment in designing, implementing, and evaluating the controls and procedures, the assumptions used in identifying the likelihood of future events, and the inability to eliminate improper conduct completely.

A controls system, no matter how well designed and operated, cannot provide absolute assurance 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. As a result, there can be no assurance that our disclosure controls and procedures will detect all errors or fraud.

We carried out an evaluation, under the supervision and with the participation of our management including our Chief Executive Officer, and Chief Financial Officer of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15(d)-15(e) under the Exchange Act as of December 31, 2007. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that these disclosure controls and procedures as of December 31, 2007 were effective to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

There were no changes in these controls or procedures identified in connection with the evaluation of such controls or procedures that occurred during the last fiscal quarter, on in other factors that have materially affected or are reasonably likely to materially affect these controls or procedures.

The annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

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

There were no changes in our internal control over financial reporting that occurred in the fourth quarter of 2007 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### **ITEM 9B. *OTHER INFORMATION***

None.

### **PART III**

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

The information required by this item regarding our directors and executive officers is incorporated by reference to our Definitive Proxy Statement to be filed with the Securities and Exchange Commission in connection with our Annual Meeting of Stockholders in 2008 (the "2008 Proxy Statement") under the captions "Election of Directors" and "Management of the Company — Executive Officers."

The information required by this item regarding "Compliance with Section 16(a) of the Exchange Act" is incorporated by reference to the 2008 Proxy Statement under the caption "Other Matters — Section 16(a) Beneficial Ownership Reporting Compliance."

We have adopted our Code of Ethics for Senior Financial Officers, a code of ethics that applies to our Chief Executive Officer and Chief Financial Officer. This code of ethics may be accessed and reviewed through our website at [www.universalbiosensors.com](http://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](http://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 2008 Proxy

Statement under the caption "Management of the Company — Nominating and Corporate Governance Committee."

The information required by this item regarding our Audit Committee is incorporated by reference to the 2008 Proxy Statement under the caption "Management of the Company — Board Committees — Audit Committee."

**ITEM 11. EXECUTIVE COMPENSATION.**

The information required by this item is incorporated by reference to the 2008 Proxy Statement under the captions "Management of the Company — Compensation of Directors" and "Executive Compensation."

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

The information regarding the security ownership of certain beneficial owners and management is incorporated by reference to the 2008 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 2008 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 2008 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 2008 Proxy Statement under the caption "Appointment of Independent Registered Public Accounting Firm."

**PART IV**

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

(a)(1) Financial Statements

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

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

## SIGNATURES

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

Universal Biosensors, Inc.  
(Registrant)

By: /s/ Mark Morrisson

Mark Morrisson  
Chief Executive Officer and Managing Director

Date: March 28, 2008

## POWER OF ATTORNEY

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

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/s/ Mark Morrisson Mark Morrisson	Chief Executive Officer and Managing Director (Principal Executive Officer)	March 28, 2008
/s/ Salesh Balak Salesh Balak	Chief Financial Officer (Principal Financial Officer)	March 28, 2008
/s/ Andrew Denver Andrew Denver	Director	March 28, 2008
/s/ Denis Hanley Denis Hanley	Director	March 28, 2008
/s/ Andy Jane Andy Jane	Director	March 28, 2008
/s/ Jane Wilson Jane Wilson	Director	March 28, 2008
/s/ Colin Adam Colin Adam	Director	March 28, 2008
/s/ Charles Kiefel Charles Kiefel	Director	March 28, 2008

**Consolidated Financial Statements and Schedules**

**UNIVERSAL BIOSENSORS, INC.**  
**(A Development Stage Enterprise)**

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PricewaterhouseCoopers  
ABN 52 780 433 757

Darling Park Tower 2  
201 Sussex Street  
GPO BOX 2650  
SYDNEY NSW 1171  
DX 77 Sydney  
Australia  
Telephone +61 2 8266 0000  
Facsimile +61 2 8266 9999  
[www.pwc.com/au](http://www.pwc.com/au)

**Report of Independent Registered Public Accounting Firm**

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, 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, 2007 and December 31, 2006, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2007 and, cumulatively, for the period from September 14, 2001 (date of inception) to December 31, 2007 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States).

Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

PricewaterhouseCoopers

March 28, 2008

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

	<u>December 31,</u> <u>2007</u>	<u>December 31,</u> <u>2006</u>
	<u>US\$</u>	<u>US\$</u>
<b>ASSETS</b>		
Current assets:		
Cash .....	\$36,990,423	\$23,885,198
Short-term investments (held-to-maturity) .....	2,753,679	—
Inventory — Raw materials .....	429,016	—
Accrued income .....	70,361	76,968
Receivables .....	485,902	—
Other current assets .....	<u>796,782</u>	<u>421,394</u>
Total current assets .....	41,526,163	24,383,560
Property, plant, and equipment .....	15,828,321	6,702,280
Less accumulated depreciation .....	<u>(1,386,070)</u>	<u>(1,034,745)</u>
Property, plant, and equipment — net .....	14,442,251	5,667,535
Spare parts .....	<u>23,907</u>	<u>—</u>
Total assets .....	<u>\$55,992,321</u>	<u>\$30,051,095</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable .....	\$ 786,296	\$ 1,226,779
Income taxes payable .....	15,869	128,982
Accrued expenses .....	808,210	613,492
Employee entitlements provision .....	<u>236,070</u>	<u>111,691</u>
Total current liabilities .....	1,846,445	2,080,944
Non-current liabilities:		
Asset Retirement Obligations .....	1,381,372	—
Employee entitlements provision .....	<u>89,239</u>	<u>55,426</u>
Total non-current liabilities .....	<u>1,470,611</u>	<u>55,426</u>
Total liabilities .....	3,317,056	2,136,370
Commitments and contingencies (note 4)		
Stockholders' equity:		
Preferred stock, \$0.01 par value. Authorized 1,000,000 shares; issued and outstanding nil in 2007 (2006: nil) .....		
Common stock, \$0.0001 par value. Authorized 300,000,000 shares; issued and outstanding 156,958,812 shares in 2007 (2006: 127,999,976) .....	15,696	12,800
Additional paid-in capital .....	58,920,901	30,144,048
Accumulated deficit .....	<u>(9,759,926)</u>	<u>(2,387,877)</u>
Accumulated other comprehensive income .....	<u>3,498,594</u>	<u>145,754</u>
Total stockholders' equity .....	<u>52,675,265</u>	<u>27,914,725</u>
Total liabilities and stockholders' equity .....	<u>\$55,992,321</u>	<u>\$30,051,095</u>

See accompanying notes to the financial statements

**UNIVERSAL BIOSENSORS, INC.**  
**(A Development Stage Enterprise)**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Period from Inception to December 31, 2007	Years Ended December 31,		
		2007	2006	2005
	US\$	US\$	US\$	US\$
Revenue . . . . .	—	—	—	—
Cost of goods sold . . . . .	—	—	—	—
Gross profit . . . . .	—	—	—	—
<b>Operating expenses:</b>				
Research and development(1 and 2) . . . . .	13,263,072	6,004,189	2,576,434	1,591,829
General and administrative(3) . . . . .	<u>7,089,944</u>	<u>3,697,584</u>	<u>1,887,642</u>	<u>703,036</u>
Total operating expenses . . . . .	20,353,016	9,701,773	4,464,076	2,294,865
Research and development income . . . . .	<u>8,652,807</u>	<u>999,981</u>	<u>2,000,000</u>	<u>2,086,013</u>
Loss from operations . . . . .	(11,700,209)	(8,701,792)	(2,464,076)	(208,852)
Interest and other income . . . . .	<u>1,934,486</u>	<u>1,208,102</u>	<u>367,858</u>	<u>171,886</u>
Net loss before tax . . . . .	(9,765,723)	(7,493,690)	(2,096,218)	(36,966)
Income tax (expense)/benefit . . . . .	<u>5,797</u>	<u>121,641</u>	<u>(122,821)</u>	<u>—</u>
Net loss . . . . .	<u>(9,759,926)</u>	<u>(7,372,049)</u>	<u>(2,219,039)</u>	<u>(36,966)</u>
Basic and diluted net loss per share . . . . .	<u>(0.17)</u>	<u>(0.06)</u>	<u>(0.04)</u>	<u>(0.00)</u>
Number of shares used to compute per share data . .	<u>56,761,670</u>	<u>129,637,286</u>	<u>49,408,822</u>	<u>45,573,580</u>

Notes:

1 Net of research grant income in these amounts . . . .	1,636,542	731,951	436,015	468,576
2 Includes non-cash compensation expense (research and development) . . . . .	391,590	285,127	106,463	—
3 Includes non-cash compensation expense (general and administrative) . . . . .	430,791	233,074	197,717	—

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		Shares	Amount US\$	Additional Paid-In Capital US\$	Accumulated Deficit US\$	Foreign Currency Translation Reserve US\$	Total Stockholders' Equity US\$
	Shares	Amount US\$						
<b>Balances at December 31, 2002</b> .....	—	—	43,533,269	4,353	1,291,727	110,670	(46,920)	1,359,830
Issuance of preference shares at \$0.29 per share for cash .....	# 10,210,926	3,000,000	—	—	—	—	—	3,000,000
<b>Comprehensive Income</b>								
Net loss for period from inception to December 31, 2003 .....	—	—	—	—	—	(186,120)	—	(186,120)
Foreign currency translation reserve .....	—	—	—	—	—	—	232,811	232,811
Total Comprehensive Income .....	—	—	—	—	—	—	—	46,691
<b>Balances at December 31, 2003</b> .....	10,210,926	3,000,000	43,533,269	4,353	1,291,727	(75,450)	185,891	4,406,521
<b>Comprehensive Income</b>								
Net loss .....	—	—	—	—	—	(56,422)	—	(56,422)
Foreign currency translation reserve .....	—	—	—	—	—	—	(22,491)	(22,491)
Total Comprehensive Income .....	—	—	—	—	—	—	—	(78,913)
<b>Balances at December 31, 2004</b> .....	10,210,926	3,000,000	43,533,269	4,353	1,291,727	(131,872)	163,400	4,327,608
<b>Comprehensive Income</b>								
Net loss .....	—	—	—	—	—	(36,966)	—	(36,966)
Foreign currency translation reserve .....	—	—	—	—	—	—	(146,992)	(146,992)
Total Comprehensive Income .....	—	—	—	—	—	—	—	(183,958)
Exercise of stock options issued to employees ..	—	—	79,745	8	23,421	—	—	23,429
<b>Balances at December 31, 2005</b> .....	10,210,926	3,000,000	43,613,014	4,361	1,315,148	(168,838)	16,408	4,167,079
Issuance of preference shares at \$0.33 per share for cash .....	# 30,176,036	9,990,000	—	—	—	—	—	9,990,000
Conversion of preference shares to ordinary shares .....	(40,386,962)	(12,990,000)	40,386,962	4,039	12,985,961	—	—	—
Issuance of ordinary shares at \$0.40 per share in private placement to American institutional and sophisticated investors in December 2006, net of issuance costs .....	# —	—	8,000,000	800	2,825,229	—	—	2,826,029
Issuance of ordinary shares at \$0.40 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	12,713,530	—	—	12,717,130
<b>Comprehensive Income</b>								
Net loss .....	—	—	—	—	—	(2,219,039)	—	(2,219,039)
Foreign currency translation reserve .....	—	—	—	—	—	—	129,346	129,346
Total Comprehensive Income .....	—	—	—	—	—	—	—	(2,089,693)
Stock option expense .....	—	—	—	—	304,180	—	—	304,180
<b>Balances at December 31, 2006</b> .....	—	—	127,999,976	12,800	30,144,048	(2,387,877)	145,754	27,914,725
Issuance of ordinary shares at \$1.10 per share, net of issuance costs .....	—	—	28,538,362	2,854	28,127,840	—	—	28,130,694
<b>Comprehensive Income</b>								
Net loss .....	—	—	—	—	—	(7,372,049)	—	(7,372,049)
Foreign currency translation reserve .....	—	—	—	—	—	—	3,352,840	3,352,840
Total Comprehensive Income .....	—	—	—	—	—	—	—	(4,019,209)
Exercise of stock options issued to employees ..	—	—	420,474	42	130,812	—	—	130,854
Stock option expense .....	—	—	—	—	518,201	—	—	518,201
<b>Balances at December 31, 2007</b> .....	—	—	156,958,812	15,696	58,920,901	(9,759,926)	3,498,594	52,675,265

**Note**

# Common stock has a par value of \$0.0001.

All share and per share amounts from inception to December 31, 2007 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, 2007	Years Ended December 31,		
	<u>2007</u>	<u>2007</u>	<u>2006</u>	<u>2005</u>
	US\$	US\$	US\$	US\$
<b>Cash flows from operating activities provided by/(used in):</b>				
Net loss . . . . .	(9,759,926)	(7,372,049)	(2,219,039)	(36,966)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and impairment of plant & equipment . . . . .	1,484,978	594,527	231,613	228,103
Share based payments expense . . . . .	822,381	518,201	304,180	—
Loss on fixed assets disposal . . . . .	97,715	97,715	—	—
Translation (gain)/loss . . . . .	250,049	591,601	(148,268)	(81,270)
Change in assets and liabilities:				
Inventory — Raw materials . . . . .	(429,016)	(429,016)	—	—
Receivables . . . . .	(485,902)	(485,902)	—	—
Prepaid expenses and other current assets . . . . .	(799,310)	(445,747)	(305,106)	(29,627)
Grants receivable . . . . .	(70,362)	6,606	(153,477)	76,510
Income tax payable . . . . .	15,869	(113,113)	128,982	—
Employee entitlements . . . . .	445,562	158,190	180,320	59,202
Accounts payable and accrued expenses . . . . .	967,483	325,153	442,324	(8,382)
Net cash provided by/(used in) operating activities . . . . .	<u>(7,460,479)</u>	<u>(6,553,834)</u>	<u>(1,538,471)</u>	<u>207,570</u>
<b>Cash flows from investing activities:</b>				
Purchases of investment securities . . . . .	(2,753,679)	(2,753,679)	—	—
Purchases of property, plant and equipment . . . . .	<u>(11,729,738)</u>	<u>(7,743,415)</u>	<u>(3,377,721)</u>	<u>(214,682)</u>
Net cash used in investing activities . . . . .	<u>(14,483,417)</u>	<u>(10,497,094)</u>	<u>(3,377,721)</u>	<u>(214,682)</u>
<b>Cash flows from financing activities:</b>				
Gross proceeds from share issue . . . . .	60,347,421	29,653,913	27,397,428	—
Transaction costs on share issue . . . . .	(3,387,488)	(1,523,219)	(1,864,269)	—
Proceeds from stock options exercised . . . . .	<u>154,283</u>	<u>130,854</u>	<u>—</u>	<u>23,429</u>
Net cash provided by financing activities . . . . .	<u>57,114,216</u>	<u>28,261,548</u>	<u>25,533,159</u>	<u>23,429</u>
Net increase in cash and cash equivalents . . . . .	35,170,320	11,210,620	20,616,967	16,317
Cash and cash equivalent at beginning of period . . . . .	—	23,885,198	3,253,426	3,225,446
Effect of exchange rate fluctuations on the balances of cash held in foreign currencies . . . . .	<u>1,820,103</u>	<u>1,894,605</u>	<u>14,805</u>	<u>11,663</u>
Cash and cash equivalents at end of period . . . . .	<u>36,990,423</u>	<u>36,990,423</u>	<u>23,885,198</u>	<u>3,253,426</u>

See accompanying notes to the financial statements.

**UNIVERSAL BIOSENSORS, INC.**  
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**Notes to Consolidated Financial Statements**  
**(for the years ended December 31, 2005, 2006 and 2007 and for the period from inception**  
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**(1) Organization of the Company**

Universal Biosensors, Inc. (the "Company") was incorporated on September 14, 2001 in the United States, and its wholly owned subsidiary and operating vehicle, Universal Biosensors Pty Ltd, was incorporated in Australia on September 21, 2001. Collectively, the Company and its wholly owned subsidiary Universal Biosensors Pty Ltd are referred to as "Universal Biosensors" or the "Group". The Company was listed on the Australian Securities Exchange ("ASX") on December 13, 2006 following the initial public offering in Australia of the Company's shares.

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 diagnostic tests comprise a novel disposable test strip and a reusable meter. The diagnostic tests 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 a C-reactive protein test 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 a C-reactive protein test and a prothrombin time test. Universal Biosensors intends to develop additional immunoassay tests by taking proven disease biomarkers currently used in the central laboratory environment and adapting those diagnostic tests to the point-of-care setting, using the Group's platform of electrochemical cell technologies.

On October 29, 2007, Universal Biosensors entered into a Master Services and Supply Agreement with LifeScan which contains the terms pursuant to which Universal Biosensors Pty Ltd will provide certain services in the field of blood glucose monitoring to LifeScan and will act as a non exclusive manufacturer of blood glucose test strips for LifeScan ("Master Services and Supply Agreement"). 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 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 United States dollars unless otherwise stated.

The Company's financial statements have been prepared assuming the Company will continue as a going concern. The Company has sustained operating losses since inception and expects such losses to continue as it furthers its research and development programs.

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**(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 in 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 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.

*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.

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***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 date of recognition.

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 4 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 grants under an R&D Start Grant Agreement as compensation for expenses incurred in respect of certain research activities into dry chemistry immuno-sensors. 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 on the balance sheet.

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Research and development expenses for years ended December 31, 2005, 2006, 2007 and for period from inception to December 31, 2007 are as follows:

	<u>Years Ended December 31,</u>			<u>Period</u>
	<u>2005</u>	<u>2006</u>	<u>2007</u>	<u>from</u>
	<u>US\$</u>	<u>US\$</u>	<u>US\$</u>	<u>Inception</u>
				<u>to Year</u>
				<u>Ended</u>
				<u>2007</u>
				<u>US\$</u>
Research and development expenses . . . . .	2,060,405	3,012,449	6,736,140	14,899,614
Research grants received recognized against related research and development expenses . .	<u>(468,576)</u>	<u>(436,015)</u>	<u>(731,951)</u>	<u>(1,636,542)</u>
Research and development expenses as reported . . . . .	<u>1,591,829</u>	<u>2,576,434</u>	<u>6,004,189</u>	<u>13,263,072</u>

***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. The Company classifies interest expense and penalties related to unrecognized tax benefits as income tax expense.

We are subject to income taxes in the United States and Australia. U.S. federal income tax returns up to the 2006 financial year have been lodged. Internationally, consolidated income tax returns up to the 2006 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.

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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.

During 2007, our overall ARO changed as follows:

	\$
<i>Movement in ARO</i>	
Opening balance at January 1 .....	—
New obligations .....	1,344,925
Accretion expense .....	34,682
Foreign currency translation .....	<u>1,765</u>
Ending balance at December 31 .....	<u><u>1,381,372</u></u>

***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.

***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***

***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 sublicense, 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

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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 2008, LifeScan is paying the Company U.S.\$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.

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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.

*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 consolidated financial statements are presented using a reporting currency of U.S. dollars.

The functional currency of the Company for financial years up to December 31, 2005 was determined by management to be U.S. dollars. This was based on the facts that the denomination of a significant proportion of transactions and the major source of finance were in U.S. 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 approximately U.S.\$33,478.

The functional currency of Universal Biosensors Pty Ltd is Australian dollars for all years presented.

*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 U.S.\$74,672, U.S.\$33,478, (U.S.\$151,758) and U.S.\$110,673 for each of the years ended December 31, 2005, 2006 and 2007 and the period from inception to December 31, 2007, 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;

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- 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, 2005, 2006 and 2007 are considered operating leases. The costs of operating leases are charged to the statement of operations on a straight-line basis over the lease term.

*Stock-based Compensation*

Prior to January 1, 2006, the Company applied 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

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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.

	<u>2005</u>
Net loss, as reported .....	\$(36,966)
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 .....	<u>(36,792)</u>
Pro forma net loss .....	<u>(73,758)</u>

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 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 and 2007 relative to amounts that would have been reported under previous accounting:

	<u>Under Previous Accounting</u>	<u>2006 SFAS 123(R) Adjustments</u>	<u>As Reported</u>
Net loss - 2006 .....	\$(1,914,859)	\$(304,180)	\$(2,219,039)
Net loss - 2007 .....	\$(6,853,848)	\$(518,201)	\$(7,372,049)

***Pension Costs***

As required by Australian law, Universal Biosensors Pty Ltd contributes to standard defined contribution superannuation funds on behalf of all employees at an amount up to 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

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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 February 2007, the Financial Accounting Standards Board ("FASB") issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities ("SFAS 159"). SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities using different measurement techniques. SFAS 159 requires additional disclosures related to the fair value measurements included in the entity's financial statements. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2007. Accordingly, we will adopt SFAS 159 in fiscal year 2008. We are currently evaluating the impact of SFAS 159 on the consolidated financial statements.

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, "Fair Value Measurements" ("SFAS 157"). SFAS 157 defines fair value as used in numerous accounting pronouncements, establishes a framework for measuring fair value in generally accepted accounting principles ("GAAP") and expands disclosure related to the use of fair value measures in financial statements. SFAS 157 does not expand the use of fair value measures in financial statements, but standardizes its definition and guidance in GAAP. The Standard emphasizes that fair value is a market-based measurement and not an entity-specific measurement based on an exchange transaction in which the entity sells an asset or transfers a liability (exit price). SFAS 157 establishes a fair value hierarchy from observable market data as the highest level to fair value based on an entity's own fair value assumptions as the lowest level. SFAS 157 is to be effective for the Group's financial statements issued in 2008; however, earlier application is encouraged. We believe that SFAS 157 will not have a material impact on the Company's consolidated financial statements.

**(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 approximately U.S.\$220,400 (equivalent to 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.

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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, 2007 are:

	U.S.\$
2008 .....	440,905
2009 .....	456,110
2010 .....	471,847
2011 .....	488,135
2012 .....	505,878
2013 and thereafter .....	<u>647,937</u>
Total minimum lease payments .....	<u>3,010,812</u>

Rent expense was \$140,348, \$159,756, \$397,139 and \$989,657 for the fiscal years ended December 31, 2005, 2006 and 2007 and for the period from inception to December 31, 2007, 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 \$1,782,829 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 December 31, 2008. 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 \$441,319 (2006: \$283,470) were received during 2007 and income of \$731,951 (2006: \$436,015, 2005: \$468,576, and period from inception to December 31, 2007: \$1,636,542) was recognized with \$70,361 recorded as accrued income at December 31, 2007 (2006: \$76,968).

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

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Government Grant at December 31, 2007 was \$132,240 (2006: \$0). This grant has been recognized against the acquisition cost of the related plant and equipment.

**(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.

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, 2007		Years Ended December 31,					
			2007		2006		2005	
	\$	%	\$	%	\$	%	\$	%
Loss before income taxes . . . . .	(9,765,723)		(7,493,690)		(2,096,218)		(36,966)	
Computed by applying income tax rate of home jurisdiction . . . . .	(2,929,717)	30	(2,248,107)	30	(628,865)	30	(11,090)	30
Research & development incentive . . . . .	(710,662)	7	(504,643)	7	(206,019)	10	—	—
Disallowed expenses/(income):								
Share based payment . . . . .	246,714	(3)	155,460	(2)	91,254	(4)	—	—
Other . . . . .	(65,281)	1	1,947	—	13,393	(1)	3,631	(10)
Change in valuation allowance . . . . .	4,021,083	(41)	2,947,178	(39)	766,870	(37)	58,554	(158)
Adjustment in respect of current income tax of prior years . . . . .	(567,934)	6	(473,476)	6	86,188	(4)	(51,095)	138
Income tax expense/(benefit) . . . . .	<u>(5,797)</u>	<u>—</u>	<u>(121,641)</u>	<u>2</u>	<u>122,821</u>	<u>(6)</u>	<u>—</u>	<u>—</u>

The income tax expense/(benefit) above relates solely to current income taxes.

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

	As of December 31,	
	2007	2006
Deferred tax assets:		
Operating loss carry forwards . . . . .	4,278,326	1,001,394
Unamortized capital raising cost . . . . .	743,885	447,425
Depreciation and amortization . . . . .	66,024	11,352
Asset retirement obligations . . . . .	31,374	—
Employee entitlements . . . . .	97,593	66,307
Other accruals . . . . .	132,095	130,403
Total deferred tax assets . . . . .	5,349,296	1,656,881
Valuation allowance for deferred tax assets . . . . .	(5,349,296)	(1,656,881)
Net deferred tax asset . . . . .	<u>—</u>	<u>—</u>

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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, 2007 the Company has \$14,261,087 (\$3,337,980 at December 31, 2006) 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. There were no stock options granted in 2005. There were 2,066,108 options granted in 2006 and 1,608,000 options granted in 2007.

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

	Grant Date				
	October 2007	September 2007	March 2007	2006	2004
Exercise Price . . . . .	\$ 1.04	\$ 1.02	\$ 0.95	\$ 0.26	\$ 0.22
Share Price at Grant Date . . . . .	\$ 1.10	\$ 1.04	\$ 0.98	\$ 0.33	\$ 0.29
Volatility . . . . .	76%	72%	74%	55%	40%-45%
Expected Life . . . . .	10 years	10 years	10 years	10 years	10 years
Risk Free Interest Rate . . . . .	6.13%	5.99%	5.86%	4.40%	4.65%
Fair Value of Option . . . . .	\$ 0.72	\$ 0.66	\$ 0.64	\$ 0.20	\$ 0.08

Each of the inputs to the Black-Scholes pricing model is discussed below.

**Share price at valuation date**

We have applied 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 2004 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

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consistent with the shares that were issued in certain private capital raisings undertaken by the Company around the respective valuation dates of the options, as these prices are most indicative of the fair value of the Company's equity in the market to a willing participant at and around the applicable valuation date of the options. Although we raised capital by issuing preferred shares, for the purposes of valuing our options we regarded our ordinary and preferred shares as being equivalent in relevant economic aspects and therefore the capital raisings served as a suitable valuation point with respect to the valuation of our options. In this regard we note that the preference shares carried the right to convert to ordinary basis on a one to one basis, and all were converted during 2006 in conjunction with our initial public offering.

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

<u>Date of Capital Raising</u>	<u>Value per Preferred Stock U.S.\$ (Post Stock Split Described in Note 11)</u>
December 2003 .....	0.29
June 2006 .....	0.33
August 2006 .....	0.33

Based on these valuation points, we applied an assumed per share price of U.S.\$0.29 with respect to the options we granted in 2004 and U.S.\$0.33 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 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 either \$0.06 or \$0.07 in accordance with the terms of the options and a formula set out in the Listing Rules of the ASX. The table below reflects the changes to the exercise price and the fair value of option as a result of the rights offering:

<u>Grant Date of Option</u>	<u>Pre Rights Offering</u>		<u>Post Rights Offering</u>	
	<u>Exercise Price</u>	<u>Fair Value of Option</u>	<u>Exercise Price</u>	<u>Fair Value of Option</u>
December 2003 .....	\$0.29	\$0.08	\$0.22	\$0.08
January 2006 .....	\$0.33	\$0.22	\$0.26	\$0.20
March 2007 .....	\$1.01	\$0.63	\$0.95	\$0.64
September 2007 .....	\$1.08	\$0.66	\$1.02	\$0.66
October 2007 .....	\$1.11	\$0.71	\$1.04	\$0.72

**Volatility**

With respect to the options granted in 2004 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 2004 and 55% for the options granted in 2006. These figures were within the range of observed volatilities for comparable listed companies.

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With respect to the options granted in 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 \$0.40. The share price at valuation date was as follows:

<u>Option Grant Date</u>	<u>Share Price</u>	<u>Volatility</u>
March 22, 2007 . . . . .	\$0.98	74%
September 19, 2007 . . . . .	\$1.04	72%
October 29, 2007 . . . . .	\$1.10	76%

Consequently, the high level of volatility on our shares was the key driver for the volatility increasing from 55% at December 31, 2006 to 74%, 72% and 76% at March, September and October, 2007, respectively.

***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:

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>
Balance at January 1, 2004 . . . . .	—	—
Granted . . . . .	<u>2,076,982</u>	<u>0.29</u>
Balance at December 31, 2004 . . . . .	2,076,982	0.29
Granted . . . . .	—	—
Exercised . . . . .	(79,745)	0.29
Forfeited . . . . .	(152,240)	0.29
Expired . . . . .	—	—
Balance at December 31, 2005 . . . . .	<u>1,844,997</u>	<u>0.29</u>
Granted . . . . .	2,066,108	0.33
Exercised . . . . .	—	—
Forfeited . . . . .	(90,618)	0.31
Expired . . . . .	—	—
Balance at December 31, 2006 . . . . .	<u>3,820,487</u>	<u>0.31</u>
Granted . . . . .	1,608,000	1.04
Exercised . . . . .	(420,471)	0.31
Forfeited . . . . .	(61,621)	0.33
Expired . . . . .	—	—
Balance at December 31, 2007 . . . . .	<u>4,946,395</u>	<u>0.55</u>

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At December 31, 2007, the number of options exercisable was 2,851,605 (2006: 2,305,341 and 2005: 1,207,042).

The following table represents information relating to stock options outstanding under the plans as of December 31, 2007, 2006 and 2005:

	Exercise Price	Options Outstanding		Options Exercisable Shares
		Shares	Weighted Average Remaining Life in Years	
2005.....	\$0.22	1,844,997	8.0	1,207,042
2006.....	\$0.26	2,011,736	9.0	532,838
	\$0.22	1,808,751	7.0	1,772,503
2007.....	\$1.04	100,000	9.8	—
	\$1.02	663,000	9.7	—
	\$0.95	845,000	9.2	281,657
	\$0.26	1,743,505	8.0	975,058
	\$0.22	1,594,890	6.0	1,594,890

The table below sets forth the number of employee stock options exercised and the number of shares issued in the period from December 31, 2005. 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
April, 2005 .....	79,745	\$0.29	\$ 23,429
January, 2007 .....	79,745	\$0.29	\$ 23,425
April, 2007 .....	7,250	\$0.33	\$ 2,400
July, 2007 .....	28,998	\$0.33	\$ 9,600
August, 2007 .....	10,874	\$0.33	\$ 3,588
August, 2007 .....	79,745	\$0.29	\$ 23,442
November, 2007 .....	36,248	\$0.29	\$ 10,512
November, 2007 .....	18,124	\$0.29	\$ 5,256
November, 2007 .....	159,487	\$0.33	\$ 52,631
Total .....	<u>500,216</u>		<u>\$154,283</u>

**(7) Economic Dependency**

The Company has entered 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.

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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.

In consideration for the rights, licenses and options granted under the Development and Research agreement, LifeScan made payments totaling \$999,981 in 2007, \$2,000,000 in 2006, \$2,086,013 in 2005 and \$8,652,807 for the period from inception to December 31, 2007.

***Master Services and Supply Agreement***

On October 29, 2007 the Company and Universal Biosensors Pty Ltd entered into a Master Services and Supply Agreement with LifeScan which contains the terms pursuant to which Universal Biosensors Pty Ltd will provide certain services in the field of blood glucose monitoring to LifeScan and will act as a non exclusive manufacturer of blood glucose test strips for LifeScan. If the Master Services and Supply Agreement is terminated as a result of a party defaulting on its material obligations, a party becoming insolvent 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, 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 a research and development agreement. The terms of the agreement are mentioned in note 7.

The following balances are outstanding at the reporting date in relation to transactions with LifeScan:

	<u>As of December, 31</u>	
	<u>2007</u>	<u>2006</u>
	\$	\$
<i>Receivables</i>		
Reimbursement of expenses . . . . .	412,032	—

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 \$396,720 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.

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

	As of December, 31	
	2007	2006
	\$	\$
Plant and equipment . . . . .	3,349,905	2,170,549
Leasehold improvements . . . . .	5,548,792	192,724
Capital work in process . . . . .	<u>6,929,624</u>	<u>4,339,007</u>
	15,828,321	6,702,280
Accumulated depreciation . . . . .	<u>(1,386,070)</u>	<u>(1,034,745)</u>
Property, plant & equipment, net. . . . .	<u>14,442,251</u>	<u>5,667,535</u>

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, 2005, 2006 and 2007 was \$53,371, \$162,990 and \$264,668, 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 \$132,240 for the year ended December 31, 2007. 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 Other Currents Assets on the balance sheet.

Depreciation expense was \$228,103, \$231,61, \$594,527 and \$1,484,978 for the fiscal years ended December 31, 2005, 2006 and 2007 and for the period from inception to December 31, 2007, respectively.

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

	<b>\$</b>
Movement in accumulated depreciation . . . . .	351,325
Written down value of fixed assets disposed. . . . .	391,542
Difference in exchange rates . . . . .	<u>(148,340)</u>
Depreciation expense for the financial year . . . . .	<u>594,527</u>

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**(10) Accrued Expenses**

Accrued expenses consist of the following:

	As of December, 31	
	2007	2006
	\$	\$
Legal, tax and accounting fees .....	519,245	265,086
Goods & services tax .....	—	218,399
Salary related on-costs .....	219,396	120,252
Other .....	69,569	9,755
	808,210	613,492

**(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 30,176,059 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 approximately \$29,653,913.

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.

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

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

**(12) Convertible preferred stock**

Up until the time of the Company's Australian initial public offering, the Company had on issue 40,386,962 Series A convertible preferred stock. The Company issued 3,758,868, 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 U.S.\$9,990,000 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,

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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 \$127,487, \$222,500, \$425,548 and \$924,024 for the fiscal years ended December 31, 2005, 2006 and 2007, and the period from inception to December 31, 2007, 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.

	<u>Period from Inception to December 31, 2007</u>	<u>Year Ended December 31,</u>		
		<u>2007</u>	<u>2006</u>	<u>2005</u>
Weighted average number of ordinary shares used as denominator in calculating basic and diluted net loss per share . . . . .	<u>56,761,670</u>	<u>129,637,286</u>	<u>49,408,822</u>	<u>45,573,580</u>

**(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

**UNIVERSAL BIOSENSORS, INC.**  
**(A Development Stage Enterprise)**

**Notes to Consolidated Financial Statements — (Continued)**  
**(for the years ended December 31, 2005, 2006 and 2007 and for the period from inception**  
**(September 14, 2001) to December 31, 2007)**

- 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, 2007.

**(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) Subsequent Events**

In January 2008, LifeScan paid the Company a one off fee of \$1,000,000 in connection with the Master Services and Supply Agreement.

On March 17, 2008 the Company announced that, subsequent to a review of employee and director performance for the year ended December 31, 2007, the directors granted 1,199,000 options under the Company's Employee Option Plan. Included within this grant are 150,000 options granted to a director which require shareholder approval.

With the exception of the above, there has not arisen in the interval between the end of the financial year and March 28, 2008 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, 2005, 2006 and 2007 and for the period from inception**  
**(September 14, 2001) to December 31, 2007)**

	<u>Balance at Beginning of Period</u>	<u>Additions</u>		<u>Deductions</u>	<u>Balance at End of Period</u>
		<u>Charged to Costs and Expenses</u>	<u>Charged to Other Accounts</u>		
	\$	\$	\$	\$	\$
<i>Year ended December 31, 2004</i>					
Deferred income tax valuation allowance . . .	111,442	160,733	—	—	272,175
<i>Year ended December 31, 2005</i>					
Deferred income tax valuation allowance . . .	272,175	58,554	—	—	330,729
<i>Year ended December 31, 2006</i>					
Deferred income tax valuation allowance . . .	330,729	766,870	559,282	—	1,656,881
<i>Year ended December 31, 2007</i>					
Deferred income tax valuation allowance . . .	1,656,881	2,947,178	745,237	—	5,349,296
<i>Period from inception to December 31, 2007</i>					
Deferred income tax valuation allowance . . .	—	4,044,777	1,304,519	—	5,349,296

**UNIVERSAL BIOSENSORS, INC.**  
**(A Development Stage Enterprise)**

**Consolidated Research and Development and Administrative Expenses**  
**(U.S. dollars)**

	Period from Inception (September 14, 2001 to December 31, 2007 \$	Years Ended December 31,		
		2007 \$	2006 \$	2005 \$
Research and development and administrative expenses:				
Employee expenses . . . . .	10,492,418	4,439,080	2,458,015	1,548,740
Government grants . . . . .	(1,636,542)	(731,951)	(436,015)	(468,576)
Material and design costs . . . . .	3,491,353	2,331,311	510,003	251,777
Depreciation and amortization . . . . .	1,484,978	594,527	231,613	228,103
Rent . . . . .	997,543	405,025	159,756	140,348
Legal fees . . . . .	698,366	331,577	152,981	106,745
Travel and related expenses . . . . .	701,255	302,659	192,861	102,925
Consulting and professional fees . . . . .	1,306,308	552,469	467,297	120,552
Other . . . . .	1,124,833	490,618	408,563	91,102
Auditors' remuneration . . . . .	563,101	358,394	121,493	32,171
Freight . . . . .	231,345	105,771	46,675	47,751
Gas and electricity . . . . .	160,656	78,466	26,070	21,150
Telephone and facsimile . . . . .	129,623	56,177	29,240	20,278
Stationery and supplies . . . . .	184,733	105,884	38,500	19,775
Insurance . . . . .	230,590	150,448	23,290	15,669
Repairs and maintenance . . . . .	139,350	87,279	28,179	14,721
Accretion expense . . . . .	34,682	34,682	—	—
Bank charges . . . . .	18,424	9,357	5,555	1,634
	<u>20,353,016</u>	<u>9,701,773</u>	<u>4,464,076</u>	<u>2,294,865</u>

## INDEX TO EXHIBITS

<u>Exhibit Number</u>	<u>Description</u>	<u>Location</u>
1.0	Underwriting Agreement, by and between Universal Biosensors, Inc. and Wilson HTM Corporate Finance Limited dated November 9, 2007.	Incorporated by reference to our Current Report on Form 8-K filed on November 16, 2007 as Exhibit 1.1.
3.1	Amended and restated articles of incorporation dated December 5, 2006.	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 3.1.
3.2	Amended and restated by-laws dated December 5, 2006.	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 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 103 Ricketts Rd, Mt Waverley by and between Universal Biosensors Pty Ltd and Jane Sergi dated May 23, 2005	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.4.
10.5	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.
10.6	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.
10.7	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
10.8	Employment agreement between Universal Biosensors Pty Ltd and Mr Satesh Balak effective November 27, 2006	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.8
10.9	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
10.10	Employment agreement between Universal Biosensors Pty Ltd and Dr Ronald Chatelier dated April 1, 2006	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 10.10
10.11	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

<u>Exhibit Number</u>	<u>Description</u>	<u>Location</u>
10.12	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
10.13	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
10.14	Master Services and Supply Agreement by and between Universal Biosensors Pty Ltd, Universal Biosensors, Inc. and LifeScan, Inc. dated October 29, 2007.	Incorporated by reference to our Quarterly Report on Form 10-Q filed on November 14, 2007 as Exhibit 10.1. Confidentiality treatment has been granted for portions of this exhibit. These confidential portions have been omitted and were filed separately with the SEC.
14.	Code of Ethics	Filed herewith
16.0	Letter from KPMG	Incorporated by reference to our General Form for Registration of Securities on Form 10 filed on April 30, 2007 as Exhibit 16.00
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
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.	Furnished herewith

# ASX Additional Information

Additional information required by ASX Ltd and not shown elsewhere in this annual report is as follows. The information is current as at April 15, 2008.

## (a) Distribution of equity securities

As at April 15, 2008 there were:

- 156,958,812 fully paid shares of common stock held by 1,030 individual shareholders. All issued shares of common stock carry one vote per share and carry the rights to dividends.
- 5,990,074 options over shares of common stock held by 49 individual option holders. The Board has also approved the grant of a further 150,000 options over shares of common stock to the chief executive officer of the Company, subject to receipt of necessary shareholder approval.

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

Holding ranges	Beneficial interests in shares of common stock	Options over shares of common stock
1 – 1,000	63	0
1,001 – 5,000	168	0
5,001 – 10,000	160	4
10,001 – 100,000	520	31
100,001 – and over	119	11
	1,030	46

There are 27 holders of CDIs with a less than marketable parcel.

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

Name	Registered holder of CDIs	
	Number	Percentage
The Principals Cornerstone Fund Pty Limited*	22,651,074	14.431
Johnson & Johnson Development Corporation	18,231,729	11.616
CM Capital Investments Pty Ltd	14,121,272	8.997
PFM Cornerstone Limited	13,476,406	8.586
Kaasim Pty Ltd	8,582,636	5.468

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

**(c) Twenty largest holders of quoted CDIs**

Name	Registered holder of CDIs	
	Number	Percentage
1. The Principals Cornerstone Fund Pty Limited	22,651,074	14.431
2. Johnson & Johnson Development Corporation	18,231,729	11.616
3. CM Capital Investments Pty Ltd	14,121,272	8.997
4. PFM Cornerstone Limited	13,476,406	8.586
5. Kaasim Pty Ltd	8,582,636	5.468
6. National Nominees	5,024,612	3.201
7. CIBC Australia VC Fund LLC	3,508,112	2.235
8. Equity Trustees Limited	3,309,778	2.109
9. Litster & Associates Pty Ltd	3,250,469	2.071
10. Dr Alastair Hodges	3,048,416	1.942
11. Mr Denis Hanley	2,313,230	1.474
12. Sayers Investments (ACT) Pty Limited	2,287,167	1.457
13. Mr Joseph Pagliaro	1,800,000	1.147
14. Mr Garry Chambers	1,750,755	1.115
15. Megreg Holdings Pty Ltd	1,632,825	1.040
16. Mr Ronald Chatelier	1,367,085	0.871
17. Dr Elizabeth Jane Wilson	1,222,223	0.779
18. Mr Andrew L Denver & Mrs Linda Denver	1,181,812	0.753
19. Mr Christopher J La Croix & Mrs Kathleen M La Croix	1,166,718	0.743
20. Mr Andrew Leslie Denver	1,087,425	0.693
	111,013,744	70.728
	156,958,812	

**(d) Restricted Securities**

	Shares	Options
Securities subject to mandatory escrow ending on:		
- December 12, 2008	27,189,052	960,560

**(e) Use of funds**

For the period from admission on the Australian Securities Exchange until the date of this report, the Company has used the cash and cash equivalents it had at the time of admission in a manner that is consistent with its business objectives.

**(f) Correction of bylaws filed with United States SEC**

An incorrect form of bylaws was inadvertently filed with the Form 10 filed with the United States SEC on April 30, 2007. The Company filed the correct form of bylaws with the United States SEC on April 29, 2008 as Exhibit 3.2 to Amendment No. 5 to the Form 10. A copy of the correct bylaws can be obtained at [www.universalbiosensors.com](http://www.universalbiosensors.com) and at [www.sec.gov](http://www.sec.gov).

# Corporate Directory

## Board of Directors

Mr Mark Morrison (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](mailto:info@universalbiosensors.com)  
Website: [www.universalbiosensors.com](http://www.universalbiosensors.com)  
ASX code: UBI

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

Corporation Service Company  
2711 Centerville Road, Suite 400,  
Wilmington, County of New Castle  
Delaware, 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: [registries@registriesltd.com.au](mailto:registries@registriesltd.com.au)  
Website: [www.registriesltd.com.au](http://www.registriesltd.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

END



**Universal Biosensors**