# **PSIVIDA LIMITED**



12,737,139 American Depositary Shares representing 127,371,390 Ordinary Shares

The selling security holder of pSivida Limited identified on page 41 of this prospectus may offer and resell up to 12,737,139 of our American Depository Shares, or ADSs, each of which is evidenced by an American Depository Receipt and represents ten of our ordinary shares. The ADSs being offered by the selling security holder hereunder are issuable to the selling security holder (i) upon conversion of a subordinated convertible note, (ii) as interest on such subordinated convertible note and (iii) upon exercise of a warrant. We will not receive any proceeds from the sale of shares by the selling security holder. We may receive proceeds from the exercise of the warrant held by the selling security holder if the selling security holder exercises the warrant through a cash exercise. We originally issued the note and the warrant to the selling security holder in a private transaction.

This offering is not being underwritten. The selling security holder may sell the ADSs being offered by them from time to time on the NASDAQ Global Market, in market transactions, in negotiated transactions or otherwise, and at prices and at terms that will be determined by the then prevailing market price for the ADSs or by a combination of such methods of sale. For additional information on the methods of sale, you should refer to the section entitled "Plan of Distribution."

Our ADSs are quoted on the NASDAQ Global Market under the symbol "PSDV." The last reported sale price of our ADSs on the NASDAQ Global Market on September 27, 2006 was US\$2.40.

Our ordinary shares are listed on the Australian Stock Exchange under the symbol "PSD." On September 27, 2006, the closing price of our ordinary shares on the Australian Stock Exchange was A\$0.30, equivalent to a price of approximately US\$2.25 per ADS based on the Federal Reserve Bank of New York noon buying exchange rate on that date of A\$1.00 = US\$0.7495. Our ordinary shares are also listed on the Frankfurt, Berlin, Munich and Stuttgart stock exchanges under the symbol "PSI" and on the OFEX International Market Service under the symbol "PSD."

Investing in our ADSs involves risks. See "Risk Factors" beginning on page 12.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY OTHER REGULATORY BODY HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is September 29, 2006

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You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information that is different. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any jurisdiction where the offer or sale of these securities is not permitted. You should assume that the information contained in this prospectus is accurate as of the date on the front of this prospectus only.

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References in this prospectus to "pSivida," "the company," "we," "us," "our," or similar terms refer to pSivida Limited, except as otherwise indicated. On December 30, 2005, we completed the acquisition of Control Delivery Systems, Inc., which was renamed pSivida Inc. We make reference to Control Delivery Systems as "CDS" or as "pSivida Inc." generally depending on whether such reference relates to that company before or after the acquisition. As of July 1, 2006, the NASDAQ National Market changed its name to the NASDAQ Global Market. References to the NASDAQ Global Market relating to periods before such date refer to the NASDAQ National Market.

In this registration statement, references to "A\$" are to Australian dollars and references to "US\$" and "US dollars" are to United States dollars, except for in the financial statements, where references to "\$" are to Australian dollars and references to "US\$" are to United States dollars. On June 30, 2005, the Federal Reserve Bank of New York Noon Buying Rate was US\$0.7618 = A\$1.00, on December 31, 2005 such exchange rate was US\$0.7342 = A\$1.00 and on June 30, 2006 such exchange rate was US\$0.7484 = A\$1.00.

## THE COMPANY

We are an Australian public company listed on the Australian Stock Exchange, the NASDAQ Global Market, Frankfurt Stock Exchange and London's OFEX International Market Service and existing pursuant to the Australian Corporations Act 2001. Our corporate headquarters are located at Level 12 BGC Centre, 28 The Esplanade, Perth WA 6000, Australia and our phone number is +61 (8) 9226 5099. We also operate subsidiaries in the United Kingdom, Singapore, Australia and the United States.

We are a global nanotechnology company focused on the development of BioSilicon<sup>TM</sup>, a novel porous form of nano-sized silicon, for therapeutic and diagnostic use in healthcare. BioSilicon is composed of elemental silicon, engineered to create a "honeycomb" structure of pores. These pores can be formed into a diverse array of shapes and sizes and can be filled with various drugs, genes and proteins. We are working toward developing applications for controlled slow release drug delivery and diagnostics. Initially, we are using BioSilicon to target primary liver cancer, but we intend to investigate BioSilicon's use as a treatment for other inoperable tumors such as pancreatic, secondary liver and tumors within the peritoneum, brain and lung. We are currently conducting a Phase IIb dose optimization BioSilicon trial in inoperable primary liver cancer patients in seven centers in South-East Asia, including Singapore General Hospital. Other potential applications for BioSilicon may include tissue engineering, orthopedics and food science.

On December 30, 2005, we completed the acquisition of CDS, which was renamed pSivida Inc. pSivida Inc. designs and develops innovative sustainedrelease drug delivery products. Our two proprietary drug delivery systems, AEON<sup>™</sup> and CODRUG<sup>™</sup>, deliver specific quantities of drugs directly to a target site in the body at controlled rates for predetermined periods of time ranging from days to years. These systems are designed to address drawbacks of systemic drug delivery for our target diseases: adverse side effects characteristic of high dosing levels and reduced treatment benefits due to variations in drug levels at the target site.

pSivida Inc. has two commercial products utilizing the AEON system approved by the U.S. Food and Drug Administration, or FDA, for treatment of two sight threatening eye diseases. These two products, Vitrasert<sup>®</sup> and Retisert<sup>TM</sup>, are the only local sustained-release products approved by the FDA for the back of the eye. Marketed by Bausch & Lomb Incorporated and sold since 1996, Vitrasert is one of the most effective treatments for CMV retinitis, a disease that afflicts late-stage AIDS patients. Approved by the FDA in April 2005 and also marketed by Bausch & Lomb, Retisert treats chronic noninfectious uveitis affecting the posterior segment of the eye, or posterior uveitis, a leading cause of vision loss. Bausch & Lomb is also conducting two long-term multi-center clinical trials of Retisert for the treatment of diabetic macular edema, or DME, another leading cause of vision loss. Medidur<sup>TM</sup>, an injectable AEON product, is also designed to treat DME and is currently in fast-track Phase III clinical trials conducted by Alimera Sciences Inc. pSivida Inc. also has two AEON product candidates in pre-clinical studies for other back of the eye diseases.

Our lead BioSilicon product, BrachySil<sup>™</sup> is based on a radioactive 32-phosphorous form of BioSilicon. BrachySil offers interventional radiologists a short-range, longer life isotope that can be delivered through a fine bore needle, making it a more user-friendly product for both patient and physician. We are currently conducting Phase IIb BrachySil dose optimization trials on inoperable primary liver cancer patients at Singapore General Hospital.

BioSilicon is composed of elemental silicon, one of the most abundant elements on the earth's crust, which is engineered to create a "honeycomb" structure of pores. We believe that BioSilicon's features include:

- Biocompatibility BioSilicon is biocompatible, meaning, it is not injurious and does not cause immunological rejection within the body.
- Non-toxicity our studies have shown that BioSilicon degrades in the body into silicic acid, the non-toxic, dietary form of silicon which is found in beer, cereal grains and wine.
- Biodegradability BioSilicon can be made biodegradable *in vivo* (in animals and humans) and *in vitro* (in solution). The rate of biodegradation depends on the degree of nanostructuring that is imparted on the material. Thus, we believe that BioSilicon can be made to dissolve in suitable environments in days, weeks or months, depending upon the size and nature of the BioSilicon implanted.

Because of these qualities, BioSilicon has the potential to serve as a biomedical device in or on the body. pSivida believes that BioSilicon may have multiple potential applications in healthcare. pSivida is currently working toward developing applications for controlled slow release drug delivery and diagnostics. pSivida believes that other potential applications may include orthopedics, tissue engineering, and food science (food sensors and nutraceutical products).

## **Our Strategy**

Our commercialization strategy is to concentrate on: internal product development based on BioSilicon; licensing of the BioSilicon technology platform; and potential sale of non-core intellectual property. Following our recent acquisition of CDS, we will also focus on the development and commercialization of products based upon the AEON and CODRUG technologies, both internally and by means of strategic collaborations.

- The focus of our internal product development is BioSilicon drug delivery, with an initial emphasis on brachytherapy products. Other potential BioSilicon drug delivery products are localized chemotherapy, slow release drugs and the delivery of generic drugs (commonly referred to as redelivered generics). We have established commercialization plans for BrachySil, pSivida's lead product, based upon market sizes, benefits offered to patients and alternative competitive therapies.
- We believe that the platform has now been developed to a stage where licensing BioSilicon to large pharmaceutical and biotech companies for delivery of their patented drugs is possible. We also intend to license diagnostic and sensor applications of the BioSilicon platform technology developed by our subsidiary, AION Diagnostics.
- We believe that sales of early stage non-core applications for BioSilicon may become another possible source of near-term revenue. Such applications include biomaterial in orthopedics, tissue engineering and regenerative medicine producing.
- We believe that the acquisition of CDS will provide us with additional opportunities for strategic growth by providing us with a U.S. presence, greater access to the U.S. market, a range of products and product candidates based upon CDS' drug-delivery technologies and strategic collaborations to develop and market these products.

## **Recent Developments**

In September 2005, we raised US\$4.3 million (A\$5.7 million) in gross proceeds in a private placement structured as a private investment in public equity, commonly known as a PIPE. In the PIPE, we sold 665,000 ADSs to investors at US\$6.50 per ADS and issued three-year warrants exercisable for 133,000 ADSs at US\$12.50 per ADS.

On October 27, 2005, we signed a license with Beijing Med-Pharm Corporation for the clinical development, marketing and distribution of BrachySil in China. Under the terms of the license, we will manufacture BrachySil and Beijing Med-Pharm will be responsible for clinical development, securing regulatory approval, marketing and distribution in China. pSivida will retain manufacturing rights for BrachySil under the license.

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On November 16, 2005, we issued a subordinated convertible promissory note in the principal amount of US\$15 million (A\$19.7 million) to the selling security holder in a private placement. The note bears interest at a rate equal to 8% per year, which we can pay in ADSs instead of cash if certain conditions are met. The note has a term of three years and was convertible into ADSs at a conversion price of US\$7.10 per ADS, subject to adjustment based upon certain events or circumstances, including, without limitation, the market price of ADSs for the ten trading days ending August 5, 2006, if such price was lower than US\$6.57. We also issued a warrant with a term of six years which entitled the selling security holder to purchase up to 633,803 ADSs at US\$7.20 per ADS, also subject to adjustment upon specified events. Since the completion of our rights issue on June 14, 2006, the exercise price under the warrant is US\$7.17 per ADS. We also entered into a registration rights agreement pursuant to which we have agreed to file a registration statement covering the resale of the ADSs underlying the note (as well as any ADSs received by the selling security holder as interest under the note) and the warrant, as soon as practicable and to have the registration statement declared effective within 180 days of issuance of the note and warrant. The registration statement of which this prospectus is a part has been filed to comply with this obligation. The gross proceeds received by us in the private placement were US\$15.0 million, and may increase to approximately US\$19.6 million if the warrant is exercised in full in cash. We expect to use these proceeds for the expanded development of BioSilicon and for general corporate purposes.

On October 3, 2005, we entered into a merger agreement with CDS, a Boston-based company engaged in the design and development of drug delivery products. The merger agreement provided that a newly-formed subsidiary of pSivida would merge into CDS, with CDS surviving the merger as a wholly-owned subsidiary of pSivida with the name of pSivida Inc. After approval by the required majorities of both companies' shareholders and the fulfillment of other closing conditions, the merger was completed on December 30, 2005. Pursuant to the merger, we issued a total of 161,047,790 ordinary shares (represented by 16,104,779 ADSs) consisting of (i) 150,820,380 ordinary shares (represented by 15,082,038 ADSs) in exchange for the outstanding CDS common and preferred shares on the date of the acquisition in accordance with the merger agreement, (ii) 1,211,180 nonvested ordinary shares (represented by 121,118 nonvested ADSs) in connection with CDS employee retention agreements, and (iii) 9,016,230 nonvested ordinary shares (represented by 901,623 nonvested ADSs) in exchange for the nonvested shares of CDS common stock outstanding on the date of the acquisition in accordance with retention agreements between CDS and its officers and employees. As of December 31, 2005, the ADSs received by the former CDS stockholders represented approximately 41.3% of the capital stock of the combined company. Certain former shareholders of CDS received cash rather than ADSs for their CDS shares. In addition, each outstanding option to purchase CDS stock was assumed by us and converted into an option to acquire such number of ADSs as the holder would have been entitled to receive in the merger if such holder had exercised such option in full immediately before completion of the merger. In connection with the merger, we entered into a registration rights agreement pursuant to which we agreed to file a registration statement covering the resale of the ADSs issued in the merger.

On February 10, 2006, we announced that Bausch & Lomb and Novartis Ophthalmics, a business unit of Novartis Pharmaceutical Corp., had reached an agreement to co-promote Retisert in the United States.

On February 21, 2006, we reported that preliminary data from Bausch & Lomb's clinical trial of Retisert for the treatment of chronic non-infectious posterior segment uveitis showed a lower recurrence rate in eyes receiving Retisert than in non-implanted eyes. This study involved 278 patients from 27 hospitals in the United States and one in Singapore. The study showed that, at three years, control of uveitis in eyes implanted with Retisert was better than in non-implanted eyes, but was less effective than at two years and that some eyes may need to be re-implanted between 24 and 36 months. In the study, patients received either a 0.59 mg or a 2.1 mg Retisert device. Data presented was the aggregate of the two doses. At three years, the recurrence rate of uveitis was 33% in the eye receiving Retisert compared to 57% of fellow eyes. A greater number of eyes receiving Retisert experienced an improvement in vision of at least 15 letters (three lines on an eye chart) compared to fellow eyes (22% versus 6%). 45% of eyes receiving Retisert required an operation to relieve elevated intraocular pressure and 92% developed a cataract.

On March 17, 2006, we announced that our ADSs had been included in the Nanotechnology.com 'Small Technology' Index. Nanotechnology.com is owned by The Nanotech Company, LLC an independent advisory firm specializing in advising nanotechnology companies.

On March 20, 2006, we announced that an independent audit of our Boston, Massachusetts facility performed by a European Qualified Person had resulted in the issuance of a certificate indicating that our product Medidur is manufactured to the standard of Good Manufacturing Practice (GMP) set out in European Union directive 2003/94/EC and the EC Guide to Good Manufacturing Practice.

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On March 21, 2006, we announced that following a planned interim review, an independent data safety monitoring board, commonly known as a DSMB, had recommended the continuation of the Phase 3 clinical trial being conducted by us and Alimera Sciences involving our product Medidur.

On April 3, 2006, we reported that randomized safety and efficacy trials conducted by Bausch & Lomb had demonstrated that after two years, 30% of eyes receiving repeat laser treatment, the current standard of care, had a worsening of their diabetic retinopathy compared with only 10% of eyes receiving a Retisert implant. We also reported that Retisert reduced retinal thickening involving the center most part of the macula responsible for sharp, central vision, or fovea, and led to a statistically significant three line improvement in vision compared to the current standard of care. The study involved 277 patients from hospitals in the U.S.

On April 6, 2006, we reported that randomized safety and efficacy trials conducted by Bausch & Lomb had demonstrated that after two years, the recurrence rate for uveitis was significantly lower in eyes receiving Retisert than in eyes receiving systemic corticosteroid or other immunosuppressive agents, the current standard of care. The study involved 146 patients across ten countries in Europe and the Middle East.

On April 6, 2006, we entered into an evaluation agreement with an undisclosed large medical device company to evaluate cardiovascular delivery of drugs using our drug delivery technologies.

On May 25, 2006, we announced that the phase IIb clinical trial for inoperable primary liver cancer for BrachySil has been extended to centers in Vietnam and Malaysia and that we are negotiating further extension to centers in the Philippines and Taiwan. In addition, we announced that the phase IIa clinical trial for the treatment of pancreatic cancer for BrachySil is expected to commence in June 2006 in hospitals in London and Singapore.

On May 30, 2006, we announced that the Medicines and Healthcare Products Regulatory Agency in the UK granted approval for the first human study of BrachySil for the treatment of inoperable pancreatic cancer. This six month phase IIa clinical trial study is expected to involve 15 patients at the Guy's and St Thomas' Hospitals in London and Singapore General Hospital, which are leading centers for cancer treatment.

On June 7, 2006, we announced that regulatory agencies in the UK, Canada and India have approved the start of Phase III clinical trials for our product device Medidur for use in the treatment of DME.

On June 8, 2006, we announced that our subsidiary AION Diagnostics has discovered that BioSilicon can be detected on the following key imaging platforms: x-ray, ultrasound, CT and MRI. This property of BioSilicon is expected to allow it to be used in tissue marker, contrast agent products and molecular imaging products currently under development by AION Diagnostics.

On July 6, 2006, we announced that BioSilicon has shown the capability to act as an adjuvant when delivered with an antigen. An adjuvant is any substance that is capable of enhancing a host response towards an active agent and is often used in conjunction with antigens to enhance the immune response of humans and animals. An antigen is any substance capable of eliciting an immune response. A patent application has been filed in the UK for the use of BioSilicon as an adjuvant.

On July 31, 2006, we announced that Gavin Rezos had resigned for personal and family reasons as Managing Director and Chief Executive Officer of pSivida and its subsidiaries. Mr. Rezos has agreed to make himself available in Australia as we may request his assistance to achieve certain goals pending the appointment of a permanent replacement.

On August 28, 2006, we announced that Heather Zampatti resigned as a director of the Company.

On September 14, 2006, revised the terms of the subordinated convertible promissory note that we issued on November 16, 2005 to an institutional investor. The note continues to have a three year term and bear 8% interest payable quarterly. We may make future interest payments in the form of our NASDAQ-listed ADSs, or, at our sole option, we may make such payments in cash. The holder of the note can now require repayment of the note in equal amounts of US\$6.25 million on July 31, 2007 and July 31, 2008. The note is now convertible into ADSs at a conversion price of US\$2.00 per ADS, subject to adjustment based upon certain events or circumstances, including, without limitation, if 108% of the market price of ADSs for the ten trading days ending April 30, 2007 is lower than the current conversion price. In connection with the amendments, we prepaid US\$2.5 million of the outstanding principal note, and agreed to prepay US\$1.0 million in related penalties. The investor retains its existing warrants to

purchase 633,803 additional ADSs, exercisable for six years at a current exercise price of US\$7.17 per ADS. In connection with the amendments, we have agreed with the institutional investor to extend the deadline for the registration statement required by the registration rights agreement with the selling security holder to be declared effective by the Securities and Exchange Commission through October 15, 2006, with increased penalties if that deadline is missed. We have also been released from the restrictions on future fundraising transactions contained in the note documentation. We also granted the investor an additional warrant to purchase 5.7 million ADSs exercisable for five years with an exercise price of US\$1.80 per ADS and a security interest in our current royalties, subject to release of that security upon any disposition by us of the royalty stream.

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## Results of Operations For the Half Year Ended December 31, 2005 Compared to the Half Year Ended December 31, 2004

The following discussion of our results of operations is presented in accordance with Australian Equivalents to International Financial Reporting Standards, or A-IFRS and should be read in conjunction with our unaudited interim consolidated financial statements which are included elsewhere herein. This discussion is not comparable to the discussion of our results of operations incorporated by reference to "Item 5: Operating and Financial Review and Prospects" of our Annual Report on Form 20-F for the fiscal year ended June 30, 2005, which are presented in accordance with accounting principles generally accepted in Australia, or A-GAAP.

#### **Restatement of A-IFRS Amounts**

As a public company in Australia, the Company is required to file consolidated financial statements with the ASX and ASIC that comply with A-IFRS. In these statutory A-IFRS consolidated financial statements as of and for the six months ended December 31, 2005 (filed with the ASX and the ASIC on March 16, 2006), the balance of the convertible note was classified as current or non-current based on the repayment schedule contained in the convertible note agreement. Additionally, the transaction costs directly attributable to the issuance of the note and the face amount of the discount were set off against the debt liability and amortized using the effective interest method over the expected life term of the loan. The embedded conversion option was not bifurcated and accounted for separately.

On June 29, 2006, the Company restated the A-IFRS amounts previously reported for the convertible note within the Registration Statement on Amendment No. 1 to Form F- 3 as follows:

- Embedded conversion option Further consideration of the terms of the convertible note and the applicable guidance resulted in management's conclusion that the embedded conversion option should be bifurcated and accounted for separately as a derivative financial instrument. In accordance with AASB139, a financial liability that is also a derivative should be classified as held for trading, and thus in conjunction with AASB 101, the derivative should be recognized as a current liability at fair value. After initial recognition, subsequent changes in the fair value of the embedded derivative are charged or credited to the statement of operations in each reporting period. The Company concluded the impact of the change in fair value of the embedded conversion option for the six months ended December 31, 2005 to be de minimis.
- Current liability classification Upon further consideration of the applicable guidance under A-IFRS, including AASB 101, "Presentation of Financial Statements" ("AASB 101"), AASB 132 and AASB 139, management concluded that since the note is convertible at the option of the holder at any time, and the Company does not have the ability to defer settlement, the entire note should be classified as a current liability.
- Debt issuance costs In conjunction with the reclassification of the convertible note as a current liability, management also concluded that under principles-based accounting, there is no justification for amortizing the debt issuance costs over the term of the loan, as such period is beyond the Company's control due to the holder's conversion option. Accordingly, such debt issuance costs should be expensed immediately at the date of issuance of the convertible note.

Subsequent to the filing of Amendment No. 1 to the Registration Statement on Form F-3, inquiries by the SEC Staff caused the Company to reconsider the contractual terms of the note in accordance with various accounting literature. Accordingly, on September 15, 2006, the Company restated the A-IFRS amounts on Amendment No. 3 to the Registration Statement on Form F-3 related to the current liability classification and debt issuance costs as follows:

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- Current liability classification As disclosed in Note 7, the Company noted that the holder of the note could require payment in equal amounts of US\$5.0 million on the 12, 18 and 24 month anniversaries of the note's issuance. Upon further consideration of this term, the Company determined that this payment could be due on demand within one-year of the balance sheet. Upon further consideration of AASB 101, management concluded that the repayment due on demand within one-year be recorded as a current liability, net of related discount and issuance costs, with the remaining balance recorded as a non-current liability. The debt discount and debt issuance costs were allocated proportionately according to the classification of the note.
- Debt issuance costs Upon further consideration of AASB 139, paragraph 9, the Company concluded that in applying the effective interest rate
  method, all contractual terms of the financial instrument, including transaction costs, should be considered. Accordingly, the accounting treatment
  for the debt issuance costs was modified so that the debt issuance costs are amortized to each of the earliest redemption dates over the expected life
  of the note.

Refer to Note 11 of the unaudited interim consolidated financial statements included elsewhere in this registration statement for further information.

# **Restatement of U.S. GAAP Amounts**

On August 14, 2006, the Company restated the US GAAP amounts previously reported for the intangible assets acquired in the CDS acquisition and the related deferred taxes, as well as for the restricted cash related to the convertible note within the Registration Statement on Amendment No. 2 to Form F-3, as follows:

- Acquired intangible assets and related deferred taxes Upon further consideration of the guidance in the AICPA Practice Aid: "Assets Acquired in a Business Combination to be Used in Research and Development Activities: A Focus on Software, Electronic Devices and Pharmaceutical Industries," the Company determined that the portion of the CDS acquisition purchase price attributable to Medidur<sup>™</sup> for DME previously allocated to patents (\$31,539,980) meets the definition of IPR&D as the product is currently in Phase III clinical trials and has not been approved by the U.S. Food and Drug Administration. Although the product candidate may have significant future importance, the Company considers that Medidur<sup>™</sup> for DME does not have an alternative future use other than the technological indications for which it is in development. As a result, the Company restated the reconciliation to U.S. GAAP and U.S. GAAP condensed consolidated financial statements as of and for the six months ended December 31, 2005 to write off an additional amount of IPR&D of \$31,539,980, equal to the estimated fair value of the patents and patent applications that relate to Medidur<sup>™</sup> on the acquisition of CDS. The decrease in the amount recognized as patents on the acquisition of CDS also results in a lower deferred tax liability in relation to acquired intangible assets on the basis that U.S. GAAP specifically prohibits the recognition of deferred income tax on IPR&D.
- Restricted cash Upon further consideration of the guidance in SEC Regulation S-X, Rule 5-02, which requires separate disclosure of account balances that are restricted as to withdrawal or usage, the Company determined that the terms of the convertible note requiring the Company to hold a net cash balance in excess of 30% of the amount of the note outstanding should be classified as restricted cash. As a result, the Company restated the US GAAP condensed consolidated balance sheet as of December 31, 2005 to separately disclose the restricted cash in the amount of \$6,163,539.

Subsequent to the filing of Amendment No. 2 to the Registration Statement on Form F-3, inquiries by the SEC Staff caused the Company to reconsider the contractual terms of the note in accordance with various accounting literature. Accordingly, on September 15, 2006, the Company restated the US-GAAP amounts on Amendment No. 3 to the Registration Statement on Form F-3 related to the current liability classification and debt issuance costs as follows:

Current liability classification — As disclosed within Note 7, the holder of the note could require payment in equal amounts of US\$5.0 million on the 12, 18 and 24 month anniversaries of the note. Upon further consideration of this term, the Company determined that as of the balance sheet date a portion of the note could be due on demand within one-year of the balance sheet date. In accordance with SFAS 6,

Classification of Short-Term Obligations Expected to Be Refinanced — an amendment of ARB No. 43, Chapter 3A, the repayment due on the 12 month anniversary of the note met the definition of a short-term obligation, and was classified as a current liability, net of related discount and issuance costs, with the remaining balance recorded as a non-current liability. The debt discount and debt issuance costs were allocated proportionately according to the classification of the note.



Debt issuance costs – Upon further consideration of FASB Concepts Statement No. 6: "Elements of Financial Statements", the Company concluded that the debt discount and debt issuance costs should be accounted for in a similar manner. Accordingly, the accounting treatment for the debt issuance costs was modified so that the debt issuance costs are deferred and amortized to each of the earliest redemption dates over the contractual term of the note. The debt issuance costs are recorded as a deferred financing cost within the condensed consolidated balance sheet under US GAAP.

Refer to Note 12 of the unaudited interim consolidated financial statements included elsewhere in this registration statement for further information.

## Net Loss

For reasons described further below, our net loss increased to A\$10.7 million for the half year ended December 31, 2005 from A\$7.3 million for the half year ended December 31, 2004, an increase of A\$3.4 million, or 46.6%. The increase in net loss in the 2005 period is primarily attributable to the commencement of a BrachySil primary liver cancer Phase IIb dose profiling study in October 2005 and additional annual costs incurred in complying with the U.S. legal, regulatory and statutory reporting requirements following our listing of our ADSs on the NASDAQ Global Market.

#### Revenue

Revenue decreased to A\$296,921 for the half year ended December 31, 2005 from A\$398,501 for the half year ended December 31, 2004, a decrease of A\$101,580, or 25.5%. Revenue in the 2005 period consisted of A\$246,189 in interest income compared to A\$384,622 in interest income in the 2004 period. The decrease in interest income in the 2005 period is primarily attributable to lower average cash balances during the period. Additionally, we recognized A\$42,282 as other income in the 2005 period which was earned in connection with a collaborative research and development agreement.

## **Research and Development**

Research and development expense increased to A\$9.0 million for the half year ended December 31, 2005 from A\$6.5 million for the half year ended December 31, 2004, an increase of A\$2.5 million, or 38.5%. This increase is primarily attributable to the commencement of a BrachySil primary liver cancer Phase IIb dose profiling study in October 2005 together with a related increase in headcount, principally at our Malvern, UK and Singapore offices to support the commencement of the trial. In addition, this increase is attributable to an additional month of amortization brought to account on the amortization of intellectual property, being patents and licenses recognized by pSivida on the August 2004 acquisition of the minority interest pSiMedica of A\$507,559.

#### Selling, General and Administrative

Selling, general and administrative costs increased to A\$4.4 million for the half year ended December 31, 2005 from A\$2.0 million for the half year ended December 31, 2004, an increase of A\$2.4 million, or 120.0%. This increase is primarily due to our listing of our ADSs on the NASDAQ Global Market and the resulting additional annual legal and accounting professional advisor costs incurred in complying with the U.S. legal, regulatory and statutory reporting requirements and increased investor relations activities and travel costs.

#### **Interest and Finance Expenses**

Interest and finance expenses increased to A\$287,613 for the half year ended December 31, 2005 from A\$3,406 for the half year ended December 31, 2004, an increase of A\$284,207. This increase is primarily due to the interest expense on the convertible note (issued in November 2005).

## Foreign Exchange Gain/(Loss)

Foreign exchange gain/(loss) increased to a gain of A\$306,841 for the half year ended December 31, 2005 from a loss of A\$1.5 million for the half year ended December 31, 2004, an increase of A\$1.8 million. This increase is primarily due to the recognition of significant unrealized foreign exchange gains as a result of favorable movements in the Pound Sterling and U.S. dollar against Australian dollar foreign exchange rates on significant cash deposits held in foreign currencies.

#### Foreign Exchange Gain/(Loss)

Foreign exchange gain/(loss) increased to a gain of A\$211,608 for the half year ended December 31, 2005 from a loss of A\$1.5 million for the half year ended December 31, 2004, an increase of A\$1.7 million. This increase is primarily due to the recognition of significant unrealized foreign exchange gains as a result of favorable movements in the Pound Sterling and U.S. dollar against Australian dollar foreign exchange rates on significant cash deposits held in foreign currencies.

#### **Income Tax Benefit**

Income tax benefit increased to A\$2.4 million for the half year ended December 31, 2005 from A\$1.9 million for the half year ended December 31, 2004, an increase of A\$498,355 or 26.7%. This increase is primarily is due to the recognition of additional deferred tax assets on the additional tax losses available to be carried forward.

#### Liquidity and Capital Resources

We have incurred operating losses since inception, and at December 31, 2005, we had a deficit accumulated during the development stage of A\$35.7 million. Since our inception, we have relied primarily on the proceeds from private sales of our equity securities, consulting revenue, license fees and collaboration payments to fund our operations.

Cash and cash equivalents totaled A\$27.7 million at December 31, 2005 compared to A\$22.0 million at December 31, 2004.

Net cash used in operating activities totaled A\$8.7 million for the half year ended December 31, 2005 compared to A\$5.3 million for the half year ended December 31, 2004. Research and development expenditure is the most significant expenditure item resulting in increased cash flows during the half years ended December 31, 2005 and 2004 and amounted to A\$5.2 million and A\$3.7 million respectively. Payments to suppliers and employees during the half years ended December 31, 2005 and 2004 were A\$4.3 million and A\$2.0 million, respectively. The increase in payments from the half year ended December 31, 2004 to the half year ended December 31, 2005 consisted of increased expenses relating to additional administrative activities and the timing of cash payments related to these activities.

Net cash used in investing activities totaled A\$1.9 million for the half year ended December 31, 2005 compared to A\$6.1 million for the half year ended December 31, 2004. Cash flows from investing activities during the half year ended December 31, 2004 included A\$4.6 million cash paid on the acquisition of the remaining minority interest in pSiMedica and the for the half year ended December 31, 2005 included \$1.1 million cash paid on the acquisition of CDS (net of cash acquired). The reduction in net cash used in investing activities was also attributable to a reduced level of expenditure required on plant and equipment following the completion of our cleanroom facility in Germany during 2005.

Net cash flows from financing activities totaled A\$25.1 million for the half year ended December 31, 2005 compared to A\$3.6 million for the half year ended December 31, 2004. Cash flows from financing activities during the half year ended December 31, 2005 reflected the following:

- in September 2005, we issued 665,000 ADSs (representing 6,650,000 of our ordinary shares) at a price of US\$6.50 (A\$8.48) each, raising A\$5.6 million before costs of A\$468,873 through a private investment in public equity ("PIPE"); and
- in November 2005, we issued a subordinated promissory note in the principal amount of US\$15 million (A\$20.5 million) before costs of A\$607,196 to an institutional investor. That note was amended and partially repaid via a payment of US\$3.5 million in August 2006 and is currently in the principal amount of US\$12,500,000 and convertible into 6,250,000 ADSs at a conversion price of US\$2.00 per ADS, subject to adjustment based on certain events or circumstances, including a reset provision based on the market price as of April 30, 2007.

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Cash flows from financing activities during the half year ended December 31, 2004 reflected that during the half year ended December 31, 2004, we raised A\$3.7 million on the issue of additional share capital upon the exercise of options previously issued. At various times during the half year, a total of 13,070,000 options were exercised at a price of A\$0.20, 2,200,000 options were exercised at a price of A\$0.50 and 150,000 options were exercised at a price of A\$0.65.

Our existing cash resources will not likely be sufficient to support the commercial introduction of any of our current product candidates. In order to fund our operating losses, therefore, we will need to raise additional funds through public or private equity offerings, debt financings or additional corporate collaboration and licensing arrangements. Our future funding requirements will depend upon many factors, including, but not limited to:

- Costs and timing of obtaining regulatory approvals;
- The costs and timing of obtaining, enforcing and defending our patent and intellectual property;
- The progress and success of pre-clinical and clinical trials of BioSilicon;
- The costs and timings of CDS research programs in development;
- The timing and degree of sales activity leading to revenue on the sale of CDS marketed product; and
- The progress and number of our research programs in development.

We do not know whether such additional financing will be available when needed or on terms favorable to us or our stockholders. Further, any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or to obtain funds through collaborations with others that are on unfavorable terms or that may require us to relinquish certain rights to our technologies or products, including potentially our lead BioSilicon product, that we would otherwise seek to develop on our own.

As the registration statements in relation to the PIPE, the convertible note financing and the acquisition of CDS are yet to be declared effective, we may be incurring monetary penalties as further detailed below under "*Contractual Obligations and Commercial Commitments – Registration Rights Agreements*."

#### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, results of operations, liquidity or capital resources.

## **Contractual Obligations and Commercial Commitments**

Our major outstanding contractual obligations relate to our operating leases, employment agreements, and license agreements with our strategic partners. Since June 30, 2005, there have been no material changes with respect to our contractual obligations as disclosed in our annual report on Form 20-F for the year ended June 30, 2005, other than as described below.

CDS Acquisition. In connection with the acquisition of CDS in December 2005, we became obligated under CDS' operating leases, employment agreements and license agreements.

*Convertible Note.* Debt service payments under our subordinated promissory note began on January 1, 2006 and were US\$746,301 through the end of the fiscal year ended June 30, 2006. Following the repayment of US\$2.5 million on the principal amount of the convertible note outstanding, interest is expected to amount to approximately US\$1 million in the year ending June 30, 2007, US\$1 million in the year ending June 30, 2008 and US\$0.4 million in the year ending June 30, 2009, assuming no prior redemptions of principal thereunder. We expect to be able to pay some amount of such interest in ADSs beginning in the year ending June 30, 2007. We also granted the holder a security interest in our current royalties, subject to release of that security upon any disposition by us of the royalty stream.

*Registration Rights Agreements.* During the half year ended December 31, 2005, we entered into registration rights agreements with purchasers of our equity securities in the PIPE, the purchaser of our convertible note and former shareholders of CDS. These registration rights agreements require us to register with the SEC the resale of ADSs issued to such persons. Our obligation to register ADSs in each of these transactions is subject to a deadline, which may be extended in certain situations, and our failure to meet this deadline results in monetary penalties against us as follows:

- With respect to the PIPE, we were required to complete the registration no later than February 19, 2006. While we believe that the agreement permits us to delay registration through the date of this registration statement, we may be subject to monthly cash penalties equal to one percent of the PIPE purchase price, or US\$43,225 (A\$59,200), from February 19 until the date the registration statement is declared effective.
- With respect to the convertible note financing, we were required to complete the initial registration no later than May 15, 2006. Since that date we have been paying and expect to continue to pay for each 30-day period from such date a cash penalty equal to one and one-half percent of the outstanding principal amount of the note until the registration statement is declared effective. From May 15, 2006 until July 31, 2006, that penalty was equal to US\$225,000 (A\$308,200) per 30-day period, and we were required to make payments of US\$577,500 (A\$791,096) through that period. We will be required to make additional payments at the same rate for the period from August 1, 2006 until the completion of the amendment documentation. Our failure to register the shares issuable under the convertible note and associated warrants by October 15, 2006 will result in a retroactive increase of the penalties described above to two and one-half percent of the initial principal amount of the note or US\$375,000 (A\$513,700) per 30-day period. In addition, our failure to register such shares within 60 days of such date will result in an event of default, the holder of the note would have the right, until 30 days after the registration statement becomes effective to require us to repay the entire principal amount of the note plus accrued interest at a premium.
- We were also required to complete the registration of ADSs issued in connection with our acquisition of CDS no later than June 28, 2006. Our agreement to register these ADSs requires that we pay cash penalties equal to one percent of the number of such ADSs multiplied by the deemed value of such ADSs at the time of closing, or \$5.087 per ADS, for every 30-day period until the registration statement becomes effective. Such penalties could amount to US\$813,089 (A\$1,113,700) per thirty day period. We are seeking a waiver of this payment requirement from the holders of ADSs issued in connection with the acquisition of CDS, however, such persons may not grant us such a waiver on reasonable terms or at all.

*Alimera Sciences.* In February 2005, CDS entered into a collaborative development and product license agreement with Alimera Sciences relating to the development of our Medidur product. According to the agreement, Alimera and pSivida share all development costs. The agreement was assigned to us by virtue of the CDS merger. Should development efforts be successful, Alimera Sciences will manufacture and sell the product for us subject to a revenue sharing arrangement. The agreement expires on the latest of ten years after the effective date, the expiration or abandonment of the patents relevant to the covered products or until Alimera Sciences is no longer selling any licensed products. Alimera Sciences may terminate the agreement if we fail to make a development payment or may terminate the agreement with respect to a particular product if we notify Alimera Sciences that it has abandoned the product or upon 30 days' notice following our failure to make development payments exceeding US\$2 million for that product. As of June 30, 2006, we have chosen not to make development payments to Alimera Sciences in an aggregate amount of approximately US\$1.5 million. Alimera Sciences may decide not to continue with or commercialize any or all of the licensed products, change strategic focus, pursue alternative technologies, develop competing products or terminate its agreement with us.

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*Bausch and Lomb Incorporated.* In June 1999, CDS entered into a development and product license agreement with Bausch & Lomb Incorporated relating to the development of our Retisert and Vitrasert products. According to the agreement as amended, Bausch & Lomb pays all marketing and development costs and pays us a royalty. The agreement was assigned to us by virtue of the CDS merger. Bausch & Lomb is currently manufacturing and selling these products and paying us royalties on such sales. The agreement expires upon the last to expire of patents covering the products being sold. B&L may decide not to continue with or commercialize any or all of the licensed products, change strategic focus, pursue alternative technologies, develop competing products or terminate its agreement with us at any time.

#### **In-Process Research and Development**

CDS' injectable Medidur product is currently in Phase III trials for treatment of DME, a disease causing swelling in the macula, the most sensitive part of the retina, and a major cause of vision loss in diabetics. CDS is not aware of any approved drug treatment for this disease. The disease is currently treated by laser therapy, which burns the retina in specific sites or in a grid, and vitrectomy, eye surgery that involves the removal of the vitreous gel from the cavity of the eye. Both have serious limitations, which include repeat treatments or invasive surgical procedures. Both treatments generally only temporarily reverse vision loss and slow the progression f the disease. Medidur is an implant small enough to be injected through a needle to the back of the eye and is expected to release drug for up to three years. Alimera Sciences is currently conducting Phase III clinical trials for Medidur to treat DME which will follow 900 patients in the U.S. and Europe for 36 months.

We determined that the portion of the purchase price attributable to the patents and patent applications relating to Medidur for DME (A\$31,539,980) meets the definition of IPR&D as the product is currently in Phase III clinical trials and has not been approved by the FDA. This amount has been determined based on a discounted cash flow analysis of Medidur for DME prepared at the time of the acquisition by us, considering known royalty rates for the product, standard industry and market discount rates and what we considered to be reasonable market penetration rate assumptions. The patents and patent applications that support Medidur for DME were evaluated by our investment banker and by management and valued in light of the Phase III stage of product development, nearness to commercialization, a license agreement in place for the use of the technology and an assessment of the risk of failure of the product.

As stated above, the product is currently in a 36 month Phase III clinical trial for treatment of DME performed by Alimera Sciences. Many factors could contribute to the delay or failure of these trials and we depend on collaborations with third parties to develop and commercialize this product, and such arrangements may not be available or scientifically or commercially successful, or may be terminated.

Although Medidur for DME may have significant future importance, we consider that Medidur for DME does not have an alternative future use other than the technological indications for which it is in development.

Smaller IPR&D projects that have been identified by us which were being undertaken by CDS at the time of the acquisition have been determined to have a fair value of A\$2,741,706. As these projects are at a very early stage of development, we determined the fair value of the projects with reference to the costs incurred by CDS at the time of the acquisition. Such IPR&D projects do not have an alternative future use.

The total amount of IPR&D recognized by us on the acquisition of CDS is A\$34,281,686 and has been capitalized under A-IFRS and expensed at the date of acquisition under U.S. GAAP for the six months ended December 31, 2005.

#### **Our Address and Phone Number**

Our principal offices are located at Level 12 BGC Centre, 28 The Esplanade, Perth WA 6000, Australia, and our telephone number is: +61 (8) 9226 5099. Our website address is www.psivida.com. We do not incorporate the information on, or accessible through, our website into this prospectus, and you should not consider it part of this prospectus.

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# **RISK FACTORS**

In considering whether to invest in our ADSs, you should carefully read and consider the risks described below, together with all of the information we have included in this prospectus.

### Risks related to our company and our business

# We will need additional capital to conduct our operations and develop our products, and our ability to obtain the necessary funding is uncertain.

We expect to require substantial additional capital resources in order to conduct our operations and develop our products. The timing and degree of any future capital requirements will depend on many factors, including:

- the accuracy of the assumptions underlying our estimates for our capital needs in the near and long term;
- continued scientific progress in our research and development programs;
- the magnitude and scope of our research and development programs;
- our ability to maintain and establish strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- our progress with preclinical and clinical trials;
- the time and costs involved in obtaining regulatory approvals; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims.

If and when it is required, we will attempt to acquire additional funding through strategic collaborations, public or private equity financings, capital lease transactions or other financing sources that may be available. Additional financing may not be available on acceptable terms, or at all. Additional equity financings could result in significant dilution to stockholders. Further, in the event that additional funds are obtained through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies, product candidates or products that we would otherwise seek to develop and commercialize ourselves. If sufficient capital is not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs, each of which could have a material adverse effect on our business.

## We have a history of losses; we expect to continue to incur losses; and we may never become profitable.

pSivida was formed in 2000. As primarily a research and development company, we have incurred operating losses in every year of existence. Under A-IFRS (effective from July 1, 2005), we incurred a net loss of A\$10.7 million for the six months ended December 31, 2005 and under A-GAAP, we incurred a net loss of A\$14.7 million, A\$3.7 million and A\$2.8 million for the years ended June 30, 2005, 2004 and 2003, respectively. As of December 31, 2005, we had an accumulated deficit under A-IFRS of A\$39.5 million. We have not achieved profitability and expect to continue to incur net losses through at least 2007, and we may incur losses beyond that time, particularly if we are not successful in having BrachySil approved and widely marketed by that time. Even if BrachySil is approved and is being marketed at some point in 2007 or beyond, we may not achieve sufficient sales of BrachySil or any other product to become profitable at that time or at any other time. The extent of future losses and whether or how long it may take for us to achieve profitability are uncertain.

We recently acquired CDS which has incurred net losses in each of its last five fiscal years (ending December 31). CDS had positive net income for the 12 month period ended June 30, 2005. As a result of the acquisition, we expect to receive royalties from sales of Vitrasert, CDS' first commercial product. However, such sales have declined in each of the past four years and we do not expect that they will comprise a significant portion of our future revenue. We also expect to receive royalties from future sales of Retisert, but we are unable to predict the amount of such future royalties.

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## We may not have sufficient funds to pay principal of and interest on our convertible notes.

On November 16, 2005, we issued a subordinated convertible promissory note in the principal amount of US\$15 million (A\$20.5 million) to an institutional investor. On September 14, 2006, we repaid US\$2.5 million (A\$3.33 million) of the principal and amended the note. The convertible note must be repaid in full in cash on the third anniversary of its issuance, unless the principal is earlier converted. In addition, the holder may require payment in cash of up to US\$6.25 million (\$8.32 million) of the principal on each of July 31, 2007 and January 31, 2008. The note is currently convertible at a conversion price of US\$2.00 per ADS, subject to adjustment based on certain events or circumstances, including the market price of ADSs for the ten trading days ended on April 30, 2007. The holder of the notes has been provided with a security interest in our existing royalty streams which represent substantially all of our current revenue. If we are unable to pay interest or principal that become due or otherwise make payments under the notes or related agreements, the holder may foreclose on and collect those royalties or sell that collateral. The proceeds of any sale would be applied to satisfy amounts owed to the holder.

We may make quarterly interest payments on the notes by issuing ADSs if certain conditions are met including the effectiveness of a registration statement covering the ADSs, continued listing of our shares or ADSs, and timely delivery of conversion ADSs during the period preceding the payment date, among others. If any of the conditions are not met, we will be required to pay the interest due in cash. Given the cash needs of our business and our current level of revenue, we cannot predict whether or not we will be able to meet any of these cash payment obligations or what impact these obligations might have on our business and operations.

# If we fail to register the resale of ADSs by the applicable deadlines, we may be subject to substantial penalties.

In connection with the acquisition of CDS and the convertible note financing, we have entered into agreements to register with the SEC the resale of ADSs issued to investors and CDS stockholders. Our obligation to register ADSs in each of these transactions is subject to a deadline, which may be extended or waived in certain situations, and our failure to meet this deadline in each case may result in monetary penalties or other remedies being available against us.

With respect to the convertible note financing, we were required to complete the initial registration no later than May 15, 2006. Since that date we have been paying and expect to continue to pay for each 30-day period from such date a cash penalty equal to one and one-half percent of the outstanding principal amount of the note until the registration statement is declared effective. From May 15, 2006 until September 14, 2006, that penalty was equal to US\$225,000 (A\$308,200) per 30-day period, and we were required to make payments of US\$915,000 (A\$1,298,391) through that period. We also paid an amount of US\$129,667 (A\$184,000) in exchange for the extension of the registration deadline. We will be required to make additional payments at the same rate for the period from August 1, 2006 until the completion of the amendment documentation. Our failure to register the shares issuable under the convertible note and associated warrants by the new deadline of October 15, 2006 will result in an additional penalty of US\$765,000 (A\$1,085,540) and an increase in the prospective penalty rate to two percent per 30-day period. In addition, our failure to register such shares within 60 days of such date will result in an event of default under the note. Upon such an event of default, the holder of the note would have the right, until 30 days after the registration statement becomes effective to require us to repay the entire principal amount of the note plus accrued interest at a premium, and we may not have sufficient funds to do so.

We were also required to complete the registration of ADSs issued in connection with our acquisition of CDS no later than June 28, 2006. Our agreement to register these ADSs requires that we pay cash penalties equal to one percent of the number of such ADSs multiplied by the deemed value of such ADSs at the time of closing, or \$5.087 per ADS, for every 30-day period until the registration statement becomes effective. Such penalties could amount to US\$813,089 (A\$1,113,700) per thirty day period. We are seeking a waiver of this payment requirement from the holders of ADSs issued in connection with the acquisition of CDS, however, such persons may not grant us such a waiver on reasonable terms or at all. If we are forced to pay the registration penalties, we may not have sufficient funds to continue developing our products or funding our operations.

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We expect to have other registration obligations with similar penalty provisions related to registration deadlines in connection with other financing activities.

Once the registrations are completed, we are obligated to keep them effective for specified periods, our failure or inability to do so may subject us to additional penalties.

## Most of our products and planned products are based upon new and unproven technologies.

We are currently developing products based upon BioSilicon<sup>TM</sup>, a biocompatible and biodegradable form of the element silicon, for multiple applications across many sectors of healthcare, including controlled slow release drug delivery, diagnostics, orthopedics and tissue engineering. BioSilicon is a new and unproven technology. The successful development and market acceptance of BioSilicon is subject to many risks. These risks include the potential for ineffectiveness, lack of safety, unreliability, failure to receive necessary regulatory clearances or approvals and the emergence of superior or equivalent products, as well as the effect of changes in future general economic conditions. Our failure to develop products based on BioSilicon that overcome these risks would have a material adverse effect on our business, financial condition and results of operations.

We have recently acquired CDS (now renamed pSivida Inc.), which develops drug delivery products based upon its proprietary AEON and CODRUG drug delivery systems. To date pSivida Inc. has developed two such products, Vitrasert and Retisert, which have been approved by the FDA for treatment of two sight-threatening eye diseases. However, these technologies may prove useful in other products which would be subject to many of the same risks as described above for BioSilicon.

# We rely heavily upon patents, trade secrets and other proprietary technologies and any future claims that our rights to such intellectual property are invalid or limited could seriously harm our business.

Protection of intellectual property rights is crucial to our business, since that is how we keep others from copying the innovations which are central to our existing and future products. Our success is dependent on whether we can obtain patents, defend our existing patents and operate without infringing on the proprietary rights of third parties. We currently have 36 patents and over 90 pending patent applications, including patents and pending applications covering BioSilicon and various uses thereof. This does not include the patents and patent applications we acquired in the acquisition of CDS. We expect to aggressively patent and protect our proprietary technologies. However, we cannot be sure that any additional patents will be issued to us as a result of our pending or future patent applications or that any of our patents will withstand challenges by others. If we were determined to be infringing any third party patent, we could be required to pay damages, alter our products or processes, obtain licenses or cease certain operations. We may not be able to obtain any required licenses on commercially favorable terms, if at all. Our failure to obtain a license for any technology that we may require to commercialize BioSilicon or our ophthalmic drug delivery products could have a material adverse effect on our business, financial condition and results of operations. In addition, many of the laws of foreign countries in which we intend to operate may treat the protection of proprietary rights differently from, and may not protect our proprietary rights to the same extent as, laws in Australia, the United States and Patent Co-operation Treaty countries.

Prior art may reduce the scope or protection of, or invalidate, patents. Previously conducted research or published discoveries may prevent patents from being granted, invalidate issued patents or narrow the scope of any protection obtained. Reduction in scope of protection or invalidation of our licensed or owned patents, or our inability to obtain patents, may enable other companies to develop products that compete with our products and product candidates on the basis of the same or similar technology. As a result, our patents and those of our licensors may not provide any or sufficient protection against competitors.

While we have not been and we are not currently involved in any litigation over intellectual property, such litigation may be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of third party proprietary rights. We may also be sued by a third party alleging that we infringe its intellectual property rights. Any intellectual property litigation would be likely to result in substantial costs to us and diversion of our efforts. If our competitors claim technology also claimed by us and if they prepare and file patent applications in the U.S., we may have to participate in interference proceedings declared by the U.S. Patent and Trademark office to determine priority of invention, which could result in substantial cost to us and diversion of our efforts. Any such litigation or interference proceedings, regardless of the outcome, could be expensive and time consuming. Litigation could subject us to significant liabilities to third parties, requiring disputed rights to be licensed from third parties or require us to cease using certain technologies and, consequently, could have a material adverse effect on our business, financial condition and results of operations.

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We also rely on trade secrets, know-how and technology that are not protected by patents to maintain our competitive position. We try to protect this information by entering into confidentiality agreements with parties that have access to it, such as our corporate partners, collaborators, employees, and consultants. Any of these parties could breach these agreements and disclose our confidential information, or our competitors might learn of the information in some other way. If any material trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our competitive position could be materially harmed.

We rely, in part, on confidentiality agreements with employees, advisors, vendors and consultants to protect our proprietary expertise. These agreements may be breached and we may not have adequate remedies in the event of a breach. In addition, our unpatented proprietary technological expertise may otherwise become known or independently discovered by competitors.

## Our ability to commercialize our products depends on our ability to achieve regulatory approvals.

Our current and future activities are and will be subject to regulation by governmental authorities in the U.S., Europe, Singapore and other countries. Before we can manufacture, market and sell any of our products, we must first obtain approval from the FDA and/or foreign regulatory authorities. In order to obtain these approvals, pre-clinical studies and clinical trials must demonstrate that each of our products is safe for human use and effective for its targeted disease. Our proposed products are in various stages of pre-clinical and clinical testing. If clinical trials for any of these products are not successful, that product cannot be manufactured and sold and will not generate revenue from sales. Clinical trials for our product candidates may fail or be delayed by many factors, including the following:

- inability to attract clinical investigators for trials;
- inability to recruit patients in sufficient numbers or at the expected rate;
- adverse side effects;
- failure of the trials to demonstrate a product's safety or efficacy;
- failure to meet FDA requirements for clinical trial design or for demonstrating efficacy for a particular product;
- inability to follow patients adequately after treatment;
- changes in the design or manufacture of a product;
- inability to manufacture sufficient quantities of materials for use in clinical trials; and
- governmental or regulatory delays.

Results from pre-clinical testing and early clinical trials often do not accurately predict results of later clinical trials. Data obtained from pre-clinical and clinical activities are susceptible to varying interpretations which may delay, limit or prevent regulatory approval. Data from pre-clinical studies, early clinical trials and interim periods in multi-year trials are preliminary and may change, and final data from pivotal trials for such products may differ significantly. Adverse side effects may develop that delay, limit or prevent the regulatory approval of products, or cause their regulatory approvals to be limited or even rescinded. Additional trials necessary for approval may not be undertaken or may ultimately fail to establish the safety and efficacy of proposed products. The FDA may not approve proposed products for manufacture and sale.

In addition to testing, the FDA imposes various requirements on manufacturers and sellers of products under its jurisdiction, such as labeling, manufacturing practices, record keeping and reporting requirements. The FDA also may require post-marketing testing and surveillance programs to monitor a product's effects. Furthermore, changes in existing regulations or the adoption of new regulations could prevent us from obtaining, or affect the timing of, future regulatory approvals.

At present Vitrasert and Retisert are our only products that have been approved for sale in the U.S. for specific purposes. BrachySil and other product candidates utilizing BioSilicon have not been approved and their approval in the future remains uncertain. In addition, the FDA may determine to regulate it as a drug, in which case we would incur significant additional cost and time in order to achieve the required regulatory approvals. Any product approvals we achieve could also be withdrawn for failure to comply with regulatory standards or due to unforeseen problems after the product's marketing approval.

# We have a limited ability to market our products ourselves, and if we are unable to find marketing partners, or our marketing partners do not successfully market our products then our business will suffer.

We presently have no marketing or sales staff. Achieving market acceptance for the use of BioSilicon and other products (including drug delivery products originated by CDS) will require extensive and substantial efforts by experienced personnel as well as expenditure of significant funds. We may not be able to establish sufficient capabilities necessary to achieve market penetration.

We intend to license and/or sell BioSilicon and our other products to companies who will be responsible in large part for sales, marketing and distribution of products utilizing BioSilicon and our other products. The amount and timing of resources which may be devoted to the performance of their contractual responsibilities by these licensees are not expected to be within our control. These partners may not perform their obligations.

Moreover, our licensees may have rights of termination under our agreements with them. Exercise of termination rights by those parties may leave us temporarily or permanently without any marketing or sales resources which may have an adverse effect on our business, financial condition and results of operations. Additionally, our interests may not continue to coincide with those of our partners, and our partners may develop independently or with third parties products or technologies which could compete with our products. Further, disagreements over rights or technologies or other proprietary interests may occur.

pSivida Inc., formerly CDS, has exclusively licensed its technology with respect to Vitrasert, Retisert and certain other ophthalmic uses to Bausch & Lomb, and with respect to Medidur for DME and certain other ophthalmic uses to Alimera Sciences. Bausch & Lomb is responsible for funding and managing the development and commercialization of all products under its agreement with pSivida Inc. and can terminate the agreement at any time upon 90 days' written notice. Alimera Sciences and pSivida Inc. are jointly funding the development of products licensed under that agreement, and Alimera Sciences may terminate its agreement with pSivida Inc. fails to make a development payment or may terminate the agreement with respect to a particular product if pSivida Inc. notifies Alimera Sciences that it has abandoned the product or upon 30 days' notice following pSivida Inc.'s failure to make development payments exceeding US\$2 million for that product. As of June 30, 2006, we have chosen not to make development payments to Alimera Sciences in an aggregate amount of approximately US \$1.5 million. Alimera Sciences was incorporated in June 2003 and has limited resources. Either Bausch & Lomb or Alimera Sciences may decide not to continue with or commercialize any or all of the licensed products, change strategic focus, pursue alternative technologies, develop competing products or terminate their agreements with pSivida Inc. While Bausch & Lomb has significant experience in the ophthalmic field and substantial resources, there is no assurance as to whether and the extent to which that experience and those resources will be devoted to pSivida Inc.'s technologies. Because we do not currently have sufficient funding or internal capabilities to develop and commercialize these products and proposed products, decisions, actions, breach or termination of these agreements by Bausch & Lomb or Alimera Sciences could delay or stop the development or commercialization of Retisert, Medidur for DME or other of our products licensed to such

Our business strategy includes entering into collaborative agreements for the development and commercialization of our product candidates. The curtailment or termination of any of these agreements could adversely affect our business and our ability to develop and commercialize our products and proposed products and fund our operations.

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The success of these and future collaboration agreements will depend heavily on the experience, resources efforts and activities of our collaborators. Our collaborators have and are expected to have significant discretion in making these decisions. Risks that we face in connection with our collaboration strategy include:

- collaboration agreements are, and are expected to be, subject to termination under various circumstances, including, in some cases, on short notice and without cause;
- we are required, and expect to be required, under our collaboration agreements not to conduct specified types of research and development in the field that is the subject of the collaboration. These agreements may have the effect of limiting the areas of research and development that we can pursue;
- our collaborators may develop and commercialize, either alone or with others, products that are similar to or competitive with our products;
- our collaborators may change the focus of their development and commercialization efforts. Pharmaceutical and biotechnology companies have
  historically re-evaluated and changed their priorities for many reasons. The ability of our products to reach their potential could be limited if our
  collaborators decrease or fail to increase spending related to such products; and
- our collaborators may lack the funding or experience to develop and commercialize our products successfully or may otherwise fail to do so.

To the extent that we choose not to or we are unable to enter into future license agreements with marketing and sales partners, we may experience increased capital requirements to develop the ability to market and sell future products. We may not be able to market or sell our technology or future products independently in the absence of such agreements.

# Our markets are competitive and our competitors could develop more effective products, making our products less competitive, uneconomical or obsolete, thereby impacting our future operations.

We are or plan to be engaged in the rapidly evolving and competitive fields of drug delivery, tissue engineering, diagnostics and orthopedics technologies. Our competitors include many major pharmaceutical companies and other biotechnology, drug delivery, diagnostics and medical products companies.

Many of our potential competitors have substantially greater financial, technological, research and development, marketing and personnel resources. Our competitors may succeed in developing alternate technologies and products that are more effective, easier to use, more economical than those which we have developed or that would render our technologies and products obsolete and non-competitive in these fields. These competitors may also have greater experience in developing products, conducting clinical trials, obtaining regulatory approvals or clearances and manufacturing and marketing such products or technologies.

We believe that pharmaceutical, drug delivery and biotechnology companies, research organizations, governmental entities, universities, hospitals, other nonprofit organizations and individual scientists are seeking to develop the drugs, therapies, products, approaches or methods to treat our targeted diseases or their underlying causes. For many of our targeted diseases, competitors have alternate therapies that are already commercialized or are in various stages of development ranging from discovery to advanced clinical trials. Any of these drugs, therapies, products, approaches or methods may receive government approval or gain market acceptance more rapidly than our products and proposed products, may offer therapeutic or cost advantages or may cure our targeted diseases or their underlying causes completely, which could reduce demand for our products and proposed products and could render them noncompetitive or obsolete. For example, sales of pSivida Inc.'s Vitrasert product for the treatment of CMV retinitis, a disease which affects people with late-stage AIDS, have declined significantly, because of new treatments that delay the onset of late-stage AIDS.

Our competitive position is based upon our ability to:

- create and maintain scientifically-advanced technology and proprietary products and processes;
- attract and retain qualified personnel;



- develop safe and efficacious products, alone or in collaboration with others;
- obtain patent or other protection for our products and processes;
- obtain required government approvals on a timely basis;
- manufacture products on a cost-effective basis; and
- successfully market products.

If we are not successful in meeting these goals, our business could be adversely affected.

### We face risks in expanding our efforts beyond our core area of experience and expertise.

We plan to expand our focus outside of our initial areas of experience and expertise to seek to broaden our product pipeline and will require additional internal expertise or external collaborations in areas in which we currently do not have internal resources and expertise. Such expertise and collaborations may be difficult to obtain. We are currently focused on targeted controlled drug delivery with a specialty, through pSivida Inc., on ophthalmic drug delivery and, through pSiMedica and pSiOncology, on brachytherapy and other controlled delivery mechanisms utilizing BioSilicon. We have begun to expand our focus into diagnostics (through AION Diagnostics) and the food industry (through pSiNutria) and plan to expand into other areas at a later time. In connection with the foregoing, we may have to enter into collaboration arrangements with others that may require us to relinquish rights to certain of our technologies or products that we would otherwise pursue independently. We may be unable to acquire the necessary expertise or enter into collaboration agreements on acceptable terms.

### Problems associated with international business operations could affect our ability to manufacture and sell our products.

We currently maintain offices in Australia, the UK, Singapore and the U.S.; BioSilicon is produced for us in Germany and the UK; we are conducting product trials in Singapore, Vietnam and Malaysia; we have research and development facilities in the UK and the U.S.; and we intend to license and/or sell products in most major world healthcare markets. A number of risks are inherent in our international strategy. In order for us to license and manufacture our products, we must obtain country-specific regulatory approvals or clearances or comply with regulations regarding safety and quality in a variety of jurisdictions. We may not be able to obtain or maintain regulatory approvals or clearances in such countries and we may be required to incur significant costs in obtaining or maintaining foreign regulatory approvals or clearances. In addition, our operations and revenues are subject to a number of risks associated with foreign commerce, including the following:

- managing foreign distributors;
- staffing and managing foreign operations;
- political and economic instability;
- foreign currency exchange fluctuations;
- foreign tax laws, tariffs and freight rates and charges;
- timing and availability of export licenses;
- inadequate protection of intellectual property rights in some countries; and
- obtaining required governmental approvals.



# There are risks relating to product manufacturing which could cause delays in product development and commercialization and impact our future profitability.

Our ability to conduct timely preclinical and clinical research and development programs, obtain regulatory approvals, commercialize our product candidates and fulfill our contract manufacturing obligations to others will depend, in part, upon our ability to manufacture our products, either directly or through third parties, in accordance with FDA and other regulatory requirements. We currently have BioSilicon production capability at our facilities in the UK, which may be augmented where required by QinetiQ's UK production facilities for use in internal and collaborative research. BrachySil is currently manufactured under contract in accordance with applicable FDA regulations by Hosokawa Micron Group, Atomising Systems Ltd, HighForce Ltd and AEA Technology QSA GmbH.

If we are unable to manufacture BioSilicon or BrachySil or other product candidates by ourselves or acquire BioSilicon from QinetiQ or acquire BioSilicon or BrachySil or other product candidates from third parties, we would be unable to proceed with or could experience delays in development and commercialization of our proposed products. We may not be able to manufacture our proposed products successfully or in a cost-effective manner at our own or third party facilities. If we are unable to develop our own manufacturing facilities or to obtain or retain third-party manufacturing on acceptable terms, we may not be able to conduct certain future preclinical and clinical testing or to supply commercial quantities of our products.

Our recently acquired subsidiary pSivida Inc. also has limited manufacturing experience and has exclusively licensed Bausch & Lomb the rights to manufacture Vitrasert, Retisert and other products covered by its license agreement with pSivida Inc., and Alimera Sciences, the rights to manufacture Medidur for DME, if approved for marketing, and other products covered by its license agreement with pSivida Inc. Our current reliance on third party manufacturers for some of our products entails risks, including:

- the possibility that third parties may not comply with the FDA's current good manufacturing practices, regulations, other regulatory requirements, and those of similar foreign regulatory bodies, and employ adequate quality assurance practices;
- supply disruption, deterioration in product quality or breach of a manufacturing or license agreement by the third party because of factors beyond CDS' control;
- the possible termination or non-renewal of a manufacturing or licensing agreement with a third party at a time that is costly or inconvenient to CDS; and
- inability to identify or qualify an alternative manufacturer in a timely manner, even if contractually permitted to do so.

# Fast track status for Medidur may not actually lead to faster development, regulatory review or approval.

The FDA has granted fast track designation to Medidur for the treatment of DME. Although this designation makes this product eligible for expedited approval procedures, it does not ensure faster development, review or approval compared to the conventional FDA procedures. Further, the FDA may withdraw the fast track designation if it determines that the designation is no longer supported by emerging data from clinical trials or if it determines that the criteria for the designation is no longer satisfied.

# Our proposed products will be subject to the uncertainty of third-party reimbursement and health care reform measures which may limit market acceptance.

In both domestic and foreign markets, our ability to commercialize our products will depend, in part, upon the availability of reimbursement from thirdparty payors, such as government health administration authorities, private health insurers and other organizations. Third-party payors are increasingly challenging the price and cost-effectiveness of medical products. If our products are not considered cost-effective, third-party payors may limit reimbursement. Government and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new therapeutic products approved for marketing by the FDA and by refusing, in some cases, to provide any coverage for uses of approved products for disease indications for which the FDA has not granted marketing approval. If government and third-party payors do not provide adequate coverage and reimbursement levels for uses of our products, the market acceptance of our products would be limited.

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There have been a number of U.S. federal and state proposals during the last few years to subject the pricing of pharmaceuticals to government control and to make other changes to the health care system of the U.S. It is uncertain what legislative proposals will be adopted or what actions federal, state or private payors for health care goods and services may take in response to any health care reform proposals or legislation. We cannot predict the effect health care reforms may have on our business.

## The loss of some or all of our key personnel could harm our business.

We are dependent upon the principal members of our management and scientific staff. In addition, we believe that our future success in developing BioSilicon and other products and achieving a competitive position will depend to a large extent on whether we can attract and retain additional qualified management and scientific personnel. There is strong competition for such personnel within the industry in which we operate and we may not be able to continue to attract such personnel either to Malvern in the United Kingdom or to Massachusetts, where our research and development is conducted. As we do not have large numbers of employees and our products are unique and highly specialized, the loss of the services of one or more of the senior management or scientific staff, or the inability to attract and retain additional personnel and develop expertise as needed, could have a material adverse effect on our results of operations and financial condition.

### We may be subject to product liability suits, and we may not have sufficient insurance to cover damages.

The testing, manufacturing, and future marketing and sale of the products utilizing BioSilicon and our other products involves risks that product liability claims may be asserted against us or our licensees. Our current clinical trial insurance may not be adequate or continue to be available, and we may be unable to obtain adequate product liability insurance on reasonable commercial terms, if at all. In the event clinical trial insurance is not adequate, our ability to continue with planned research and development in the relevant area could be negatively impacted.

# We have experienced rapid growth and changes in our business, and our failure to manage this and any future growth and changes could harm our business.

As evidenced by our purchase of the remaining shares of pSiMedica on August 4, 2004, the incorporation and planned spin-off of AION Diagnostics, the incorporation of pSiNutria Limited and our acquisition of CDS on December 30, 2005, our business is rapidly changing. See "Risks related to our recent acquisition of CDS and other recent transactions."

We expect to continue increasing the number of our employees, and we may suffer if we do not manage and train our new employees effectively. Further, our efforts span various geographies. Continued rapid growth and operation in multiple locations may place significant strains on our managerial, financial and other resources. The rate of any future expansion, in combination with our complex technologies and products, may demand a level of managerial effectiveness in anticipating, planning, coordinating and meeting our operational needs which we may not be able to successfully provide.

In addition, if we make additional acquisitions or divestitures, we could encounter difficulties that harm our business. We may acquire companies, products or technologies that we believe to be complementary to our business. If we do so, we may have difficulty integrating the acquired personnel, operations, products or technologies. In addition, acquisitions may distract our management and employees and increase our expenses, which could harm our business. We may also sell businesses or assets as part of our strategy or if we receive offers from third parties. If we do so, we may sell an asset or business for less than its full value or may lose valuable opportunities attendant to such asset or business.

## If we fail to comply with environmental laws and regulations, our ability to manufacture and commercialize products may be adversely affected.

Medical and biopharmaceutical research and development involves the controlled use of hazardous materials, such as radioactive compounds and chemical solvents. We are subject to federal, state and local laws and regulations in the U.S. and abroad governing the use, manufacture, storage, handling and disposal of such materials and waste products. We could be subject to both criminal liability and civil damages in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials. In addition, claimants may sue us for injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed our total assets. Compliance with environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development or production efforts or harm our operating results.

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#### Risks related to our being headquartered and incorporated outside of the United States

#### You may have difficulty in effecting service of legal process and enforcement of judgments against us or our management.

We are a public company limited by shares, registered and operating under the Australian Corporations Act 2001. Several of our directors and most of our officers reside outside the U.S. Substantially all or a substantial portion of the assets of those persons are located outside the U.S. As a result, it may not be possible to effect service on such persons in the U.S. or to enforce, in foreign courts, judgments against such persons obtained in U.S. courts and predicated on the civil liability provisions of the federal securities laws of the U.S. Furthermore, a large percentage of our directly owned assets are located outside the U.S., and, as such, any judgment obtained in the U.S. against pSivida may not be collectible within the U.S. There is doubt as to the enforceability in the Commonwealth of Australia, in original actions or in actions for enforcement of judgments of U.S. courts, of civil liabilities predicated solely upon federal or state securities laws of the U.S., especially in the case of enforcement of judgments of U.S. courts where the defendant has not been properly served in Australia.

#### As a foreign private issuer we do not have to provide you with the same information as an issuer of securities based in the U.S.

Because we are a foreign private issuer within the meaning of the rules under the Exchange Act, we are exempt from certain provisions of that law that are applicable to U.S. public companies, including (i) the rules under the Exchange Act requiring the filing with the U.S. Securities and Exchange Commission, or SEC, of quarterly reports on Form 10-Q or current reports on Form 8-K; (ii) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a registered security; and (iii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time. Thus, you are not afforded the same protections or information which would be made available to you were you investing in a U.S. public corporation.

In accordance with the requirements of the Australian Stock Exchange, we disclose annual and semi-annual results. Our results are presented in accordance with A-GAAP. Effective July 1, 2005, our results are presented in accordance with A-IFRS. Our annual results reported in the U.S. with the SEC include a reconciliation to U.S. GAAP. Based on our evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Securities Exchange Act of 1934, we have concluded that, as of June 30, 2005, our disclosure controls and procedures were ineffective in that we had insufficient accounting personnel who have sufficient knowledge and experience in U.S. GAAP and the U.S. SEC accounting requirements.

Our annual results are audited, and our semi-annual results undergo a limited review by our independent auditors. Subject to certain exceptions, we are also required to immediately disclose to the Australian Stock Exchange any information concerning us that a reasonable person would expect to have a material effect on the price or value of our shares. This would include matters such as (i) any major new developments relating to our business which are not public knowledge and may lead to a substantial movement in our share price; (ii) any changes in our board of directors; (iii) any purchase or redemption by pSivida of its own equity securities; (iv) interests of directors in our shares or debentures; and (v) changes in our capital structure. We are required to provide our semi-annual results and other material information that we disclose in Australia in the U.S. under the cover of Form 6-K. Nevertheless, this information is not the same and may not be as much information as would be made available to you were you investing in a U.S. public corporation.

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#### Risks related to our stock and our ADSs

### If we are a passive foreign investment company, holders of our shares and ADSs may suffer adverse tax consequences.

U.S. holders of our ADSs can experience unfavorable tax consequences if we are treated as a passive foreign investment company, or PFIC, under the U.S. Internal Revenue Code of 1986, as amended, for any year during which the U.S. holder owns our ADSs. For example, if a U.S. holder disposes of an ADS at a gain, and during any year of its holding period we were a PFIC, then such gain would be taxable as ordinary income and not as capital gain and would be subject to additional taxation based on the length of time the U.S. holder held such stock. Most of the tax consequences of our being a PFIC can be mitigated if the U.S. holder makes certain elections as described in our Annual Report on Form 20-F for the fiscal year ended June 30, 2005, filed with the SEC on January 18, 2006 in Item 10.E under "U.S. Federal Income Tax Considerations."

In general, we will be a PFIC for any taxable year if either (1) 75% or more of our gross income in the taxable year is passive income, or (2) 50% or more of the average value of our assets in the taxable year produces, or is held for the production of, passive income. We do not yet know whether we will be classified as a PFIC in the year ending June 30, 2006 or thereafter. Most of the tax consequences of pSivida being a PFIC can be mitigated if the U.S. holder makes certain mitigating elections as described in Item 10.E of our Annual Report. In the event we are classified as a PFIC, we intend to provide U.S. holders with sufficient information to enable them to make a mitigating election if so desired. However, we may fail to provide such information, and if we do, you may not be aware of our status as a PFIC and may be subject to additional taxes and penalties.

# Holders of ADSs may have limited rights relative to holders of our Ordinary Shares in certain circumstances.

The rights of holders of ADSs with respect to voting of ordinary shares and the right to receive certain distributions may be limited in certain respects by the deposit agreement entered into by us and Citibank, N.A. For example, although ADS holders are entitled under the deposit agreement, subject to any applicable provisions of Australian law and of our constitution, to instruct the depositary as to the exercise of the voting rights pertaining to the ordinary shares represented by the American Depositary Shares, and the depositary has agreed that it will vote the ordinary shares so represented in accordance with such instructions, ADS holders may not receive notices sent by depositary in time to ensure that the depositary will vote the ordinary shares. This means that holders of ADSs may not be able to exercise their right to vote. In addition, under the deposit agreement, the depositary has the right to restrict distributions to holders of the ADSs in the event that it is unlawful or impractical to make such distributions. We have no obligation to take any action to permit distributions to holders of our American Depositary Receipts, or ADRs. As a result, holders of ADRs may not receive distributions made by us.

# Our stock price is volatile and can fluctuate significantly based on events both within and outside our control; our trading volume may affect the liquidity of our ADSs.

Since December 2000, the price of our ordinary shares has ranged from A\$0.09 to A\$1.44 per share, and since January 27, 2005, the price of our ADSs has ranged from US\$2.06 to US\$12.14. The price of our ordinary shares and ADSs may be affected by developments directly affecting our business and by developments out of our control or unrelated to pSivida. The biotechnology sector in particular and the stock market generally are vulnerable to abrupt changes in investor sentiment. Prices of securities and trading volume of companies in the biotechnology industry, including ours, can swing dramatically in ways unrelated or that bear a disproportionate relationship to operating performance. Our share and ADS prices and their trading volume may fluctuate based on a number of factors including, but not limited to:

- clinical trial results and other product and technological developments and innovations;
- FDA and other governmental regulatory actions, receipt and timing of approvals of our proposed products, and any denials and withdrawals of approvals;
- competitive factors including new product ideas and technologies, clinical trial results and approvals of competitive products in our markets;
- advancements with respect to treatment of the diseases targeted by our proposed products;

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- developments relating to collaborative partners including execution and termination of agreements, achievement of milestones and receipt of payments;
- availability and cost of capital and our financial and operating results;
- changes in reimbursement policies or other practices related to our proposed products or the pharmaceutical industry generally;
- meeting, exceeding or failing to meet analysts' or investors' expectations, and changes in evaluations and recommendations by securities analysts;
- economic, industry and market conditions, changes or trends; and
- other factors unrelated to us and the biotechnology industry.

In addition, low trading volume may increase the volatility of the price of our ADSs. Trading volume in our ordinary shares on other markets has not been historically high, and trading volume of our ADSs on the NASDAQ Global Market has also been low. Further, because each of our ADSs represents ten of our ordinary shares, trading volume in our ADSs may be lower than that for our ordinary shares. A thin trading market could cause the price of our ADSs to fluctuate significantly more than the stock market as a whole. For example, trades involving a relatively small number of our ADSs may have a greater impact on the trading price for our ADSs than would be the case if their trading volume were higher. Accordingly, holders of our ADSs may not be able to liquidate a position in our ADSs in the desired time or at the desired price.

# The fact that we do not expect to pay cash dividends may lead to decreased prices for our stock.

We have never paid a cash dividend on our Ordinary Shares and we do not anticipate paying any cash dividend. We intend to retain future cash earnings, if any, for reinvestment in the development and expansion of our business. Our convertible note agreement limits our ability to pay dividends.

# Future issuances and sales of our stock could dilute your ownership and cause our stock price to decline.

As of December 31, 2005, we have outstanding options to purchase 31,169,162 of our ordinary shares, representing 8.1% of the total outstanding ordinary shares. In 2005, we raised capital through the issuance of 665,000 ADSs and warrants to acquire 133,000 ADSs and issued a convertible note currently convertible into 6,250,000 ADSs together with warrants to acquire an additional 633,803 ADSs and 5,700,000 ADSs, respectively. In addition, under certain circumstances, the convertible note will become convertible into a larger number of ADSs and the accrued interest on the principal amount of the note may be converted, in either case, potentially resulting in the issuance of a substantially larger number of ADSs. We issued a further 150,820,380 ordinary shares (represented by 15,082,038 ADSs) in exchange for the outstanding CDS common and preferred shares on the date of the acquisition in accordance with the merger agreement, 1,211,180 nonvested ordinary shares (represented by 121,118 nonvested ADSs) in connection with employee retention agreements, and 9,016,230 nonvested ordinary shares (represented by 901,623 nonvested ADSs) in exchange for the shares of nonvested CDS common stock outstanding on the date of the acquisition in accordance with retention agreements between CDS and its officers and employees. Exercise and conversion of these options, warrants and convertible securities would dilute existing shareholders. Further, we intend to continue to finance our operations through the issuance of equity securities, if feasible.

# Certain of our shareholders own a significant percentage of our ordinary shares and therefore may be able to influence our business in ways that are less beneficial to you.

Our executive officers, directors (including the officers and directors of our subsidiaries) and their affiliates beneficially own or control approximately 15.20% of our outstanding ordinary shares (based on the number of our ordinary shares outstanding on December 31, 2005 and assuming the issuance of shares upon the exercise of options vested or vesting within 60 days of December 31, 2005). As a result, if our executive officers and directors and their affiliates were all to vote in the same way, they would have the ability to exert significant influence over our board of directors and how we operate our business. The concentration of ownership may also have the effect of delaying, deferring or preventing a change in control of our company.



## If we fail to comply with internal controls evaluations and attestation requirements our stock price could be adversely affected.

We are subject to United States securities laws, including the Sarbanes-Oxley Act of 2002 and the rules and regulations adopted by the SEC pursuant to such Act. Under Section 404 of the Sarbanes-Oxley Act and the related regulations, we are required to perform an evaluation of our internal controls over financial reporting and have our independent registered public accounting firm publicly attest to this evaluation beginning in the year ending June 30, 2008. We will however shortly commence the evaluation and expect to complete it in the second quarter of 2007. We expect internal control evaluations and attestation requirements to be time-consuming and expensive. If we fail to complete the evaluation of our internal controls over financial reporting in time, if we identify material weaknesses in these internal controls or if our independent accountant does not timely attest to our evaluation, we could be subject to regulatory scrutiny and decreased public confidence in our internal controls, which may adversely affect the market price of our stock.

## Risks related to our recent acquisition of CDS and other recent transactions

The following risk factors relate to our December 30, 2005 acquisition of CDS, as well as two recently completed transactions: (1) our US\$4.3 million private placement structured as a private investment in public equity, referred to herein as the PIPE, and (2) our US\$15 million convertible note financing, referred to herein as the convertible note financing. For a description of the CDS acquisition, the PIPE and the convertible note financing, see, "The Company—Recent Developments."

# We may fail to integrate our operations successfully with the operations of CDS. As a result, pSivida and CDS may not achieve the anticipated benefits of the merger, which could adversely affect the price of ADSs.

We entered into the merger agreement and consummated the merger with the expectation that the merger will result in benefits to the combined companies, including the opportunities to combine the two companies' technologies, products and product candidates and the opportunity for pSivida to establish a substantial presence in the U.S. which would facilitate access to U.S. markets. However, these expected benefits may not be fully realized. Failure of the combined company to meet the challenges involved with successfully integrating the personnel, products, technology and research and development operations of the two companies following the merger or to realize any of the other anticipated benefits of the merger, could have a material adverse effect on our business, financial condition and results of operations as well as on that of our subsidiaries, including CDS (now pSivida Inc.). These integration efforts may be difficult and time consuming, especially considering the highly technical and complex nature of each company's products. The challenges involved in this integration include the following:

- coordinating research and development operations in a rapid and efficient manner;
- combining platform technologies of disparate sources;
- demonstrating to collaboration partners that the merger will not result in adverse changes in technology focus or development standards;
- retaining key alliances with collaboration partners;
- absorbing costs and delays in implementing overlapping systems and procedures, including financial accounting systems and accounting principles;
- persuading employees that our business culture and that of CDS are compatible, maintaining employee morale and retaining key employees; and
- overcoming potential distraction of management attention and resources from the business of the combined company.

We may not successfully integrate our operations and technology with those of CDS in a timely manner, or at all. We may not realize the anticipated benefits of the merger to the extent, or in the timeframe, anticipated, which could significantly harm our business.

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# Our operating results could be adversely affected as a result of purchase accounting treatment, and the corresponding impact of amortization or impairment of other intangibles relating to the merger, if the results of the combined company do not offset these additional expenses.

Under A-IFRS (effective from July 1, 2005), we accounted for the merger with CDS using the purchase method of accounting. Under purchase accounting, we recorded the market value of our ADSs, cash, and other consideration issued in connection with the merger and the amount of direct transaction costs as the cost of acquiring the business of CDS. We allocated that cost to the individual assets acquired and liabilities assumed, including identifiable intangible assets, based on their respective estimated fair values. Based on our preliminary allocation of the purchase price, which is subject to change, the amount allocated to goodwill is approximately A\$28.7 million, the amount allocated to patents is approximately A\$88.5 million and the amount allocated to IPR&D is approximately A\$34.3 million, giving rise to a gross deferred tax liability of approximately A\$49.8 million (approximately A\$29.1 million net of deferred tax assets). Goodwill is not subject to amortization but is subject to at least an annual impairment analysis, which may result in an impairment charge if the carrying value of the cash-generating unit to which goodwill has been allocated exceeds its fair value. If patents were amortized in equal quarterly amounts over a 12 year period following completion of the merger, the amortization attributable to these items would be approximately A\$1.8 million per quarter and A\$7.4 million per fiscal year. As a result, purchase accounting treatment of the merger will increase our net loss or decrease our net income in the foreseeable future, which could have a material and adverse effect on the future market value of our ADSs.

# We incurred significant costs in connection with the merger.

We incurred direct transaction costs of approximately US\$3.8 million (approximately A\$5.2 million) associated with the merger, which are included as a part of the total purchase consideration for accounting purposes. In addition, prior to completing the merger, CDS incurred direct transaction costs for accounting, investment banking and legal services of approximately US\$2.4 million (approximately A\$3.3 million), which were expensed in the period in which they were incurred. We believe the combined entity may incur charges to operations, which currently are not reasonably estimable, in the quarter in which the merger was completed or the following quarters, to reflect costs associated with integrating the two companies and that such charges may be material.

# Regulatory agencies, private parties, state attorneys general and other antitrust authorities may raise challenges to the merger on antitrust grounds.

We believe that the merger could be completed without making any filings with the Federal Trade Commission, or FTC, the Antitrust Division of the U.S. Department of Justice, or the Antitrust Division, or any other governmental authority whether under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, or the HSR Act, or otherwise and without waiting for the expiration of any waiting period requirements. However, the FTC and the Antitrust Division frequently scrutinize the legality under the antitrust laws of transactions like the merger, and at any time after the completion of the merger, the FTC or the Antitrust Division could take any action under the antitrust laws as it deems necessary or desirable in the public interest, including seeking the divestiture of our substantial assets or those of CDS. In addition, certain private parties, as well as state attorneys general and other antitrust authorities, may challenge the transaction under antitrust laws under certain circumstances.

In addition, the merger may be subject to the antitrust laws of Australia or other foreign jurisdictions. Anti-competitive mergers or acquisitions in Australia are regulated under sections 50 and 50A of the Commonwealth Trade Practices Act, or TPA, which generally prohibits any acquisition of shares or assets which is likely to have the effect of substantially lessening competition in a market in Australia. The Australian antitrust regulator, the Australian Competition and Consumer Commission, or ACCC, may on its own initiative apply to an Australian Court under that law in order to block a merger, or to obtain orders for the divestiture of assets, or for other remedies. A private party may also apply to an Australian Court under that law for a more limited range of remedies.

There can be no assurance that a challenge to the merger on antitrust grounds will not be made, or, if such a challenge is made, what the result will be.

## If CDS' former stockholders sell substantial amounts of ADSs after the merger, the market price of ADSs may decline.

The resale by former CDS stockholders of pSivida ADSs after the merger could cause the market price of our ADSs to decline. In connection with the merger, we have issued 16,104,779 ADSs. While those ADSs will not initially be freely tradable, we have agreed to register their resale within six months (subject to certain extensions) for stockholders entering into the registration rights agreement. Therefore, approximately 16,104,779 pSivida ADSs issued in the merger are expected to become freely tradable under U.S. securities laws six months from the closing date of the merger which was December 30, 2005. However, certain shareholders are subject to lock-ups for as long as nine months after the closing date of the merger.

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#### We may have liability under the U.S. securities laws related to the recent changes to our outstanding convertible note.

On September 15, 2006, we revised certain terms of the subordinated convertible promissory note that we issued on November 16, 2005. In connection with the amendments, we prepaid US\$2.5 million of the outstanding principal of the existing note and granted the holder an additional warrant to purchase 5,700,000 ADSs and a security interest in our current royalties. Because we had earlier filed a registration statement related to the ordinary shares represented by ADSs underlying the original note and the warrant issued with it, the revisions to the note and the issuance of the additional warrant, and our subsequent filing of an amendment to our registration statement to include the shares issuable pursuant thereto, may have resulted in a violation of the federal securities laws.

If the investor were to bring an action in court successfully making such an argument, we could be required to rescind the modified note and warrants for a period of one year following the date of the violation. In addition, if it is determined that we offered securities without properly registering them under federal or state law, or securing an exemption from registration, regulators could impose monetary fines or other sanctions as provided under these laws.

#### FORWARD-LOOKING STATEMENTS

The statements incorporated by reference or contained in this prospectus discuss our future expectations, contain projections of our results of operations or financial condition, and include other forward-looking information within the meaning of Section 27A of the Securities Act of 1933, as amended. Our actual results may differ materially from those expressed in forward-looking statements made or incorporated by reference in this prospectus. Forward-looking statements that express our beliefs, plans, objectives, assumptions or future events or performance may involve estimates, assumptions, risks and uncertainties. Therefore, our actual results and performance may differ materially from those expressed in the forward-looking statements. Forward-looking statements often, although not always, include words or phrases such as the following: "will likely result," "are expected to," "will continue," "is anticipated," "estimate," "intends," "plans," "projection" and "outlook."

You should not unduly rely on forward-looking statements contained or incorporated by reference in this prospectus. Various factors discussed in this prospectus, including, but not limited to, all the risks discussed in "Risk Factors" may cause actual results or outcomes to differ materially from those expressed in forward-looking statements. You should read and interpret any forward-looking statements together with these risks.

Any forward-looking statement speaks only as of the date on which that statement is made. We will not update any forward-looking statement to reflect events or circumstances that occur after the date on which such statement is made.

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# CAPITALIZATION AND INDEBTEDNESS

The following table sets forth our capitalization and indebtedness as of July 31, 2006 in accordance with A-IFRS. We have not included an "As Adjusted" column because we will not receive proceeds from the sale of ADSs by the selling shareholders.

	As of July 31, 2006 Actual (In Australian Dollars)
Indebtedness	
Short-term debt (unsecured, unguaranteed) (1), (2)	10,952,655
Long-term debt (unsecured, unguaranteed) (1), (2)	3,915,212
Total debt	14,867,867
Stockholders' equity	
Share capital	231,827,334
Reserves	(5,015,358)
Deficit accumulated prior to development stage	(3,813,181)
Deficit accumulated during development stage	(61,946,598)
Total stockholders' equity	161,052,197
Total capitalization and indebtedness in accordance with A-IFRS	175,920,064

<sup>(1)</sup> On September 14, 2006, pSivida agreed to repay US\$2.5 million (A\$3,422,314) and agreed to convert unsecured, unguaranteed debt into secured, guaranteed.

(2) The debt is recorded net of a \$4,052,175 discount related to the embedded conversion feature and the freestanding warrants, which has been allocated proportionately between short-term and long-term.

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# UNAUDITED PRO FORMA CONSOLIDATED FINANCIAL INFORMATION

On December 30, 2005, we completed the acquisition of 100% of the issued capital of CDS. The acquisition of CDS has been accounted for under the purchase method of accounting.

The unaudited pro forma consolidated statements of operations for the six months ended December 31, 2005 and the year ended June 30, 2005 are prepared in accordance with US GAAP, and are derived from, and should be read in conjunction with: (i) the historical audited consolidated financial statements of pSivida, which are incorporated by reference to our Annual Report on Form 20-F for the fiscal year ended June 30, 2005, filed with the SEC on January 18, 2006; and (ii) the historical unaudited interim consolidated financial statements of pSivida, which are included elsewhere in this registration statement. Although pSivida and CDS have different fiscal year ends, the historical consolidated financial statements of CDS have been adjusted to reflect the same fiscal year as pSivida.

The adjustments necessary to fairly present the unaudited pro forma consolidated statements of operations have been made based on available information and assumptions that pSivida's management believes are reasonable. The unaudited pro forma consolidated statements of operations are for informational purposes only and do not purport to present what pSivida's results would actually have been had the acquisition actually occurred on the dates presented or to project pSivida's results of operations for any future period. The unaudited pro forma consolidated statements of operations reflect preliminary estimates of the allocation of the purchase price for the acquisition of CDS that may be adjusted based on the actual outcome of an independent valuation expected to be finalized during the first quarter of the fiscal year ending June 30, 2007.

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# Unaudited Pro Forma Consolidated Statement of Operations Six Months Ended December 31, 2005 (in Australian dollars except number of shares)

	pSivida Historical (3a)	CDS Historical (3b)	Pro Forma Adjustments	Pro Forma
Revenue:	()	()	- <b>J</b>	
Revenue, related party	—	446,226	—	446,226
Revenue, other	50,732	197,831	—	248,563
Total revenue	50,732	644,057		694,789
Operating expenses:				
Research and development	9,058,338	1,312,649	3,685,834 (3e)	14,135,350
			78,529 (3f)	
Selling, general and administrative	4,369,570	6,117,630	55,450 (3f)	10,542,650
Write off of in-process research and development	34,281,686	—	—	34,281,686
Foreign exchange gain	(306,841)	—	—	(306,841)
Total operating expenses	47,402,753	7,430,279	3,819,813	58,652,845
Loss from operations	(47,352,021)	(6,786,222)	(3,819,813)	(57,958,056)
Interest and other income (expense), net	(41,424)	30,178	_	(11,246)
Loss before income tax benefit	(47,393,445)	(6,756,044)	(3,819,813)	(57,969,302)
Income tax benefit	2,380,063	—	4,230,343 (3g)	6,610,406
Net loss	(45,013,382)	(6,756,044)	410,530	(51,358,896)
Accretion of redeemable convertible preferred stock	—	(1,742,780)	1,742,780 (3h)	
Net income (loss) attributable to common stockholders	(45,013,382)	(8,498,824)	2,153,310	(51,358,896)
Basic and diluted loss per common share	(0.20)	(4.08)		(0.14)
Basic and diluted weighted average number of shares	225,327,359	2,083,072	(6)	376,147,739

See accompanying notes to the unaudited pro forma consolidated statements of operations.

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# Unaudited Pro Forma Consolidated Statement of Operations Year Ended June 30, 2005 (in Australian dollars except number of shares)

	pSivida Historical (3c)	CDS Historical (3d)	Pro Forma Adjustments	Pro Forma
Revenue:	( )	ζ,	5	
Revenue, related party	—	12,768,626	—	12,768,626
Revenue, other	161,666	158,385		320,051
Total revenue	161,666	12,927,011	_	13,088,677
Operating expenses:				
Research and development expense	14,445,241	2,107,953	7,371,668 (3e)	25,426,549
			1,501,687 (3f)	
Selling, general and administrative	5,320,930	8,242,608	672,769 (3f)	14,236,307
Foreign currency loss	1,623,484	—	_	1,623,484
Total operating expenses	21,389,655	10,350,561	9,546,124	41,286,340
Income (loss) from operations	(21,227,989)	2,576,450	(9,546,124)	(28,197,663)
Interest and other income (expense), net	667,310	(213,568)		453,742
Income (loss) before income tax benefit	(20,560,679)	2,362,882	(9,546,124)	(27,743,921)
Income tax benefit	3,620,891	_	2,873,297 (3g)	6,494,188
Net loss attributable to minority interest	378,276	—		378,276
Net income (loss)	(16,561,512)	2,362,882	(6,672,827)	(20,871,457)
Accretion of redeemable convertible preferred stock		(3,246,135)	3,246,135 (3h)	
Net loss attributable to common stockholders	(16,561,512)	(883,253)	(3,426,692)	(20,871,457)
Basic and diluted loss per common share	(0.08)	(0.43)		(0.06)
Basic and diluted weighted average number of shares	207,802,540	2,068,990	(6)	358,622,920

See accompanying notes to the unaudited pro forma consolidated statements of operations.

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# Notes to Unaudited Pro Forma Consolidated Financial Statements (in Australian dollars)

### 1. Basis of Presentation

The unaudited pro forma consolidated statements of operations have been prepared in accordance with US GAAP and are presented in Australian dollars.

## 2. Purchase Price Allocation

The primary reasons for the acquisition of CDS were: CDS' commercialized products, including Vitrasert<sup>®</sup> for cytomegalovirus retinitis and the recently launched Retisert<sup>™</sup> for uveitis; diversified product portfolio; existing license and development agreements, including those with Bausch & Lomb and Alimera Sciences; and extensive patent portfolio. CDS also could provide a base for us near Boston, Massachusetts which is a biotechnology hub that would allow our further expansion into the US market. In addition, as a result of the acquisition, we will receive royalty income which is expected to contribute significantly to the continued development of the expanded product portfolio. These factors contributed to the purchase price that resulted in recognition of a significant amount of goodwill as further noted below.

The purchase price of \$143,081,155 consists of:

- § \$114,319 cash;
- § 150,820,380 ordinary fully paid shares of pSivida (represented by 15,082,038 ADSs), with an estimated fair value of \$130,610,449 (\$0.866 per share, represented by US\$6.602 per ADS). The fair value of the shares was determined based on the weighted average of the closing share prices of pSivida for the period two days before and two days after October 3, 2005, being the date that the terms of the acquisition were agreed to and announced;
- § 9,016,230 nonvested ordinary shares of pSivida (represented by 901,623 nonvested ADSs), with an estimated fair value of \$6,231,034, net of \$1,577,021 allocated to unearned compensation based on the portion of the fair value at the consummation date related to the future service (vesting) period. As the holders of the nonvested ADSs have the rights of a normal shareholder, the fair value of these nonvested ADSs was determined based on the fair value of pSivida's ordinary ADSs as stated above;
- § 1,724,460 share options in pSivida (represented by 172,446 options over ADSs), with an estimated fair value of \$876,204; and
- § direct acquisition costs of \$5,249,149.

The purchase price does not include 1,211,180 nonvested ordinary shares (represented by 121,118 nonvested ADSs) issued by pSivida in connection with employee retention agreements for which employee service subsequent to the consummation date of the acquisition is required in order for the shares to vest. As the holders of the nonvested ADSs have the rights of a normal shareholder, the fair value of these nonvested ADSs was determined at the grant date based on the fair value of pSivida's ordinary ADSs;

A final determination of required purchase accounting adjustments, including the allocation of the purchase price, has not yet been made. Accordingly, the purchase accounting adjustments made in connection with these unaudited pro forma consolidated financial statements are preliminary. The amounts that we may record based on the final assessment and determination of fair values may differ significantly from those based on the preliminary purchase price allocation. In particular, the amounts allocated to intangible assets (being primarily intellectual property in the form of patents acquired), the related deferred tax liability, IPR&D and goodwill may be revised and may ultimately differ from those used in these consolidated financial statements, any of which could have a material impact on the financial position and results of our operations.

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# Notes to Unaudited Pro Forma Consolidated Financial Statements

(in Australian dollars)

Following is a preliminary estimate of the allocation of the purchase price:

	Total fair value
	(in Australian dollars)
Cash	228,464
Receivables	460,351
Other	282,588
Patents	88,460,020
In-Process Research and Development	34,281,686
Property, Plant and Equipment	624,035
Payables	(3,549,399)
Provisions	(621,399)
Deferred Revenue	(1,826,699)
Deferred Tax Liability, Net	(14,679,007)
Total	103,660,640
Purchase price	143,081,155
Goodwill	39,420,515

### 3. Pro Forma Adjustments

Footnotes to the pro forma statements

- (a) Reflects the historical results of operations of pSivida for the six months ended December 31, 2005 on a U.S. GAAP basis, as restated. Refer to Note 12 to our unaudited interim consolidated financial statements included elsewhere in this registration statement for a description and summary of the significant effects of the restatement.
- (b) Reflects the historical results of operations of CDS on a US GAAP basis for the period July 1, 2005 to December 29, 2005, derived from internal accounting records. The historical statement of operations data was translated from US dollars to Australian dollars using a weighted average exchange rate of \$0.752 for the period July 1, 2005 to December 29, 2005.
- (c) Reflects the historical results of operations of pSivida for the year ended June 30, 2005 on a US GAAP basis.
- (d) Reflects the historical results of operations of CDS on a US GAAP basis for the period July 1, 2004 to June 30, 2005, which have been derived by combining the US GAAP results of operations for the year ended December 31, 2004 minus the US GAAP results of operations for the six months to June 30, 2004 plus the US GAAP results of operations for the six months to June 30, 2005. The historical statement of operations data was translated from US dollars to Australian dollars using a weighted average exchange rate of \$0.754 for the year ended June 30, 2005. Refer to Note 7 to our unaudited interim consolidated financial statements included elsewhere in this registration statement,
- (e) Reflects the amortization of the fair value of patents acquired over an estimated useful life of 12 years (see Note 5).
- (f) Reflects the recognition of compensation cost over the requisite service period for both the 1,211,180 non-vested ordinary shares issued by pSivida in connection with the employee retention agreements and the unearned compensation attributable to the 9,016,230 non-vested ordinary shares issued by pSivida as part of the purchase price. At the date of grant, the individual awards were scheduled to vest over a minimum service period of six months to a maximum service period of 29 months from the acquisition date. In April 2006, the individual awards with six month and 12 month vesting periods were modified pursuant to an agreement between us and the employees to extend the vesting of these awards to periods ranging from 13 to 15 months from the date of the acquisition. The modification is not reflected in the pro forma statements of operations as the modification is not directly attributable to the acquisition.



# Notes to Unaudited Pro Forma Consolidated Financial Statements (in Australian dollars)

- (g) Reflects the deferred tax benefit attributable to the reduction of the gross deferred tax liability for the difference between the fair value and tax basis of the acquired patents over the 12 year amortization period, partially offset by deferred tax expense due to a change in the CDS historical valuation allowance as a result of the acquisition, using the CDS combined federal and state statutory tax rate of 40%. There is no impact on current income taxes due to the net operating loss of the combined entity.
- (h) Reflects the elimination of accretion of the CDS Series A redeemable preferred stock due to the elimination of such stock.

### 4. In-process research and development

As indicated in Note 2, pSivida recorded IPR&D of \$34,281,686 in connection with the acquisition. The IPR&D was expensed at the acquisition date since the acquired IPR&D projects had no alternative future use. Such adjustment has been excluded from the pro forma consolidated statement of operations for the year ended June 30, 2005 as the charge is a non-recurring charge directly attributable to the acquisition.

### 5. Patents

As indicated in Note 2, we acquired patents and filed patent applications with respect to multiple aspects of CDS' technologies, products, and processes, including but not limited to, Vitrasert<sup>®</sup>, Retisert<sup>TM</sup>, Medidur<sup>TM</sup>, CODRUG<sup>TM</sup> and AEON.

In determining the allocation of the purchase price to patents, we only considered patents and patent applications that relate to the Retisert<sup>TM</sup> for Uveitis product. We determined the estimated fair value of these patents acquired with reference to a discounted cash flow analysis of the Retisert<sup>TM</sup> product.

In determining the estimated useful life of the patents acquired to be 12 years, we considered the following attributes described by paragraph 11 of SFAS No. 142, "Goodwill and Other Intangible Assets", to be key factors :

- § The patents are currently being commercialized in the form of the Retisert<sup>™</sup> for Uveitis product identified above.
- § The patents acquired related to this product will expire from 12 to 15 years from the time of the acquisition.
- § Although technological progress may cause some of the existing technology to become commercially obsolete before the expiration of the related patent life, on an overall basis we believe that the products developed using the capitalized intellectual property will continue to be sold over the next 12 years.
- § The patents do not require any material maintenance expenditure to obtain the expected future cash flows.

We will evaluate the patents for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

#### 6. Loss per share

Pro forma per share data is based on the number of shares of pSivida's ordinary shares that would have been outstanding had the acquisition of CDS occurred on July 1, 2004. In order to compute the number of ordinary shares used in the calculation of pro forma basic and diluted loss per common share, the number of ordinary shares (represented by ADSs) to be issued by pSivida to former holders of shares in CDS common stock and preferred stock was added to the weighted average number of pSivida ordinary shares outstanding for the six months ended December 31, 2005 and the year ended June 30, 2005. Under the terms of the agreements a total of 150,820,380 ordinary shares (represented by 15,082,038 ADSs) have been issued in exchange for the outstanding CDS common and preferred shares on the date of the acquisition. A reconciliation of shares used to compute historical basic and diluted loss per share to shares used to compute pro forma basic and diluted loss per common share follows:

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## PSIVIDA LIMITED AND SUBSIDIARIES

# Notes to Unaudited Pro Forma Consolidated Financial Statements

(in Australian dollars)

	Six months ended December 31, 2005	Year ended June 30, 2005
Ordinary shares used to compute pSivida historical basic and diluted loss per share	225,327,359	207,802,540
Ordinary shares issued to former holders of shares of vested CDS common stock	74,307,640	74,307,640
Ordinary shares issued to former holders of shares of CDS convertible redeemable preferred		
stock	76,512,740	76,512,740
Ordinary shares used to compute pro forma basic and diluted loss per share	376,147,739	358,622,920

Securities that could potentially dilute earnings (loss) per share in the future, including the pSivida nonvested ordinary shares, share options, warrants and convertible note, are not included in the computation of pro forma diluted loss per share because the effect would be antidilutive due to the net loss attributable to common stockholders.

## 7. CDS historical results of operations

The following table demonstrates how the historical results of operations of CDS were conformed to pSivida's fiscal year-end for purposes of the pro forma consolidated statement of operations for the year ended June 30, 2005.

	Year ended December 31, 2004 CDS Historical US GAAP US\$ A	Six months ended June 30, 2004 CDS Historical US GAAP US\$ B	Six months ended December 31, 2004 CDS Historical US GAAP US\$ C=A-B	Six months ended June 30, 2005 CDS Historical US GAAP US\$ D	Year ended June 30, 2005 CDS Historical US GAAP US\$ =C+D	Year ended June 30, 2005 CDS Historical US GAAP A\$
Revenue:						
Revenue, related party	3,120,086	51,631	3,068,455	6,552,960	9,621,415	12,768,626
Revenue, other		_	—	119,346	119,346	158,385
Total revenue	3,120,086	51,631	3,068,455	6,672,306	9,740,761	12,927,011
Operating expenses:						
Research and development	3,083,525	1,960,803	1,122,722	465,663	1,588,385	2,107,953
Selling, general and						
administrative	5,705,148	2,614,520	3,090,628	3,120,341	6,210,969	8,242,608
Total operating expenses	8,788,673	4,575,323	4,213,350	3,586,004	7,799,354	10,350,561
Income (loss) from operations	(5,668,587)	(4,523,692)	(1,144,895)	3,086,302	1,941,407	2,576,450
Interest and other income			(100.000)			
(expense), net	(206,727)	(97,507)	(109,220)	(49,154)	(158,374)	(213,568)
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# PSIVIDA LIMITED AND SUBSIDIARIES

# Notes to Unaudited Pro Forma Consolidated Financial Statements (in Australian dollars)

	Year ended December 31, 2004 CDS Historical US GAAP US\$ A	Six months ended June 30, 2004 CDS Historical US GAAP US\$ B	Six months ended December 31, 2004 CDS Historical US GAAP US\$ C=A-B	Six months ended June 30, 2005 CDS Historical US GAAP US\$ D	Year ended June 30, 2005 CDS Historical US GAAP US\$ =C+D	Year ended June 30, 2005 CDS Historical US GAAP A\$
Income (loss) before income	(= === = ( ))		<i>(, , , , , , , , , , , , , , , , , , , </i>			
tax benefit	(5,875,314)	(4,621,199)	(1,254,115)	3,037,148	1,783,033	2,362,882
Income tax benefit		—		—	—	
Net loss attributable to minority interest		_	_	_	_	_
Net income (loss)	(5,875,314)	(4,621,199)	(1,254,115)	3,037,148	1,783,033	2,362,882
Accretion of redeemable convertible preferred stock	(2,123,761)	(947,941)	(1,175,820)	(1,270,208)	(2,446,028)	(3,246,135)
Net income (loss) attributable to common stockholders	(7,999,075)	(5,569,140)	(2,429,935)	1,766,940	(662,995)	(883,253)
Basic and diluted income (loss) per common share	(3.50)	(2.83)	(1.34)	0.85	(0.32)	(0.43)
Basic and diluted weighted average number of shares	2,284,730	1,971,332	1,810,746 -35-	2,083,072	2,068,990	2,068,990

## SELECTED CONSOLIDATED FINANCIAL DATA

The following table presents our selected historical consolidated financial data as of the dates and for each of the periods indicated. The information set forth below is not necessarily indicative of future results and should be read in conjunction with (i) the historical audited consolidated financial statements of pSivida, which are incorporated by reference to our Annual Report on Form 20-F for the fiscal year ended June 30, 2005, filed with the SEC on January 18, 2006; and (ii) the historical unaudited interim consolidated financial statements of pSivida, which are included elsewhere in this registration statement.

We will adopt A-IFRS for the first time in our financial statements for the year ending June 30, 2006, which will include comparative financial statements for the year ended June 30, 2005. AASB 1 "First-time Adoption of Australian Equivalents to International Financial Reporting Standards" ("AASB 1") requires that an entity develop accounting policies based on the standards and related interpretations effective at the reporting date of its first annual A-IFRS financial statements (e.g., June 30, 2006). AASB 1 also requires that those policies be applied as of the date of transition to A-IFRS (e.g., July 1, 2004) and throughout all periods presented in the first A-IFRS financial statements. The selected consolidated financial data as of December 31, 2005 and for the six month periods ended December 31, 2005 and 2004 have been derived from our unaudited interim consolidated financial statements and the notes thereto included elsewhere in this registration statement, which have been prepared in accordance with AASB standards and Urgent Issues Group ("UIG") interpretations issued and effective, or issued and early-adopted, at June 29, 2006. As a result, the accounting policies used to prepare the unaudited interim consolidated financial statements. An explanation of how the transition from superseded policies to A-IFRS has affected our financial position, financial performance and cash flows is discussed in Note 9 to the unaudited interim consolidated financial statements. In the opinion of our management, the unaudited interim consolidated financial statements include all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included.

The selected consolidated financial data as of June 30, 2005 and 2004 and for each of the three years in the period ended June 30, 2005 have been derived from our audited consolidated financial statements and the notes thereto, prepared in accordance with superseded policies (A-GAAP), which are incorporated by reference to our Annual Report on Form 20-F for the fiscal year ended June 30, 2005. The selected consolidated financial data as of June 30, 2003, 2002 and 2001, for the year ended June 30, 2002 and for the period from December 1, 2000 (inception date) to June 30, 2001 have been derived from our audited consolidated financial statements and notes thereto, prepared in accordance with superseded policies (A-GAAP), which are not included in this document.

A-IFRS and superseded policies (A-GAAP) differ in certain significant respects from U.S. GAAP. Please refer to Note 12 to the unaudited interim consolidated financial statements included elsewhere herein for a description of the differences between A-IFRS and U.S. GAAP as they relate to us, and a reconciliation of net loss and total equity to U.S. GAAP for the periods and as of the dates indicated. Also refer to Note 27 to the audited consolidated financial statements incorporated by reference to our Annual Report on Form 20-F for the fiscal year ended June 30, 2005 for a description of the differences between superseded policies (A-GAAP) and U.S. GAAP as they relate to us, and a reconciliation of net loss and total equity to U.S. GAAP for the periods and as of the dates indicated.

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	Six months ended	December 31.
	2005	2004
	(In Australia	n Dollars)
STATEMENT OF OPERATIONS DATA:		
A-IFRS (as restated for the six months ended December 31, 2005) (1)		
Revenue	296,921	398,501
Loss before income tax	(13,070,400)	(9,598,661)
Net loss	(10,702,745)	(7,330,165)
	Six months ende	
	2005 (In Australi	2004 an Dollars)
Loss per share – basic and diluted	(0.05)	(0.04)
U.S. GAAP (as restated for the six months ended December 31, 2005) (2)		
Revenue	50,732	13,879
Loss from operations	(47,352,021)	(10,050,086)
Net loss	(45,013,382)	(7,421,294)
Loss per share – basic and diluted	(0.20)	(0.04)
		As of December 31, 2005
BALANCE SHEET DATA:		
A-IFRS (as restated) (1)		
Total assets		256,114,314
Net assets		189,230,222
Contributed equity		224,897,860
U.S. GAAP (as restated) (2)		
Total assets		240,621,265
Net assets		187,998,912

(1) The A-IFRS consolidated financial statements as of and for the six months ended December 31, 2005 have been restated. Refer to Note 11 to our unaudited interim consolidated financial statements included elsewhere in this registration statement for a description and summary of the significant effects of the restatement.

(2) The U.S. GAAP financial information as of and for the six months ended December 31, 2005 has been restated. Refer to Note 12 to our unaudited interim consolidated financial statements included elsewhere in this registration statement for a description and summary of the significant effects of the restatement.

					Period from Inception of Development
		Years ended	June 30,		Stage (Dec 1, 2000) to June
	2005	2005 2004 2003 2002 (In Australian Dollars)			
STATEMENT OF OPERATIONS		· ·	,		
DATA:					
A-GAAP					
Revenue from ordinary activities	828,976	381,679	110,675	916,600	113,145
Loss from ordinary activities before income					
tax	(15,125,719)	(7,518,976)	(5,356,328)	(3,997,024)	(851,730)
Net loss	(14,726,523)	(3,683,205)	(2,765,153)	(2,190,419)	(738,501)
Loss per share – basic and diluted	(0.07)	(0.03)	(0.03)	(0.02)	(0.01)
U.S. GAAP (as restated as of June 30, 2004 and 2003 (4))					
Revenues from ordinary activities	161,666	56,200		N/A	N/A
Loss from operations	(20,560,679)	(10,195,615)	(6,076,013)	N/A	N/A
Net loss	(16,561,512)	(5,019,974)	(2,268,603)	N/A	N/A
Loss per share – basic and diluted	(0.08)	(0.04)	(0.02)	N/A	N/A
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		As of June 30,		
2005	2004	2003	2002	2001 (3)
82,035,313	40,367,058	7,175,342	11,273,860	9,247,729
79,987,614	38,428,943	6,299,519	10,712,821	8,962,180
107,883,835	49,957,982	15,602,184	14,649,616	12,107,849
100,063,276	41,295,099	8,220,492	N/A	N/A
87,650,337	37,794,706	7,140,316	N/A	N/A
117,798,149	51,030,718	15,428,635	N/A	N/A
	82,035,313 79,987,614 107,883,835 100,063,276 87,650,337	82,035,313         40,367,058           79,987,614         38,428,943           107,883,835         49,957,982           100,063,276         41,295,099           87,650,337         37,794,706	2005         2004         2003           82,035,313         40,367,058         7,175,342           79,987,614         38,428,943         6,299,519           107,883,835         49,957,982         15,602,184           100,063,276         41,295,099         8,220,492           87,650,337         37,794,706         7,140,316	2005         2004         2003         2002           82,035,313         40,367,058         7,175,342         11,273,860           79,987,614         38,428,943         6,299,519         10,712,821           107,883,835         49,957,982         15,602,184         14,649,616           100,063,276         41,295,099         8,220,492         N/A           87,650,337         37,794,706         7,140,316         N/A

(3) The legal entity that became pSivida was incorporated as the Sumich Group Ltd in April 1987. The Sumich Group operated an agriculture business which was placed into administration or receivership on September 30, 1998. pSivida was subsequently formed on December 1, 2000 following upon entering into a court-approved arrangement with Sumich Group's creditors which fully extinguished all prior liabilities as of that time. We then appointed new directors and officers and re-listed on the Australian Stock Exchange under its new name.

(4) The U.S. GAAP financial information as of and for the years ended June 30, 2004 and 2003 has been restated. Refer to Note 27 in our audited consolidated financial statements incorporated by reference to our Annual Report on Form 20-F for the fiscal year ended June 30, 2005 for a description and summary of the significant effects of the restatement.

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## THE OFFERING

On November 16, 2005, we issued a subordinated convertible promissory note in the principal amount of US\$15.0 million in a private placement to the selling security holder. On September 14, 2006, we and the selling security holder amended the terms of the note.

The note may be converted into ADSs by the holder at any time prior to November 16, 2008 at a conversion price of US\$2.00 per ADS, subject to adjustment upon specified events, including a price-based anti-dilution provision, and further subject to adjustment for stock splits, combinations or similar events. The conversion price will also be adjusted to 108% of the average of the volume weighted average market price of the ADSs for the ten consecutive trading days ending April 30, 2007, if such adjustment would result in a conversion price lower than US\$2.00 or the then current conversion price. We can automatically convert the note into ADSs at the conversion price, as adjusted, in certain specified circumstances, including if the ADSs consistently trade at a price that is twice the conversion price over a specified period. We can also redeem all or any part of the note at any time at our option at 108% of the redemption amount if we issue a warrant to the holder over ADSs representing 30% of the redemption amount with an exercise price equal to the lower of the conversion price or 75% of the then current market price. The note bears interest at a rate of 8% per year which is payable quarterly, and in certain circumstances we may be able to pay the interest in ADSs instead of cash.

As part of the November 16 private placement, we also issued to the selling security holder a warrant to purchase up to an additional 633,803 ADSs at a price of US\$7.20 per ADS, subject to anti-dilution provisions in the event of a rights offering and further subject to adjustment for stock splits, combinations or similar events. Since the completion of our rights issue on June 14, 2006, the exercise price under the warrant is US\$7.17 per ADS. The warrant is exercisable immediately after the closing date of the private placement and expires six years from the date of issuance.

The selling security may redeem up to US\$6.25 million of the principal amount of the note on either of July 31, 2007 and January 31, 2008. Further, the requirement that we maintain a minimum cash balance will be struck upon the later of future aggregate capital raisings of US\$16 million or effectiveness of the registration statement of which this prospectus is a part. The selling security holder has also released us from any restrictions involving future fundraising efforts subject to its right to participate in exchange for redemption of the principal of the note.

The gross proceeds of the private placement to us were initially US\$15.0 million, or approximately US\$29.8 million if the warrants are exercised in full. We intend to use the proceeds for working capital and general corporate purposes. We will not receive any proceeds from the selling security holder from the sale of the ADSs pursuant to this prospectus.

Pursuant to a registration rights agreement dated November 16, 2005, we agreed to register for resale 130% of the number of ADSs issuable upon conversion of the note and exercise of warrant issued in the private placement, as well as any ADSs received by the selling security holder in payment of interest under the note. Pursuant to that agreement, we have filed with the Securities and Exchange Commission, or SEC, the Registration Statement, of which this prospectus is a part, to register the resale of those ADSs and the maximum number of shares that could be issued in payment of interest under the note based on a recent trading price. We will amend the Registration Statement from time to time to register the resale of additional ADSs if necessary to cover any ADSs issued to the holder of the note.

This prospectus relates to the offer and sale by the selling security holder during the period in which the Registration Statement containing this prospectus is effective of up to 12,737,139 ADSs. Such number also includes a number of ADSs that may be issued and resold to prevent dilution resulting from stock splits, stock dividends or similar transactions.

The ADSs offered under this prospectus may be sold by the selling security holder on the NASDAQ Global Market, in negotiated transactions with a broker-dealer or market maker as principal or agent, or in privately negotiated transactions not involving a broker or dealer. Information regarding the selling security holder, the ADSs it is offering to sell under this prospectus and the times and manner in which it may offer and sell those shares is provided in the sections of this prospectus captioned "Selling Security Holder," "Plan of Distribution" and "Description of Securities".

The registration of ADSs pursuant to this prospectus does not necessarily mean that any of those ADSs will ultimately be offered for sale by the selling security holder.

#### **USE OF PROCEEDS**

The proceeds from the sale of ADSs offered pursuant to this prospectus are solely for the account of the selling security holder. Accordingly, we will receive no proceeds from the sale of the ADSs. However, we may receive cash consideration of up to US\$4.6 million in connection with the exercise of the warrant issued on November 16, 2005. The warrant issued on November 16, 2005 is exercisable at any time before November 16, 2011 at a price of US\$7.17 per ADS, subject to further adjustment upon specified events. We would use such proceeds for general corporate purposes.

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## SELLING SECURITY HOLDER

The ADSs being offered by the selling security holder are issuable (i) upon conversion of the convertible note, (ii) as interest on the convertible note and (iii) upon exercise of the warrant. For additional information regarding the notes and warrant, see "The Offering" above. We are registering the ADSs in order to permit the selling security holder to offer the ADSs for resale from time to time. Except for the ownership of the note and the warrant, the selling security holder has not had any material relationship with us within the past three years.

The table below states the name of the selling security holder and other information regarding the selling security holder's beneficial ownership of the ordinary shares underlying the ADSs. The second column lists the number of ordinary shares beneficially owned (directly or indirectly through ADSs) by the selling security holder, based on its ownership of the note and the warrant, as of August 7, 2006, assuming conversion of the note and exercise of the warrant held by the selling security holder on that date, without regard to any limitations on conversions or exercise.

The third column lists the ordinary shares being offered by this prospectus by the selling security holder.

In accordance with the terms of our registration rights agreement with the selling security holder, this prospectus generally covers the resale of at least 130% of the sum of (i) the maximum number of ADSs issuable upon conversion of the note (assuming that the note is convertible at \$2.00 and without taking into account any limitations on the conversion of the note set forth in the note) and (ii) the maximum number of ADSs issuable upon exercise of the related warrant (without taking into account any limitations on the exercise of the warrant set forth in the warrant). In addition, this prospectus covers the resale of the maximum number of ADSs issuable in payment of interest on the note assuming that the shares payable as interest are valued at a recent market price. Because the conversion price of the note and the exercise price of the warrant may be adjusted, the number of ADSs that will actually be issued may be more or less than the number of ADSs being offered by this prospectus. In addition, as of the date of this prospectus, no ADSs have been issued in payment of interest on the convertible note. The actual number of ADSs issued in payment of interest on the convertible note will vary based on the market price of the ADSs preceding each such interest payment. We will amend this prospectus and the Registration Statement of which it is a part to register ADSs issued to the selling security holder in excess of those offered hereby, if any. The fourth column assumes the sale of all of the ADSs offered by the selling security holder pursuant to this prospectus.

Under the terms of the note and the warrant, the selling security holder may not convert the note, or exercise the warrant, to the extent such conversion or exercise would cause the selling security holder, together with its affiliates, to beneficially own a number of ordinary shares (directly or indirectly through ADSs) which would exceed 4.99% of our then outstanding ordinary shares following such conversion or exercise, excluding for purposes of such determination ordinary shares issuable upon conversion of the note which has not been converted and upon exercise of the warrant that has not been exercised. The number of shares in the second column does not reflect this limitation. The selling security holder may sell all, some or none of its ADSs in this offering. See "Plan of Distribution."

The ADSs offered by this prospectus may be offered from time to time by the persons or entities named below:

		Maximum Number of ADSs to be Sold Pursuant to this	
Name of Selling Security Holder	Number of ADSs Owned Prior to Offering (1)	Prospectus (2)(3)	Number of ADSs Owned After Offering
Castlerigg Master Investments (4)	12,583,803	12,737,139	_

<sup>(1)</sup> The number of shares beneficially owned is determined in accordance with Rule 13d-3 of the Exchange Act, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rule, beneficial ownership includes any shares as to which an individual has sole or shared voting power or investment power and also any shares which an individual has the right to acquire within 60 days of the date of this prospectus through the exercise of any stock option or other right. The shares listed in this column include shares underlying the note and shares underlying the warrants acquired in November 2005 and August 2006, in each case, which the selling security holder has the right to acquire within 60 days of August 7, 2006 assuming a conversion price under the note of \$2.00. The shares listed in this column do not reflect the 4.99% ownership limitation noted above. Unless otherwise indicated, the selling security holder has sole voting and investment power with respect to the ordinary shares it holds through its ADSs. The inclusion of any ordinary shares in this table does not constitute an admission of beneficial ownership for the selling security holder.

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- (2) Assumes the full conversion of the selling security holder's note at a conversion price of \$2.00 and interest payments due after August 7, 2006 at a conversion price of \$2.52 and the full exercise of the warrant issued to the selling security holder on November 16, 2005. Pursuant to Rule 416 of the Securities Act, this registration statement also shall cover any additional ordinary shares that become issuable in connection with the ordinary shares registered for sale hereby by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without the receipt of consideration that results in an increase in the number of our outstanding ordinary shares.
- (3) The number of ordinary shares to be sold by the selling security holder is based on 130% of the estimated number of our ordinary shares issuable to the selling security holder upon conversion of the note and upon exercise of the warrants (assuming for purposes of such calculation, that the note was converted at a conversion price of \$2.00 per ADS and the warrants were exercised in full).
- (4) Sandell Asset Management Corp. ("SAMC") is the investment manager of Castlerigg Master Investments Ltd. ("Master"). Thomas Sandell is the controlling person of SAMC and may be deemed to share beneficial ownership of the shares beneficially owned by Master. Castlerigg International Ltd. ("Castlerigg International") is the controlling shareholder of Castlerigg International Holdings Limited ("Holdings"). Holdings is the controlling shareholder of Master. Each of Holdings and Castlerigg International may be deemed to share beneficial ownership of the shares beneficially owned by Castlerigg Master Investments. SAMC, Mr. Sandell, Holdings and Castlerigg International each disclaims beneficial ownership of the securities with respect to which indirect beneficial ownership is described.

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## PLAN OF DISTRIBUTION

We are registering the ADSs issuable upon conversion of the note and upon exercise of the warrant and as interest on the convertible note to permit the resale of these ADSs by the selling security holder from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling security holder of the ADSs. We will bear all fees and expenses incident to our obligation to register the ADSs.

The selling security holder may sell all or a portion of the ADSs beneficially owned by it and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the ADSs are sold through underwriters or broker-dealers, the selling security holder will be responsible for underwriting discounts or commissions or agent's commissions. The ADSs may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions,

- on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;
- in the over-the-counter market;
- in transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- through the writing of options, whether such options are listed on an options exchange or otherwise;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the ADSs as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- pursuant to Rule 144 under the Securities Act;
- broker-dealers may agree with the selling security holder to sell a specified number of such ADSs at a stipulated price per ADS;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

If the selling security holder effects such transactions by selling ADSs to or through underwriters, broker-dealers or agents, such underwriters, brokerdealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling security holder or commissions from purchasers of the ADSs for whom they may act as agent or to whom they may sell as principal (which discounts, concessions or commissions as to particular underwriters, broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of the ADSs or otherwise, the selling security holder may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the ADSs in the course of hedging in positions they assume. The selling security holder may also sell ADSs short and deliver ADSs covered by this prospectus to close out short positions. The selling security holder may also loan or pledge ADSs to broker-dealers that in turn may sell such ADSs.

The selling security holder may pledge or grant a security interest in some or all of the note, warrant or the ADSs owned by it and, if it defaults in the performance of its secured obligations, the pledgees or secured parties may offer and sell the ADSs from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933, as amended, amending, if necessary, the list of selling security holders to include the pledgee, transferee or other successors in interest as selling security holder under this prospectus. The selling security holder also may transfer and donate the ADSs in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling security holder and any broker-dealer participating in the distribution of the ADSs may be deemed to be "underwriters" within the meaning of the Securities Act, and any commission paid, or any discounts or concessions allowed to, any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of the ADSs is made, a prospectus supplement, if required, will be distributed which will set forth the aggregate amount of ADSs being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the selling security holder and any discounts, commissions or concessions allowed or reallowed or paid to broker-dealers.

Under the securities laws of some states, the ADSs may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the ADSs may not be sold unless such ADSs have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that the selling security holder will sell any or all of the ADSs registered pursuant to the shelf registration statement, of which this prospectus forms a part.

The selling security holder and any other person participating in such distribution will be subject to applicable provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder, including, without limitation, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the ADSs by the selling security holder and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of the ADSs to engage in market-making activities with respect to the ADSs. All of the foregoing may affect the marketability of the ADSs and the ability of any person or entity to engage in market-making activities with respect to the ADSs.

We will pay all expenses of the registration of the ADSs pursuant to the registration rights agreement, estimated to be \$854,870 in total, including, without limitation, SEC filing fees and expenses of compliance with state securities or "blue sky" laws; provided, however, that the selling security holder will pay all underwriting discounts and selling commissions, if any. We will indemnify the selling security holder against liabilities, including some liabilities under the Securities Act, in accordance with the registration rights agreement, or the selling security holder will be entitled to contribution. We may be indemnified by the selling security holder against civil liabilities, including liabilities under the Securities Act, that may arise from any written information furnished to us by the selling security holder specifically for use in this prospectus, in accordance with the related registration rights agreements, or we may be entitled to contribution.

Once sold under the shelf registration statement, of which this prospectus forms a part, the ADSs will be freely tradable in the hands of persons other than our affiliates.

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## **DESCRIPTION OF SECURITIES**

For a full description of our ADSs and the underlying ordinary shares, please see the documents identified in the section "Incorporation by Reference." As of September 6, 2006, 397,564,507 ordinary shares were issued and outstanding.

## PRICE HISTORY OF OUR SECURITIES

Our ordinary shares were listed on the Australian Stock Exchange, referred to as ASX, in December 2000. The following tables set forth, for the periods indicated, the highest and lowest market quotations for the ordinary shares reported on the daily official list of the ASX.

## Annual High and Low Market Price for the Five Most Recent Fiscal Years on the ASX

Fiscal Year Ended	High	Low
June 30, 2006	A\$ 1.05	A\$0.485
June 30, 2005	A\$ 1.43	A\$0.535
June 30, 2004	A\$ 1.44	A\$ 0.23
June 30, 2003	A\$0.275	A\$ 0.10
June 30, 2002	A\$ 0.34	A\$ 0.09

## Quarterly High and Low Market Price for the Two Most Recent Fiscal Years and Any Subsequent Period on the ASX

Quarter Ended	High	Low
June 30, 2006	A\$ 0.75	A\$0.485
March 31, 2006	A\$0.785	A\$0.575
December 31, 2005	A\$ 0.94	A\$ 0.55
September 30, 2005	A\$ 1.05	A\$ 0.75
June 30, 2005	A\$0.945	A\$ 0.50
March 31, 2005	A\$ 1.27	A\$ 0.81
December 31, 2004	A\$ 1.43	A\$ 1.02
September 30, 2004	A\$ 1.16	A\$ 0.90

## Monthly High and Low Market Price for the Most Recent Six Months on the ASX

Month Ended	High	Low
August 31, 2006	A\$ 0.38	A\$ 0.26
July 31, 2006	A\$ 0.57	A\$ 0.32
June 30, 2006	A\$ 0.62	A\$0.485
May 31, 2006	A\$0.645	A\$ 0.53
April 30, 2006	A\$ 0.75	A\$ 0.63
March 31, 2006	A\$0.785	A\$ 0.63

Our ADSs were listed on the NASDAQ Global Market in January 2005. The following tables set forth, for the periods indicated, the highest and lowest market quotations for the ADSs reported on the daily official list of the NASDAQ Global Market.

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#### Annual High and Low Market Price for the Two Most Recent Fiscal Years on the NASDAQ Global Market

Fiscal Year Ended	High	Low
June 30, 2006	US\$ 8.75	US\$3.79
June 30, 2005	US\$12.14	US\$4.15

#### Quarterly High and Low Market Price for the Two Most Recent Fiscal Years and Any Subsequent Period on the NASDAQ Global Market

Quarter Ended	High	Low
June 30, 2006	US\$ 5.32	US\$3.79
March 31, 2006	US\$ 5.70	US\$4.40
December 31, 2005	US\$ 7.00	US\$4.21
September 30, 2005	US\$ 8.75	US\$5.60
June 30, 2005	US\$ 8.00	US\$4.15
March 31, 2005	US\$12.14	US\$6.30

#### Monthly High and Low Market Price for the Most Recent Six Months on the NASDAQ Global Market

Month Ended	High	Low
August 31, 2006	US\$3.14	US\$2.06
July 31, 2006	US\$4.64	US\$2.40
June 30, 2006	US\$4.95	US\$3.79
May 31, 2006	US\$5.27	US\$4.10
April 30, 2006	US\$5.32	US\$4.90
March 31, 2006	US\$5.61	US\$4.65

#### LEGAL MATTERS

The validity of the ordinary shares will be passed upon by Blake Dawson Waldron, Level 32, Exchange Plaza, 2 The Esplanade, Perth, WA 6000, Australia, our Australian counsel.

## EXPERTS

The consolidated financial statements incorporated in this prospectus by reference from our Annual Report on Form 20-F for the year ended June 30, 2005 have been audited by Deloitte Touche Tohmatsu, an independent registered public accounting firm, as stated in their report, which is incorporated herein by reference, and have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

The audited historical financial statements of CDS for the three year period ended December 31, 2004, included in pSivida Limited's Form 6-K furnished to the SEC on December 22, 2005 have been so incorporated in reliance upon the report of PricewaterhouseCoopers LLP, independent accountants, given upon the authority of said firm as experts in auditing and accounting.

#### ENFORCEABILITY OF CIVIL LIABILITIES

We are a public company limited by shares incorporated under the laws of Western Australia. Most of our directors and executive officers and current employees named in this Registration Statement reside outside the United States, and the assets of those non-resident directors and most of our assets are located outside the United States. It may be difficult for investors to effect service of process upon these directors and executive officers. In addition, there may be difficulties in certain circumstances in using the courts of Australia to enforce judgments obtained in United States courts in actions against us or our directors, including judgments based on the civil liability provisions of the federal securities laws of the United States.

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#### EXPENSES

We will pay all expenses in connection with the registration and sale of the ADSs by the selling security holder. The estimated expenses of issuance and distribution are set forth below.

SEC Registration Fees	\$ 5,384
Transfer Agent Fees	\$ 509,486
Legal Fees and Expenses	\$ 85,000
Accounting Fees	\$ 250,000
Miscellaneous (including EDGAR filing costs)	\$ 5,000
Total	\$ 854,870

#### WHERE YOU CAN FIND ADDITIONAL INFORMATION

As required by the Securities Act, we have filed with the SEC a registration statement on Form F-3, of which this prospectus is a part, with respect to the ADSs offered hereby. This prospectus does not contain all of the information included in the registration statement. Statements in this prospectus concerning the provisions of any document are not necessarily complete. You should refer to the copies of the documents filed as exhibits to the registration statement or otherwise filed by us with the SEC for a more complete understanding of the matter involved. Each statement concerning these documents is qualified in its entirety by such reference.

We are subject to the information reporting requirements of the Securities and Exchange Act of 1934, as amended, applicable to foreign private issuers and we comply with those requirements by submitting reports to the SEC. Those reports or other information may be inspected without charge at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. Our SEC filings and submissions also are available to the public on the SEC's website at www.sec.gov. As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file quarterly and current reports with the SEC, unlike United States companies whose securities are registered under the Exchange Act. However, we are required to file with the SEC, within six months after the end of each fiscal year, an annual report on Form 20-F containing financial statements audited by an independent registered public accounting firm.

## **INCORPORATION BY REFERENCE**

The SEC allows us to "incorporate by reference" in this prospectus the information that we file with them. This means that we can disclose important information to you in this document by referring you to other filings we have made with the SEC. The information incorporated by reference is considered to be part of this prospectus, and later information we file with the SEC will update and supersede this information. We incorporate by reference the documents listed below:

- Our Annual Report on Form 20-F for the fiscal year ended June 30, 2005, filed with the SEC on January 18, 2006;
- Our report on Form 6-K furnished to the SEC on November 15, 2005;
- The audited historical financial statements of CDS as of December 31, 2004 and 2003 and for each of the three years in the period December 31, 2004, included in our report on Form 6-K furnished to the SEC on December 22, 2005;
- Our report on Form 6-K furnished to the SEC on January 31, 2006;
- Our report on Form 6-K furnished to the SEC on February 22, 2006;

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- Our two reports on Form 6-K furnished to the SEC on February 23, 2006;
- Our report on Form 6-K furnished to the SEC on March 2, 2006;
- Our report on Form 6-K furnished to the SEC on April 28, 2006;
- Our report on Form 6-K furnished to the SEC on May 2, 2006;
- Our report on Form 6-K furnished to the SEC on May 23, 2006;
- Our report on Form 6-K furnished to the SEC on May 25, 2006;
- Our report on Form 6-K furnished to the SEC on May 31, 2006;
- Our report on Form 6-K furnished to the SEC on June 13, 2006;
- Our later report on Form 6-K furnished to the SEC on June 14, 2006;
- Our earlier report on Form 6-K furnished to the SEC on July 31, 2006;
- Our amended report on Form 6-K furnished to the SEC on August 14, 2006;
- Our two reports on Form 6-K furnished to the SEC on August 28, 2006;
- Our Appendix 4E Preliminary Final Report for the year ended June 30, 2006 included as Exhibit 99.2 to Form 6-K furnished to the SEC on September 14, 2006 ;
- Our report on Form 6-K furnished to the SEC on September 19, 2006;
- Our report on Form 6-K furnished to the SEC on September 26, 2006; and
- The description of our securities contained in our Registration Statement on Form 20-F, filed with the SEC on January 20, 2005 and any amendment or report filed for the purpose of updating that description.

In addition, all subsequent annual reports filed on Form 20-F prior to the termination of this offering are incorporated by reference into this prospectus. Also, we may incorporate by reference our future reports on Form 6-K by stating in those Forms that they are being incorporated by reference into this prospectus.

This prospectus may contain information that updates, modifies or is contrary to information in one or more of the documents incorporated by reference in this prospectus. Reports we file with the SEC after the date of this prospectus may also contain information that updates, modifies or is contrary to information in this prospectus or in documents incorporated by reference in this prospectus. Investors should review these reports as they may disclose a change in our business, prospects, financial condition or other affairs after the date of this prospectus.

Upon your written or oral request, we will provide at no cost to you a copy of any and all of the information that is incorporated by reference in this prospectus.

Requests for such documents should be directed to:

Lori Freedman, Esq. Vice President, Corporate Affairs, General Counsel and Secretary pSivida Limited 400 Pleasant Street Watertown, MA 02472 Telephone: (617) 926-5000

You may also access the documents incorporated by reference in this prospectus through our website www.psivida.com. Except for the specific incorporated documents listed above, no information available on or through our website shall be deemed to be incorporated in this prospectus or the registration statement of which it forms a part.



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# CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

(in Australian dollars) (Unaudited)

		Six months ended December 31,		
	2005 As restated (Refer Note 11)	2004		
Revenue	\$ 296,921	<b>\$</b> 398,501		
Research and development	(9,016,979)	(6,498,640)		
Selling, general and administrative	(4,369,570)	(2,008,050)		
Interest and finance expenses	(287,613)	(3,406)		
Foreign exchange gain / (loss)	306,841	(1,487,066)		
Loss before income tax	(13,070,400)	(9,598,661)		
Income tax benefit	2,367,655	1,869,300		
Loss for the period	(10,702,745)	(7,729,361)		
Loss attributable to minority interest	_	399,196		
Loss attributable to members of the parent entity	(10,702,745)	(7,330,165)		
Loss per share:				
Basic and diluted	(0.05)	(0.04)		
	× ,			

Notes to the financial statements are included on pages F-6 to F-45.

## CONDENSED CONSOLIDATED BALANCE SHEET (in Australian dollars) (Unaudited)

		As of	
		December 31, 2005 As restated (Refer Note 11)	June 30, 2005
Current assets	Notes	\$	\$
Cash and cash equivalents	7	27,683,278	12,892,061
Trade and other receivables, net	,	1,238,335	709,418
Other		514,988	322,933
Total current assets		29,436,601	13,924,412
Non-current assets			
Property, plant and equipment, net	2	3,854,981	3,273,663
Goodwill		52,366,787	23,305,698
Other intangible assets, net	3	170,455,945	51,362,329
Total non-current assets		226,677,713	77,941,690
Total assets		256,114,314	91,866,102
Current liabilities			
Trade and other payables		9,157,003	2,017,820
Deferred revenue		1,821,445	_
Borrowings	7	6,848,377	_
Conversion option derivative	7	6,163,539	—
Provisions		735,929	29,879
Total current liabilities		24,726,293	2,047,699
Non-current liabilities			
Borrowings		5,279,996	
Deferred tax liability		36,877,803	10,122,656
Total non-current liabilities		42,157,799	10,122,656
Total liabilities		66,884,092	12,170,355
Net assets		189,230,222	79,695,747
Equity			
Issued capital	13(b)	224,897,860	107,883,835
Reserves	(-)	3,797,322	574,127
Deficit accumulated prior to development stage		(3,813,181)	(3,813,181)
Deficit accumulated during development stage	13(b)	(35,651,779)	(24,949,034)
Total equity		189,230,222	79,695,747

Notes to the financial statements are included on pages F-6 to F-45.

## CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY (in Australian dollars) (Unaudited)

	Issued capital \$	Foreign currency translation reserve S	Option premium reserve \$	Employee equity- settled benefits reserve \$	Accumulated deficit S	Minority interest \$	Total \$
Balance at July 1,	Ŷ	Ŷ	Ŷ	Ŷ	Ŷ	Ŷ	Ŷ
2005	107,883,835	(350,287)	292,828	631,586	(28,762,215)	—	79,695,747
Loss attributable to members of the parent entity Foreign currency	_	_	_	_	(10,702,745)	_	(10,702,745)
translation							
adjustment		(40,456)					(40,456)
Total recognized income and expense	_	(40,456)	_	_	(10,702,745)	_	(10,743,201)
Shares issued, net of							
issue costs	117,014,025	—	—	—	—	—	117,014,025
Warrants attached to convertible loan			1 710 021				1 710 021
note Share options and			1,719,831	_			1,719,831
warrants issued			758,837	784,983			1,543,820
Balance at December 31, 2005	224,897,860	(390,743)	2,771,496	1,416,569	(39,464,960)		189,230,222
Balance at July 1, 2004	49,957,982	_	_	39,689	(11,968,378)	1,583,200	39,612,493
Loss attributable to members of the parent entity	_	_	_	_	(7,330,165)	_	(7,330,165)
Foreign currency translation adjustment	_	(127,278)	_	_	_	79,361	(47,917)
Minority interest share of loss	_	_	_		_	(399,196)	(399,196)
Total recognized income and expense	_	(127,278)			(7,330,165)	(319,835)	(7,777,278)
Shares issued, net of issue costs	57,925,853		_	_			57,925,853
Share options issued			587,454	35.967	_		623,421
Reversal of minority interest	_	_			_	(1,263,365)	(1,263,365)
Balance at December 31, 2004	107,883,835	(127,278)	587,454	75,656	(19,298,543)		89,121,124
01,2004	107,000,000	(12/,2/0)		/ 3,030	(10,200,040)		00,121,127

Notes to the financial statements are included on pages F-6 to F-45.

# CONDENSED CONSOLIDATED CASH FLOW STATEMENT

(in Australian dollars) (Unaudited)

	Six months ended December 31,	
	2005 \$	2004 \$
Cash flows from operating activities	Ŷ	Ŷ
Payments to suppliers, employees and consultants	(4,256,428)	(1,999,802)
Research and development expenditure	(5,218,473)	(3,734,578)
Interest received	246,189	384,622
Other income	42,283	13,880
Income received in advance	493,702	—
Net cash used in operating activities	(8,692,727)	(5,335,878)
Cash flows from investing activities		
Purchase of property, plant and equipment	(843,746)	(1,459,773)
Proceeds on sale of property, plant and equipment	21,376	—
Net cash paid for increased interest in subsidiary	—	(4,644,966)
Net cash paid for acquisitions of businesses	(1,086,076)	—
Net cash used in investing activities	(1,908,446)	(6,104,739)
Cash flows from financing activities		
Proceeds from issue of ordinary shares	5,636,102	3,666,500
Payment of share issue costs	(468,873)	(27,422)
Proceeds from convertible loan note	20,500,500	—
Costs of convertible loan note financing	(607,196)	_
Net cash provided by financing activities	25,060,533	3,639,078
Net increase / (decrease) in cash and cash equivalents	14,459,360	(7,801,539)
Cash and cash equivalents at the beginning of the period	12,892,061	31,350,656
Effects of exchange rate changes on the balance of cash and cash equivalents held in foreign currencies	331,857	(1,548,515)
Cash and cash equivalents at the end of the period	27,683,278	22,000,602

Notes to the financial statements are included on pages F-6 to F-45.

#### NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

#### 1. Background and summary of accounting policies

#### Background

pSivida Limited, or pSivida, together with its subsidiaries, referred to as the "Company", is incorporated in Perth, Australia and is committed to biomedical applications of nano-technology and has as its core focus the development and commercialization of a modified form of the silicon chip (porosified or nano-structured silicon) known as BioSilicon<sup>™</sup>. BioSilicon<sup>™</sup> offers multiple potential applications across the high growth healthcare sector, including controlled slow release drug delivery, brachytherapy, tissue engineering and orthopedics and the Company is currently in the development stage of assessing these potential applications.

On May 18, 2001, the Company re-listed on the Australian Stock Exchange (ASX Code: PSD). pSivida's shares are also listed in Germany on the Frankfurt Stock Exchange on the XETRA system (German Symbol: PSI. Securities Code (WKN) 358705), in the United Kingdom on the OFEX International Market Service (IMS) under the ticker symbol PSD and on the NASDAQ Global Market under the ticker symbol PSDV.

### **Basis of preparation**

The half-year financial report is a general purpose financial report prepared in accordance with the Corporations Act 2001, Australian Accounting Standards Board ("AASB") 134 "Interim Financial Reporting" ("AASB 134"). Compliance with AASB 134 ensures compliance with International Accounting Standard 34: "Interim Financial Reporting." Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with the annual financial report shall be read in conjunction with the annual financial report for the year ended June 30, 2005 and any public announcements made by the Company during the half-year in accordance with continuous disclosure requirements arising under the Corporations Act 2001.

In the opinion of the Company's management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the six months ended December 31, 2005 are not necessarily indicative of the results that may be expected for the year ending June 30, 2006.

The financial report has been prepared on the basis of historical cost, except for derivative financial instruments, which are measured at fair value. Cost is based on the fair values of the consideration given in exchange for goods and services.

The Company will adopt Australian equivalents to International Financial Reporting Standards ("A-IFRS") for the first time in its financial statements for the year ending June 30, 2006, which will include comparative financial statements for the year ended June 30, 2005. Compliance with A-IFRS ensures compliance with International Financial Reporting Standards. AASB 1 "First-time Adoption of Australian Equivalents to International Financial Reporting Standards" ("AASB 1") requires that an entity develop accounting policies based on the standards and related interpretations effective at the reporting date of its first annual A-IFRS financial statements (e.g., June 30, 2006). AASB 1 also requires that those policies be applied as of the date of transition to A-IFRS (e.g., July 1, 2004) and throughout all periods presented in the first A-IFRS financial statements. The accompanying interim financial information as of December 31, 2005 and June 30, 2005 and for the six month periods ended December 31, 2005 and 2004, have been prepared in accordance with those AASB standards and Urgent Issues Group ("UIG") interpretations issued and effective, or issued and early-adopted, at June 29, 2006. The accounting policies used to prepare the Company's first annual A-IFRS financial statements are subject to change up to the reporting date. An explanation of how the transition from superseded policies to A-IFRS has affected the Company's financial position, financial performance and cash flows is discussed in Note 9.

## NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

In the application of A-IFRS management is required to make judgments, estimates and assumptions about carrying values of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and various other factors that are believed to be reasonable under the circumstance, the results of which form the basis of making the judgments. Actual results may differ from these estimates. The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

The accounting policies set out below have been applied in preparing the financial statements for the half-year ended December 31, 2005, the comparative information presented in these financial statements, and in the preparation of the opening A-IFRS balance sheet at July 1, 2004 (as disclosed in Note 9), the Company's date of transition.

The Company has not restated comparative information for financial instruments, as permitted under the first-time adoption transitional provisions. The accounting policies for financial instruments applicable to the comparative information are consistent with those adopted and disclosed in the 2005 annual financial report. The impact of changes in these accounting policies on July 1, 2005, the date of transition for financial instruments, is discussed further in Note 1(s).

#### Reclassification

The directors have reconsidered the classification of expenses in the condensed consolidated statements of operations and have determined that the function of expense method provides the most relevant and reliable presentation. Accordingly, the expenses have been reclassified by function.

#### Significant accounting policies

The following significant accounting policies have been adopted in the preparation and presentation of the half-year financial report:

#### (a) Principles of consolidation

The consolidated financial statements are prepared by consolidating the financial statements of all the entities that comprise the consolidated entity, being the parent entity and its subsidiaries as defined in Accounting Standard AASB 127 "Consolidated and Separate Financial Statements". Consistent accounting policies are employed in the preparation and presentation of the consolidated financial statements.

On acquisition and step acquisition (including increases in interests in controlled entities), the assets, liabilities and contingent liabilities of a subsidiary are measured at their fair values at the date of acquisition. Any excess of the cost of acquisition over the fair values of the identifiable net assets acquired is recognized as goodwill. If, after reassessment, the fair value of the identifiable net assets acquired exceeds the cost of acquisition, the deficiency is credited to profit and loss in the period of acquisition.

The interest of minority shareholders is stated at the minority's proportion of the fair values of the assets and liabilities recognized.

The consolidated financial statements include information and results of each subsidiary from the date on which the company obtains control and until such time as the Company ceases to control such entity.

In preparing the consolidated financial statements, all intercompany balances and transactions, and unrealized profits arising within the consolidated entity are eliminated in full.

#### NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

#### (b) Foreign currency

Functional and presentation currency

The functional currency of each of the subsidiaries is measured using the currency of the primary economic environment in which that entity operates.

The parent entity, pSivida Limited, changed its functional currency from Australian dollars to United States dollars following the acquisition of pSivida Inc (formerly Control Delivery Systems Inc) effective January 1, 2006 as it was determined that the United States was the primary economic environment in which the parent entity operates as of that date.

Unless otherwise noted, the consolidated financial statements are presented in Australian dollars which is the parent entity's presentation currency.

#### Foreign currency transactions

All foreign currency transactions during the financial period are brought to account using the exchange rate in effect at the date of the transaction. Foreign currency monetary items at reporting date are translated at the exchange rate existing at reporting date.

Exchange differences are recognized in profit and loss in the period in which they arise.

#### Foreign operations

On consolidation, the assets and liabilities of the Company's overseas operations are translated at exchange rates prevailing at the reporting date. Income and expense items are translated at the average exchange rates for the period unless exchange rates fluctuate significantly. Exchange differences arising, if any, are recognized in the foreign currency translation reserve, and recognized in profit or loss on disposal of the foreign operation.

Goodwill and fair value adjustments arising on the acquisition of a foreign entity are treated as assets and liabilities of the foreign entity and translated at exchange rates prevailing at the reporting date.

#### (c) Cash and cash equivalents

Cash and cash equivalents comprise cash on hand, cash in banks and investments in money market instruments with original maturity of three months or less, net of outstanding bank overdrafts. Bank overdrafts are shown within borrowings in current liabilities in the balance sheet.

#### (d) Financial assets

#### Receivables

Trade and other receivables are recorded at amortized cost less impairment.

## (e) Property, plant and equipment

Plant and equipment and leasehold improvements are stated at cost less accumulated depreciation and impairment. Cost includes expenditure that is directly attributable to the acquisition of the item. In the event that settlement of all or part of the purchase consideration is deferred, cost is determined by discounting the amounts payable in the future to their present value as at the date of acquisition.

## NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

Depreciation is provided on property, plant and equipment, including freehold buildings but excluding land. Depreciation is calculated on a straight line basis so as to write off the net cost of each asset over its expected useful life to its estimated residual value. Leasehold improvements are depreciated over the period of the lease or estimated useful life, whichever is the shorter, using the straight line method. The estimated useful lives, residual values and depreciation method are reviewed at the end of each annual reporting period.

The following estimated useful lives are used in the calculation of depreciation:

Leasehold improvements Plant and equipment

(f) Goodwill

Goodwill, representing the excess of the cost of acquisition over the fair value of the identifiable assets, liabilities and contingent liabilities acquired, is recognized as an asset and not amortized, but tested for impairment annually and whenever there is an indication that the goodwill may be impaired. Any impairment is recognized immediately in profit and loss and is not subsequently reversed. Refer also Note 1(0).

Lease term 3 years

### (g) Intangible assets

Intangible assets acquired in a business combination

All potential intangible assets acquired in a business combination are identified and recognized separately from goodwill where they satisfy the definition of an intangible asset and their fair value can be measured reliably.

## Patents and intellectual property

Acquired patents and intellectual property are recorded at cost less accumulated amortization and impairment. Amortization is calculated on a straight line basis so as to write off the cost of the asset over its estimated useful life of 12 years, commencing on the date the asset is available for use. The expected useful life is reviewed at the end of each annual reporting period.

#### In-process research and development

In-process research and development ("IPR&D") projects acquired in a business combination are recorded at cost, subject to any impairment writedowns. Amortization is charged over the estimated useful life once a project included in IPR&D has been successfully developed and is available for use.

## Research and development costs

Expenditure on research activities is recognized as an expense in the period in which it is incurred. Where no internally-generated intangible asset can be recognized, development expenditure is recognized as an expense in the period as incurred.

An intangible asset arising from development (or from the development phase of an internal project) is recognized if, and only if, all of the following are demonstrated:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;
- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

# NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars)

(Unaudited)

To date, no development costs have been capitalized.

## (h) Payables

Trade payables and other accounts payable are recognized when the Company becomes obliged to make future payments resulting from the purchase of goods and services.

#### (i) Borrowings

Borrowings are recorded initially at fair value, net of transaction costs.

Subsequent to initial recognition, borrowings are measured at amortized cost with any difference between the initial recognized amount and the redemption value being recognized in profit and loss over the period of the borrowing.

## (j) Financial instruments issued by the Company

Debt and equity instruments

Debt and equity instruments are classified as either liabilities or as equity in accordance with the substance of the contractual arrangement.

#### Compound instruments

The component parts of compound instruments, such as convertible debt with detachable warrants, are classified separately as liabilities and equity in accordance with the substance of the contractual arrangement. At the date of issue, the fair value of the liability component is estimated using the prevailing market interest rate for a similar non-convertible debt. The equity component initially brought to account is determined by deducting the amount of the liability component from the amount of the compound instrument as a whole.

The Company reviews the terms of compound instruments to determine whether there are embedded derivatives, such as a holder's conversion option, that may be required to be bifurcated and accounted for separately as a derivative financial instrument. Bifurcated embedded derivatives are recorded at fair value on the balance sheet and classified as an asset or liability, as appropriate. After initial recognition, subsequent changes in the fair value of the embedded derivative are charged or credited to the statement of operations in the period.

The stated interest on the instrument is amortized through periodic charges to income using the effective interest method over the expected life of the instrument.

#### Transaction costs on the issue of equity instruments

Transaction costs arising on the issue of equity instruments are recognized directly in equity as a reduction of the proceeds of the equity instruments to which the costs relate. Transaction costs are the costs that are incurred directly in connection with the issue of those equity instruments and which would not have been incurred had those instruments not been issued.

## Transaction costs and discount on the issue of debt instruments

Transaction costs relating to the issuance of debt and the discount from the face amount of the debt are set off against the debt liability and amortized using the effective interest method over the expected life of the instrument.

## NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

Transaction costs and discount on the convertible note entered into on November 15, 2006 amounted to \$8,460,498, of which \$81,888 was amortized as of December 31, 2005.

## Interest and dividends

Interest and dividends are classified as expenses or as distributions of profit consistent with the balance sheet classification of the related debt or equity instruments or component parts of compound instruments.

#### (k) Provisions

Provisions are recognized when the Company has a present obligation, the future sacrifice of economic benefits is probable, and the amount of the provision can be measured reliably.

The amount recognized as a provision is the best estimate of the consideration required to settle the present obligation at reporting date, taking into account the risks and uncertainties surrounding the obligation. Where a provision is measured using the cash flows estimated to settle the present obligation, its carrying amount is the present value of those cash flows.

#### (l) Revenue recognition

The Company recognizes revenue by reference to the stage of completion of a transaction involving the rendering of services at the reporting date when all the following conditions are satisfied:

- (a) the amount of revenue can be estimated reliably;
- (b) it is probable that the economic benefits associated with the transaction will flow to the entity;
- (c) the stage of completion of the transaction at the reporting date can be measured reliably; and
- (d) the costs incurred for the transaction and the costs to complete the transaction can be measured reliably.

Amounts received in advance of satisfying the revenue recognition criteria are classified as deferred revenue and recognized when the revenue is earned.

In addition to the aforementioned general policy, the following are the specific revenue recognition policies for each major category of revenue:

#### **Royalties**

Royalty revenue is generally recognized on an accrual basis in accordance with the substance of the relevant agreement. Non-refundable royalties received in advance for which the Company has no obligation to perform future services are recognized when received.

#### Collaborative research and development

Collaborative research and development revenue comprises amounts received for research and development activities under the Company's collaboration agreements. For contracts with specifically defined milestones, revenues from milestone payments related to agreements under which the Company has no continuing performance obligations are recognized upon achievement of the related milestone which represents the culmination of the earnings process. Revenues from milestone payments related to research collaboration agreements under which the Company has continuing performance obligations are recognized as revenue upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; substantive effort is involved in achieving the milestone; and the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue when the collaborating party confirms that the performance obligations have been met.



### NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars)

## (Unaudited)

#### Interest

Interest revenue is recognized on a time proportionate basis that takes into account the effective yield on the financial asset.

## (m) Employee benefits

Provision is made for benefits accruing to employees in respect of wages and salaries, annual leave, long service leave and sick leave when it is probable that settlement will be required and they are capable of being measured reliably.

Provisions made in respect of employee benefits expected to be settled within 12 months, are measured at their nominal values using the remuneration rate expected to apply at the time of settlement.

Provisions made in respect of employee benefits which are not expected to be settled within 12 months are measured as the present value of the estimated future cash outflows to be made by the Company in respect of services provided by employees up to reporting date.

Contributions to defined contribution superannuation plans are expensed when incurred.

#### (n) Goods and services tax

Revenues, expenses and assets are recognized net of the amount of goods and services tax (GST), except:

- where the amount of GST incurred is not recoverable from the taxation authority, it is recognized as part of the cost of acquisition of an asset or as part of an item of expense; or
- for receivables and payables which are recognized inclusive of GST.

The net amount of GST recoverable from, or payable to, the taxation authority is included as part of receivables or payables.

Cash flows are included in the statement of cash flows on a gross basis. The GST component of cash flows arising from investing and financing activities which is recoverable from, or payable to, the taxation authority is classified as operating cash flows.

### (o) Impairment of assets

At each reporting date, the Company reviews the carrying amounts of its tangible and intangible assets to determine whether there is any indication that those assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss (if any). Where the asset does not generate cash flows that are independent from other assets, the Company estimates the recoverable amount of the cash-generating unit to which the asset belongs.

Goodwill and in-process research and development are tested for impairment annually and whenever there is an indication that the asset may be impaired. An impairment of goodwill is not subsequently reversed.

Recoverable amount is the higher of fair value less costs to sell and value in use. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset for which the estimates of future cash flows have not been adjusted.

If the recoverable amount of an asset (or cash-generating unit) is estimated to be less than its carrying amount, the carrying amount of the asset (cash-generating unit) is reduced to its recoverable amount. An impairment loss is recognized in profit or loss immediately.

## NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

Where an impairment loss subsequently reverses, the carrying amount of the asset (cash-generating unit) is increased to the revised estimate of its recoverable amount, but only to the extent that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognized for the asset (cash-generating unit) in prior years. A reversal of an impairment loss (other than goodwill impairment) is recognized in profit and loss immediately.

#### (p) Income tax

#### Current tax

Current tax is calculated by reference to the amount of income taxes payable or recoverable in respect of the taxable profit or tax loss for the period. It is calculated using tax rates and tax laws that have been enacted or substantively enacted by reporting date. Current tax for current and prior periods is recognized as a liability (or asset) to the extent that it is unpaid (or refundable).

#### Deferred tax

Deferred tax is accounted for using the comprehensive balance sheet liability method in respect of temporary differences arising from differences between the carrying amount of assets and liabilities in the financial statements and the corresponding tax base of those items.

In principle, deferred tax liabilities are recognized for all taxable temporary differences. Deferred tax assets are recognized to the extent that it is probable that sufficient taxable amounts will be available against which deductible temporary differences or unused tax losses and tax offsets can be utilized. However, deferred tax assets and liabilities are not recognized if the temporary differences giving rise to them arise from the initial recognition of assets and liabilities (other than as a result of a business combination) which affects neither taxable income nor accounting profit. Furthermore, a deferred tax liability is not recognized in relation to taxable temporary differences arising from goodwill.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period(s) when the asset and liability giving rise to them are realized or settled, based on tax rates (and tax laws) that have been enacted or substantively enacted by reporting date. The measurement of deferred tax liabilities and assets reflects the tax consequences that would follow from the manner in which the Company expects, at the reporting date, to recover or settle the carrying amount of its assets and liabilities.

Deferred tax assets relating to carry forward tax losses are recognized where it is probable that taxable profit will be available against which the carry forward tax losses can be utilized.

Deferred tax assets and liabilities are offset when they relate to income taxes levied by the same taxation authority and the Company intends to settle its current tax assets and liabilities on a net basis.

## Current and deferred tax for the period

Current and deferred tax is recognized as an expense or as income in the statement of operations, except when it relates to items credited or debited directly to equity, in which case the deferred tax is also recognized directly in equity, or where it arises from the initial accounting for a business combination, in which case it is taken into account in the determination of goodwill.

## (q) Leased assets

Leases are classified as finance leases whenever the terms of the lease transfer substantially all the risks and rewards of ownership to the lessee. All other leases are classified as operating leases.

Operating lease payments are recognized as an expense on a straight line basis over the lease term.

## NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

## (r) Share-based payments

Equity-settled share-based payments granted after November 7, 2002 that were unvested as of January 1, 2005 are measured at fair value at the date of grant (or the measurement date in the case of share-based payments granted to non-employees). Fair value is measured by use of the Black-Scholes option pricing model in most instances. Where conditions of the options make use of the Black-Scholes method inappropriate, such as where employee options have long lives, and are exercisable during the period between vesting date and the end of the option's life and the exercise date cannot be reliably estimated, the entity will use another more appropriate option valuation method, such as the Binomial method. The expected life used in the Binomial model is adjusted, based on management's best estimate, for the effects of exercise restrictions and behavioral considerations.

The fair value of the equity-settled share-based payments is expensed over the vesting period, based on the Company's estimate of shares that will eventually vest.

## (s) Comparative information — financial instruments

The Company has elected not to restate comparative information for financial instruments within the scope of AASB 132 "Financial Instruments: Disclosure and Presentation" ("AASB 132") and AASB 139 "Financial Instruments: Recognition and Measurement" ("AASB 139"), as permitted on the first-time adoption of A-IFRS. The Company's review indicates that the changes in the accounting policies for financial instruments has a nil effect on the balance sheet as at July 1, 2005.

## 2. Property, plant and equipment

	As of	As of	
	December 31, 2005 \$	June 30, 2005 \$	
At cost	5,838,668	4,423,767	
Accumulated depreciation	(1,983,687)	(1,150,104)	
	3,854,981	3,273,663	

## 3. Other intangible assets

	As of	As of	
	December 31, 2005 \$	June 30, 2005 \$	
At cost	182,173,592	59,761,840	
Accumulated amortization	(11,717,647)	(8,399,511)	
	170,455,945	51,362,329	

## 4. Segment information

## **Business segment** — primary segment

The Company operates in only one business segment, being the biotechnology sector.

#### NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

#### 5. Subsequent events

On January 11, 2006 Ms. Heather Zampatti was appointed as a Non-executive Director of the Company. The appointment of Ms. Zampatti to the pSivida board replaced Ms. Alison Ledger who stepped down after 18 months of service.

The Company announced a one for eight rights issue ("Rights Issue") on May 2, 2006 at an issue price of \$0.60 per share. The issue price represented an approximately 18% discount to the 30 day volume weighted average closing price ("VWAP") on the ASX up to May 1, 2006, being the last trading day and a 7% discount to the five day VWAP. The Company concluded the rights issue on June 13, 2006, raising a total of \$6.3 million through the issue of 10,515,811 shares.

Capital raised from the placement of the shortfall will primarily fund the phase III clinical trials of Medidur<sup>TM</sup> for the treatment of Diabetic Macular Edema (DME), and phase IIa clinical trials of our lead BioSilicon<sup>TM</sup> product, BrachySil<sup>TM</sup> which is being developed for the treatment of inoperable pancreatic cancer. pSivida expects to receive a significantly greater return by funding the Medidur<sup>TM</sup> trials under the Co-Development Agreement to receive a profit share with Alimera Sciences rather than a straight royalty which would be payable if we did not co-fund the trials.

On May 23, 2006 the Company announced that Mr. Michael Soja has been appointed Vice President, Finance and Chief Financial Officer, and Ms. Lori Freedman has been appointed Vice President, Corporate Affairs, General Counsel and Secretary. Both Mr. Soja and Ms. Freedman are based at pSivida's Boston facility in the United States.

On July 31, 2006, the Company announced that Gavin Rezos had resigned for personal and family reasons as Managing Director and Chief Executive Officer of pSivida and its subsidiaries. Mr. Rezos has agreed to make himself available in Australia as the Company may request his assistance to achieve certain goals pending the appointment of a permanent replacement.

On August 28, 2006, the Company announced that Heather Zampatti resigned as a director of the Company.

On September 14, 2006, the Company revised the terms of the subordinated convertible promissory note that the Company issued on November 16, 2005 to an institutional investor. The note continues to have a three year term and bear 8% interest payable quarterly. The Company may make future interest payments in the form of its NASDAQ-listed ADSs, or, at its sole option, the Company may make such payments in cash. The note is now convertible into ADSs at a conversion price of US\$2.00 per ADS, subject to adjustment based upon certain events or circumstances, including, without limitation, if 108% of the market price of ADSs for the ten trading days ending April 30, 2007 is lower than the current conversion price. In connection with the amendments, the Company prepaid US\$2.5 million of the outstanding principal note by means of a US\$3.5 million payment. The investor retains its existing warrants to purchase 633,803 additional ADSs, exercisable for six years at a current exercise price of US\$7.17 per ADS. In connection with the amendments, the Company has agreed with the institutional investor to extend the deadline for the registration statement required by the registration rights agreement with the selling security holder to be declared effective by the SEC through October 15, 2006, with increased penalties if that deadline is missed. The Company has also been released from the restrictions on future fundraising transactions contained in the note documentation. The Company also granted the investor an additional warrant to purchase 5.7 million ADSs exercisable for five years with an exercise price of US\$1.80 per ADS and a security interest in our current royalties, subject to release of that security upon any disposition by us of the royalty stream.

## 6. Acquisition

On October 3, 2005, the Company entered into a merger agreement with Control Delivery Systems Inc ("CDS"), a Boston-based company engaged in the design and development of drug delivery products. The agreement provided that a newly-formed subsidiary of pSivida would merge into CDS, with CDS surviving as a wholly-owned subsidiary of pSivida with the name of pSivida Inc. The acquisition was consummated on December 30, 2005.

#### NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

The primary reasons for the acquisition of CDS were: CDS' commercialized products, including Vitrasert<sup>®</sup> for cytomegalovirus retinitis and the recently launched Retisert<sup>™</sup> for uveitis; diversified product portfolio; existing license and development agreements, including those with Bausch & Lomb and Alimera Sciences; and extensive patent portfolio. CDS also could provide a base for the Company near Boston, Massachusetts which is a biotechnology hub that would allow the Company's further expansion into the US market. In addition, as a result of the acquisition, the Company will receive royalty income which is expected to contribute significantly to the continued development of the expanded product portfolio. These factors contributed to the purchase price that resulted in recognition of a significant amount of goodwill as further noted below.

The purchase price of the acquisition of \$117,956,417 consists of:

- 150,820,380 ordinary fully paid shares of pSivida, represented by 15,082,038 ADSs, with an estimated fair value of \$107,082,470 (\$0.71 per share, represented by US\$5.169 per ADS);
- 9,016,230 non-vested ordinary shares of pSivida, represented by 901,623 non-vested ADSs, with an estimated fair value of \$4,824,502, net of unearned compensation of \$1,577,021;
- 1,724,460 share options in pSivida, represented by 172,446 options over ADSs, with an estimated fair value of \$685,977; and
- direct acquisition costs of \$5,249,149.

A final determination of required purchase accounting adjustments, including the allocation of the purchase price, has not yet been made. The Company believes that the current allocation of the purchase price is reasonable, but is subject to revision upon completion of an independent valuation study, which is expected to be finalized during the first quarter of the fiscal year ending June 30, 2007. In particular, the amounts allocated to intangible assets, being primarily intellectual property in the form of patents acquired and goodwill, and the related deferred tax liabilities, may be revised and may ultimately differ from those used in these consolidated financial statements, either of which could have a material impact on the financial position and results of operations of the Company. Since the filing of the A-IFRS financial statements with the Australian Stock Exchange ("ASX") and the Australian Securities and Investments Commission ("ASIC") on March 16, 2006, the Company has refined the estimate of the purchase price allocation to attribute \$2,741,706 to IPR&D. In addition to the recognition of IPR&D, this change in estimate resulted in a change to the deferred tax liability and goodwill. Additionally, since the filing of the Form F-3 registration statement with the SEC on June 29, 2006, the Company further refined the estimate to reclassify \$31,539,980 of the purchase price attributable to Medidur<sup>™</sup> for diabetic macular edema ("DME") from patents to IPR&D. Following is the revised estimate of the preliminary allocation of the purchase price as of December 30, 2005, the date of acquisition:

	Total fair value \$
Cash	228,464
Receivables	460,351
Other	282,588
Property, plant and equipment	624,035
Deferred tax asset	20,705,001

 <sup>\$114,319</sup> cash;

#### NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

	Total fair value
Patents	88,460,020
In-process research and development	34,281,686
Payables	(3,549,399)
Deferred revenue	(1,826,699)
Provisions	(621,399)
Deferred tax liability	(49,827,804)
Total	89,216,844
Purchase price	117,956,417

#### Goodwill

The Company acquired patents and filed patent applications with respect to multiple aspects of CDS' technologies, products, and processes, including but not limited to, Vitrasert<sup>®</sup>, Retisert<sup>™</sup>, Medidur<sup>™</sup>, CODRUG<sup>™</sup> and AEON<sup>™</sup>. At the date of the acquisition by the Company, CDS owned, or held exclusive rights, to 12 United States patents and 26 foreign patents. In addition, CDS owned, or held exclusive rights to, 40 patent applications pending in the United States and 163 patent applications pending in foreign countries. However, in determining the allocation of the purchase price to patents, the Company has only considered patents and patent applications that relate to CDS' Retisert<sup>™</sup> for Uveitis products that have been approved by the FDA. The Company determined the estimated fair value of the patents acquired with reference to a discounted cash flow analysis of the Retisert<sup>™</sup> for Uveitis product prepared at the time of the acquisition. The Company has determined the estimated useful life of the patents acquired to be 12 years, and considered the following attributes to be key factors:

28,739,573

- The patents are currently being commercialized in the form of the Retisert<sup>™</sup> for Uveitis product identified above.
- The patents acquired related to this products will expire from 12 to 15 years from the time of the acquisition.
- Although technological progress may cause some of the existing technology to become commercially obsolete before the expiration of the related patent life, on an overall basis the Company believes that the products developed using the capitalized intellectual property will continue to be sold over the 12 years.
- The patents do not require any material maintenance expenditure to obtain the expected future cash flows.

The Company will evaluate the patents for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

Since December 30, 2005, the date of acquisition of CDS (now pSivida Inc) for accounting purposes, a loss relating to pSivida Inc of \$3,469 has been included in the Company's loss for the half-year.

The following unaudited pro forma financial data presents the combined results of operations of the Company and CDS in accordance with A-IFRS as if the acquisition had occurred at the beginning of each period presented.

		Six months ended December 31,	
	2005 \$	2004 \$	
Revenue	972,739	4,579,755	
Loss for the period	(17,048,260)	(10,648,043)	
Basic and diluted loss per share	(0.05)	(0.03)	

## NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

The pro forma data is based on historical information and does not necessarily reflect the actual results that would have occurred, nor is it indicative of future results of operations.

## 7. Issuances of securities

During the six months ended December 31, 2005, the Company issued 665,000 ADSs (representing 6,650,000 ordinary shares in the Company) at a price of US\$6.50 (\$8.48) each, raising US\$4.3 million (\$5.6 million) before costs through a private investment in public equity ("PIPE"). The Company also issued warrants over 133,000 ADSs (representing options over 1,330,000 ordinary shares) to non-employees in connection with assisting in closing the PIPE. The fair value of the warrants was determined using the Black-Scholes model and the value was recorded as a reduction of the net proceeds received in the PIPE.

On November 16, 2005, the Company issued a subordinated convertible promissory note in the principal amount of US\$15 million (\$20.5 million) to an institutional investor. The note has a three year term to maturity from November 16, 2005 and accrues interest at a rate of 8% per annum. Interest is payable quarterly in arrears in cash and/or ADSs on the first day of each calendar quarter beginning January 1, 2006. The holder of the note could require payment of the note in equal amounts of \$5.0 million on the 12, 18 and 24 month anniversaries of the note, and could convert the note into ADSs at any time in accordance with the note agreement. As of December 31, 2005, the note was convertible into ADSs at a conversion price of US \$7.10 per ADS, subject to adjustment based on certain events or circumstances, in addition to a reset provision effective on August 5, 2006. Under the terms of the note, the Company is required to hold a net cash balance in excess of 30% of the amount of the note outstanding. Accordingly, the Company classified \$6,163,539 as restricted cash as of December 31, 2005.

On November 16, 2005, the Company recorded a discount on the US\$15 million note in the amount of US\$8,793,323 (\$11,988,170). As of December 31, 2005, the Company recorded amortization related to such discount in the amount of US\$61,601 (\$81,888), for a total net debt balance of US\$8,854,924 (\$12,128,372).

The Company also issued detachable warrants over 633,803 ADSs (representing options over 6,338,030 ordinary shares) as party of the convertible note agreement. The value of the detachable warrants was determined using the residual value method and was recorded as a separate component of equity. The embedded conversion option within the notes was bifurcated and accounted for as a derivative financial instrument that is adjusted to fair value at each reporting date with changes in fair value reported in earnings.

As the shareholders approved the issuance of the convertible note on November 15, 2005, all equity instruments to be issued on the conversion of the note, on the conversion of the warrants or any other conversion or issue of securities in any way related to the convertible note, do not require further shareholder approval and therefore there is no restriction on the Company in issuing the shares, despite the variable conversion price. On that basis, the Company is able to assert that it will have sufficient authorized and unissued shares to settle the conversion option.

On September 14, 2006, the Company closed agreements to amend the note. The terms were amended so that the holder of the note can require repayment of the note in equal amounts of US\$6.25 million on July 31, 2007 and January 31, 2008. Additionally, while the holder can convert the note into ADSs at any time in accordance with the note agreement, it is currently convertible into 6,250,000 ADSs at a conversion price of US\$2.00 per ADS, subject to adjustment based on certain events or circumstances, in addition to a reset provision effective on April 30, 2007. Subject to certain provisions, the minimum cash retention was struck from the notes.

As part of the amendment, the Company issued detachable warrants over 5,700,000 ADSs (representing over 57,000 ordinary shares) exercisable over five years and agreed to prepay \$2.5 million of the existing principal of such note prior to the end of the term. The Company also agreed to prepay \$1.0 million in related penalties.

## NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

The Company issued 3,150,000 options over ordinary shares to directors and employees of the Company under its employee share option plan during the six months ended December 31, 2005.

As discussed in Note 6, in consideration for the acquisition of CDS, the Company issued 15,082,038 ADSs to former holders of CDS stock, 901,623 non-vested ADSs to former holders of CDS non-vested stock, and 172,446 options over ADSs to former holders of CDS options.

The Company also issued 121,118 non-vested Company ADSs on December 30, 2005 in connection with employee retention agreements for which employee service subsequent to the consummation date of the acquisition is required in order for the shares to vest.

#### 8. Contingencies

A potential lender to pSivida Inc has claimed a break-up fee as a result of the royalty advance agreement between pSivida Inc and Bausch & Lomb, entered into by pSivida Inc in June 2005. An investment banker has claimed an advisory fee in connection with that agreement as well as the acquisition of pSivida Inc by pSivida Limited. The Company intends to defend against these claims. The Company has continued to provide for the claims in the financial statements as at December 31, 2005, having provided for the claims in the completion balance sheet of pSivida Inc at acquisition.

#### 9. Impacts of the adoption of A-IFRS

The Company changed its accounting policies on July 1, 2005 to comply with A-IFRS. The transition to A-IFRS is accounted for in accordance with Accounting Standard AASB 1: "First-time Adoption of Australian Equivalents to International Financial Reporting Standards", with July 1, 2004 as the date of transition, except for financial instruments, where the date of transition is July 1, 2005 (refer Note 1).

An explanation of how the transition from superseded policies to A-IFRS has affected the Company's financial position, financial performance and cash flows is set out in the following tables and the notes that accompany the tables.

## Effect of A-IFRS on the balance sheet as at July 1, 2004

	Notes	Superseded policies * \$	Consolidated effects of transition to A-IFRS \$	A-IFRS \$
Current assets				
Cash and cash equivalents		31,350,656	—	31,350,656
Trade and other receivables		340,482		340,482
Other		38,958	—	38,958
Total current assets		31,730,096	—	31,730,096
Non-current assets				
Property, plant and equipment		669,699	—	669,699
Other intangible assets	b	7,934,622	1,183,550	9,118,172
Other		32,641	—	32,641
Total non-current assets		8,636,962	1,183,550	9,820,512
Total assets		40,367,058	1,183,550	41,550,608
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## NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

		Superseded policies *	Consolidated effects of transition to A-IFRS	A-IFRS
Current liabilities	Notes	\$	\$	\$
Trade and other payables		1,938,115	—	1,938,115
Total current liabilities		1,938,115	_	1,938,115
Total liabilities		1,938,115		1,938,115
Net assets		38,428,943	1,183,550	39,612,493
Equity				
Issued capital		49,957,982	—	49,957,982
Reserves	c, d	78,220	(38,531)	39,689
Deficit accumulated prior to development stage		(3,813,181)	—	(3,813,181)
Deficit accumulated during development stage	f	(9,377,278)	1,222,081	(8,155,197)
Parent entity interest		36,845,743	1,183,550	38,029,293
Total minority interest		1,583,200	—	1,583,200
Total equity		38,428,943	1,183,550	39,612,493

\* Reported financial position as at June 30, 2004.

Effect of A-IFRS on the statement of operations for the half-year ended December 31, 2004

	Notes	Superseded policies * \$	Consolidated effects of transition to A-IFRS \$	A-IFRS \$
Revenue		398,501	—	398,501
Corporate office expenses	b, d, e	(3,905,247)	(2,403,853)	(6,309,100)
Research and development		(3,688,062)	_	(3,688,062)
Loss before income tax		(7,194,808)	(2,403,853)	(9,598,661)
Income tax benefit	a	—	1,869,300	1,869,300
Loss for the period		(7,194,808)	(534,553)	(7,729,361)
Loss attributable to minority interest		399,196		399,196
Loss attributable to members of the parent entity		(6,795,612)	(534,553)	(7,330,165)

## NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

# Effect of A-IFRS on the statement of operations for the financial year ended June 30, 2005

	Notes	Superseded policies * \$	Consolidated effects of transition to A-IFRS \$	A-IFRS \$
Revenue		828,976	—	828,976
Corporate office expenses	b, d, e	(7,666,765)	(5,688,204)	(13,354,969)
Research and development		(8,287,930)	—	(8,287,930)
Loss before income tax		(15,125,719)	(5,688,204)	(20,813,923)
Income tax benefit	а		3,620,891	3,620,891
Loss for the period		(15,125,719)	(2,067,313)	(17,193,032)
Loss attributable to minority interest		399,196		399,196
Loss attributable to members of the parent entity		(14,726,523)	(2,067,313)	(16,793,836)

\* Reported financial results under previous Australian GAAP.

Effect of A-IFRS on the balance sheet as at December 31, 2004

	Notes	Superseded policies * \$	Consolidated effects of transition to A-IFRS \$	A-IFRS \$
Current assets				
Cash and cash equivalents		22,000,602	—	22,000,602
Trade and other receivables		246,437	—	246,437
Other		93,310	_	93,310
Total current assets		22,340,349		22,340,349
Non-current assets				
Property, plant and equipment		1,756,367	_	1,756,367
Goodwill	е	9,119,459	14,186,239	23,305,698
Other intangible assets	b	56,642,559	(1,627,027)	55,015,532
Other		16,587	—	16,587
Total non-current assets		67,534,972	12,559,212	80,094,184
Total assets		89,875,321	12,559,212	102,434,533
Current liabilities				
Trade and other payables		1,431,127	—	1,431,127
Provisions		8,034	—	8,034
Total current liabilities		1,439,161		1,439,161
Non-current liabilities				
Deferred tax liabilities	а	—	11,874,248	11,874,248
Total non-current liabilities		_	11,874,248	11,874,248
Total liabilities		1,439,161	11,874,248	13,313,409
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## NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

	Notes	Superseded policies * \$	Consolidated effects of transition to A-IFRS \$	A-IFRS \$
Net assets		88,436,160	684,964	89,121,124
Equity				
Issued capital		107,883,835	—	107,883,835
Reserves	c, d	538,396	(2,564)	535,832
Deficit accumulated prior to development stage		(3,813,181)	_	(3,813,181)
Deficit accumulated during development stage	f	(16,172,890)	687,528	(15,485,362)
Total equity		88,436,160	684,964	89,121,124

\* Reported financial position under previous Australian GAAP.

Effect of A-IFRS on the balance sheet as at June 30, 2005

Current assets Cash and cash equivalents Trade and other receivables Other Total current assets	Notes	\$ 12,892,061 709,418 322,933 13,924,412	\$ — — — —	\$ 12,892,061 709,418 322,933 13,924,412
Trade and other receivables Other <b>Total current assets</b>		709,418 322,933		709,418 322,933
Other Total current assets		322,933	-	322,933
Total current assets				,
		13,924,412	—	13,924,412
Non-current assets				
Property, plant and equipment		3,273,663	—	3,273,663
Goodwill	е	8,588,228	14,717,470	23,305,698
Other intangible assets	b	56,249,010	(4,886,681)	51,362,329
Total non-current assets		68,110,901	9,830,789	77,941,690
Total assets		82,035,313	9,830,789	91,866,102
Current liabilities				
Trade and other payables		2,017,820	—	2,017,820
Provisions		29,879	—	29,879
Total current liabilities		2,047,699		2,047,699
Non-current liabilities				
Deferred tax liabilities	а	_	10,122,656	10,122,656
Total non-current liabilities			10,122,656	10,122,656
Total liabilities		2,047,699	10,122,656	12,170,355
Net assets		79,987,614	(291,867)	79,695,747
Equity				
Issued capital		107,883,835	_	107,883,835
Reserves	c, d	20,761	553,366	574,127
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# NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars)

(Unaudited)

Deficit accumulated prior to development stage	Notes	Superseded policies * \$ (3,813,181)	Consolidated effects of transition to A-IFRS \$	A-IFRS \$ (3,813,181)
Deficit accumulated during development stage	f	(24,103,801)	(845,233)	(24,949,034)
Total equity		79,987,614	(291,867)	79,695,747

\* Reported financial position under previous Australian GAAP.

### Effect of A-IFRS on the cash flow statement

There are no material differences between the cash flow statement presented under A-IFRS and the cash flow statement presented under the superseded policies.

### Explanatory notes to the reconciliations

### (a) Deferred income tax

Under superseded policies, the Company adopted tax-effect accounting principles whereby income tax expense was calculated on pre-tax accounting profits after adjustment for permanent differences. The tax-effect of timing differences, which occur when items were included or allowed for income tax purposes in a period different to that for accounting purposes, were recognized at current taxation rates as deferred tax assets and deferred tax liabilities, as applicable.

Under A-IFRS, deferred tax is determined using the balance sheet liability method in respect of temporary differences arising from differences between the carrying amount of assets and liabilities in the financial statements and their corresponding tax bases. This includes temporary differences arising from business combinations, which differs from superseded policies.

The effect of the deferred tax adjustments on deferred tax balances is as follows:

	July, 1 2004 \$	December 31, 2004 \$	June 30, 2005 \$
Deferred tax assets not recognized under previous GAAP	2,708,039	4,830,630	5,611,096
Deferred tax liabilities not recognized under previous GAAP	(2,708,039)	(16,704,878)	(15,733,752)
Net increase in deferred tax balances		(11,874,248)	(10,122,656)
		Six months	

	ended December 31, 2004 \$	Year ended June 30, 2005 \$
Net impact on deferred tax at beginning of period	—	—
Impact on loss for period	1,869,300	3,620,892
Deferred tax capitalized to goodwill	(13,743,548)	(13,743,548)
Net impact of deferred tax at end of period	(11,874,248)	(10,122,656)

### NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

### (b) Other intangible assets

At the date of transition to A-IFRS, the Company elected to restate all business combinations occurring from December 1, 2000, the date of the entity's re-listing on the Australian Stock Exchange.

As part of this restatement, the Company has capitalized direct acquisition costs previously expensed under superseded policies on the acquisition of a controlling interest in pSiMedica Limited in May 2001 totaling \$112,278, resulting in an increase to intangibles of this amount on transition (and also applicable at December 31, 2004 and June 30, 2005) and a corresponding decrease to accumulated losses.

The restatement of business combinations has also resulted in an increase in other intangible assets of \$3,400,552 on transition (and also applicable at December 31, 2004 and June 30, 2005) as a result of the gross-up of intangible assets resulting from changes to deferred tax balances. Amortization expense must also be charged on the additional intangible amount. This has resulted in a decrease in intangibles of \$692,513 at transition, \$849,293 at December 31, 2004 and \$1,003,517 at June 30, 2005. A corresponding increase to accumulated losses of \$692,513 on transition, and an additional amortization expense of \$156,780 for the half-year ended December 31, 2004, and \$311,004 for the year ended June 30, 2005 has been recorded.

Further, under A-IFRS the Company has chosen to amortize its intangible assets from the date that they are available for use, which differs from superseded policies whereby the Company did not amortize intangible assets until such time as they resulted in the generation of revenue. This has resulted in a decrease in intangibles of \$1,636,767 at transition, \$4,290,565 at December 31, 2004 and \$7,395,994 at June 30, 2005. A corresponding increase to accumulated losses of \$1,636,767 on transition, and an additional amortization expense of \$2,653,798 for the half-year ended December 31, 2004, and \$5,759,227 for the year ended June 30, 2005 has been recorded.

#### (c) Cumulative exchange differences

At the date of transition, the Company elected to reset the foreign currency translation reserve to zero. An amount of \$78,220 was reclassified from the foreign currency translation reserve to accumulated losses on transition (and also applicable at December 31, 2004 and June 30, 2005), thereby reducing the balance of reserves by this amount.

(d) Share-based payments

As at the date of transition to A-IFRS, the Company has recognized an increase in the employee equity-settled payments reserve and a corresponding increase in accumulated losses of \$39,689.

For the half-year ended December 31, 2004, share-based payments of \$35,967 (of which \$28,865 was included in employee expenses and \$7,102 in professional fees) which were not recognized under the superseded policies were recognized under A-IFRS, with a corresponding increase in the employee equity-settled payments reserve.

For the financial year ended June 30, 2005, share-based payments of \$591,897 (of which \$508,610 was included in employee expenses and \$83,287 in professional fees) which were not recognized under the superseded policies were recognized under A-IFRS, with a corresponding increase in the employee equity-settled payments reserve.

These adjustments had no material tax or deferred tax consequences.

(e) Goodwill

There is no goodwill at the date of transition to A-IFRS.



#### NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

In accordance with AASB 3, "Business Combinations", the Company recognized an increase of goodwill of \$13,743,547 for the half-year ended December 31, 2004, and for the year ended June 30, 2005.

Further, goodwill, which was amortized under superseded policies in the comparative period, being the half-year ended December 31, 2004, is not amortized under A-IFRS from the date of acquisition for those business combinations restated. The effect of this change is an increase in the carrying amount of goodwill by \$442,692 and a decrease in net loss before tax of \$442,692 for the half-year ended and as at December 31, 2004 and an increase in the carrying amount of goodwill by \$973,923 and a decrease in net loss before tax of \$973,923 for the financial year ended and as at June 30, 2005. There is no tax effect as deferred taxes are not recognized for temporary differences arising from goodwill from which amortization is not deductible for tax purposes.

#### (f) Accumulated losses

The effect of the above adjustments on accumulated losses is as follows:

	Notes	July 1, 2004 \$	December 31, 2004 \$	June 30, 2005 \$
Income tax benefit / expense	а	3,400,552	5,269,852	7,021,443
Direct acquisition costs capitalized	b	112,278	112,278	112,278
Amortization of grossed-up intangible	b	(692,513)	(849,293)	(1,003,517)
Amortization of intangibles previously unamortized	b	(1,636,767)	(4,290,565)	(7,395,994)
Transfer from foreign currency translation reserve	С	78,220	78,220	78,220
Expensed share-based payments	d	(39,689)	(75,656)	(631,586)
Goodwill no longer amortized	e	—	442,692	973,923
Total adjustment to accumulated losses		1,222,081	687,528	(845,233)
Attributable to members of the parent entity		1,222,081	687,528	(845,233)
Attributable to minority interests			_	
		1,222,081	687,528	(845,233)



### 10. Share-based payments

### (a) Granted by pSivida

pSivida issues equity-settled share-based payments to certain directors, employees and non-employees. The fair value of each option and warrant is estimated on the date of grant (or measurement date in the case of options and warrants issued to non-employees) using the Black-Scholes pricing model and the following assumptions:

		Six months ended December 31,		
	2005	2004		
Expected volatility	55%	60%		
Expected dividends	0%	0%		
Expected term	3 months – 3.65 years	2 years – 3.12 years		
Risk-free rate	4.92% – 5.35%	5.10% - 5.36%		

*Expected volatility* — The Company estimates expected volatility based on historical volatility over the estimated life of the option and other factors.

*Expected dividends* — The Company has never declared or paid dividends on its common stock and does not anticipate paying any dividends in the foreseeable future.

*Expected term* — This is the period of time that the options granted are expected to remain outstanding. This estimate is based primarily on future expectations and on historical trends of option holders.

*Risk-free rate* — This is the government bond rate (having a term that most closely resembles the expected life of the option) in effect at the grant date.

#### Options granted to directors and employees

pSivida grants share options to certain directors and employees under the Company's Employee Share Option Plan. Such options may be subject to service-based and / or milestone-based vesting conditions, are issued for terms not exceeding five years, and are settled through the issue of equity. The following table summarizes the activity of share options granted to directors and employees under the Employee Share Option Plan for the six months ended December 31, 2005 and 2004.

	Six months ended December 31,			
	2005		2004	
		Weighted average exercise		Weighted average exercise
	Number of options	price \$	Number of options	price \$
Outstanding at beginning of period	15,831,713	0.97	6,595,000	0.52
Granted	3,150,000	0.89	8,889,537	1.18
Exercised	—	—	(1,050,000)	0.30
Sold	—	—	(1,650,000)	0.40
Forfeited	(325,041)	0.92	(29,804)	0.80
Expired		—		
Outstanding at end of period	18,656,672	0.95	12,754,733	1.01
Exercisable at end of period	13,879,672	0.99	12,354,733	1.02
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#### NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

The weighted average grant date fair value of options granted to directors and employees during the six months ended December 31, 2005 and 2004 is \$0.26 and \$0.46, respectively. The options outstanding at December 31, 2005 have a weighted average remaining contractual life of 3.5 years and exercise prices in the following ranges:

		Weight	ed average
Range of exercise price	Number of options	exerc	cise price
\$0.50 to \$0.75	3,875,000	\$	0.61
\$0.75 to \$1.00	6,052,000	\$	0.84
\$1.00 to \$1.25	8,729,672	\$	1.18
	18.656.672		

#### Options granted to non-employees

pSivida grants share options to certain consultants as remuneration for services rendered. Such options may be subject to market-based vesting conditions, are issued for terms not exceeding five years, and are settled through the issue of equity. The following table summarizes the activity of share options granted to non-employees for services rendered for the six months ended December 31, 2005 and 2004:

		Six months end	ed December 31,	
	200		2004	
		Weighted		Weighted
		average exercise		average exercise
	Number of	price	Number of	price
	options	\$	options	\$
Outstanding at beginning of period	3,130,000	1.00	500,000	0.61
Granted	—	—	2,275,000	1.10
Forfeited	(10,000)	1.18		
Outstanding at end of period	3,120,000	1.00	2,775,000	1.01
Exercisable at end of period	3,070,000	1.00	2,725,000	1.01

The weighted average measurement date fair value of options granted to non-employees for services rendered during the six months ended December 31, 2004 is \$0.40. The options outstanding at December 31, 2005 have a weighted average remaining contractual life of 2.7 years and exercise prices in the following ranges:

		Weighted average
Range of exercise price	Number of options	exercise price
\$0.50 to \$0.75	500,000	\$0.61
\$0.75 to \$1.00	165,000	\$0.80
\$1.00 to \$1.25	2,455,000	\$1.09
	3,120,000	

### Warrants granted to non-employees

pSivida grants warrants over ADSs issued to certain consultants as remuneration for services rendered. Such warrants vest at the date of issue, are issued for terms not exceeding three years, and are settled through the issue of equity. The following table summarizes the activity of warrants over ADSs granted to non-employees for services rendered for the six months ended December 31, 2005. No warrants over ADSs were granted in prior periods.

#### NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

	Six months ended December 31, 2005 Weighted ave exercise	
	Number of warrants	price US\$
Outstanding at beginning of period	—	—
Granted	133,000	12.50
Outstanding at end of period	133,000	12.50
Exercisable at end of period	133,000	12.50

The weighted average measurement date fair value of warrants granted to non-employees for services rendered during the six months ended December 31, 2005 is US\$0.55. The warrants outstanding at December 31, 2005 have an exercise price of US\$12.50 and a remaining contractual life of 2.7 years.

As discussed in Note 6, pSivida also issued detachable warrants over 633,803 ADSs as part of the convertible note agreement during the six months ended December 31, 2005.

### Non-vested ADSs issued to CDS employees

On December 30, 2005, pSivida granted non-vested ADSs to CDS employees in connection with employee retention agreements for which employee services subsequent to the consummation date of the acquisition is required in order for the ADSs to vest. The following table summarizes the activity of such non-vested ADSs for the six months ended December 31, 2005.

		Six months ended December 31, 2005 Weighted	
	Number of ADSs	average grant date value \$	
Outstanding at beginning of period	—		
Granted	121,118	7.42	
Outstanding at end of period	121,118	7.42	
Exercisable at end of period		_	

As the holders of the non-vested ADSs have the rights of a normal shareholder, the grant date fair value of the non-vested ADSs is measured at the fair value of pSivida's ordinary ADSs as if the non-vested ADSs were vested and issued on the grant date.

Other

During the six months ended December 31, 2005, pSivida granted 901,623 non-vested ADSs and 172,446 options over ADSs as part of the consideration for the acquisition of CDS. See Note 6.

During the six months ended December 31, 2004, pSivida granted 638,537 share options as part of the consideration for the acquisition of pSiMedica Limited.

### (b) Granted by subsidiary AION Diagnostics Limited

AION Diagnostics Limited ("AION"), a wholly-owned subsidiary of pSivida, grants share options to certain directors and employees as an incentive. Such options are subject to performance-based vesting conditions, are issued for terms not exceeding three years, and are settled through the issue of equity. The fair value of each option granted by AION is estimated on the date of grant using the Black-Scholes pricing model and the following assumptions:

#### NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

	Six months ended December 31, 2005
Expected volatility	75%
Expected dividends	0%
Expected term (in years)	2.43 years
Risk-free rate	5.25%

The following table summarizes the activity of the share options granted to directors and employees of AION for the six months ended December 31, 2005. All options were granted in February 2005.

	Six months ended December 31, 2005	
		Weighted average exercise
	Number of options	price \$
Outstanding at beginning of period	1,200,000	Nil
Granted		
Outstanding at end of period	1,200,000	Nil
Exercisable at end of period	501,776	Nil

The options outstanding at December 31, 2005 have an exercise price of nil and a remaining contractual life of 2.1 years.

## 11. Restatement of A-IFRS amounts

As a public company in Australia, the Company is required to file consolidated financial statements with the ASX and ASIC that comply with A-IFRS. In these statutory A-IFRS consolidated financial statements as of and for the six months ended December 31, 2005 (filed with the ASX and the ASIC on March 16, 2006), the balance of the convertible note was classified as current or non-current based on the repayment schedule contained in the convertible note agreement. Additionally, the transaction costs directly attributable to the issuance of the note and the face amount of the discount were set off against the debt liability and amortized using the effective interest method over the expected life term of the loan. The embedded conversion option was not bifurcated and accounted for separately.

On June 29, 2006, the Company restated the A-IFRS amounts previously reported for the convertible note within the Registration Statement on Amendment No. 1 to Form F- 3 as follows:

- Embedded conversion option Further consideration of the terms of the convertible note and the applicable guidance resulted in management's conclusion that the embedded conversion option should be bifurcated and accounted for separately as a derivative financial instrument. In accordance with AASB139, a financial liability that is also a derivative should be classified as held for trading, and thus in conjunction with AASB 101, the derivative should be recognized as a current liability at fair value. After initial recognition, subsequent changes in the fair value of the embedded derivative are charged or credited to the statement of operations in each reporting period. The Company concluded the impact of the change in fair value of the embedded conversion option for the six months ended December 31, 2005 to be *de minimis*.
- Current liability classification Upon further consideration of the applicable guidance under A-IFRS, including AASB 101, "Presentation of Financial Statements" ("AASB 101"), AASB 132 and AASB 139, management concluded that since the note is convertible at the option of the holder at any time, and the Company does not have the ability to defer settlement, the entire note should be classified as a current liability.

### NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

Debt issuance costs — In conjunction with the reclassification of the convertible note as a current liability, management also concluded that under principles-based accounting, there is no justification for amortizing the debt issuance costs over the term of the loan, as such period is beyond the Company's control due to the holder's conversion option. Accordingly, such debt issuance costs should be expensed immediately at the date of issuance of the convertible note.

Subsequent to the filing of Amendment No. 1 to the Registration Statement on Form F-3, inquiries by the SEC Staff caused the Company to reconsider the contractual terms of the note in accordance with various accounting literature. Accordingly, on September 15, 2006, the Company restated the A-IFRS amounts on Amendment No. 3 to the Registration Statement on Form F-3 related to the current liability classification and debt issuance costs as follows:

- Current liability classification As disclosed in Note 7, the Company noted that the holder of the note could require payment in equal amounts of US\$5.0 million on the 12, 18 and 24 month anniversaries of the note's issuance. Upon further consideration of this term, the Company determined that this payment could be due on demand within one-year of the balance sheet. Upon further consideration of AASB 101, management concluded that the repayment due on demand within one-year be recorded as a current liability, net of related discount and issuance costs, with the remaining balance recorded as a non-current liability. The debt discount and debt issuance costs were allocated proportionately according to the classification of the note.
- Debt issuance costs Upon further consideration of AASB 139, paragraph 9, the Company concluded that in applying the effective interest rate
  method, all contractual terms of the financial instrument, including transaction costs, should be considered .. Accordingly, the accounting treatment
  for the debt issuance costs was modified so that the debt issuance costs are amortized to each of the earliest redemption dates over the expected life
  of the note.

A summary of the significant effects of each of the restatements as of and for the six months ended December 31, 2005 is as follows:

Condensed Consolidated Statement of Operations (A-IFRS)

	As of December 31, 2005		
	As previously reported \$	As restated \$	As further restated \$
Finance and interest expense	(287,613)	(817,807)	(287,613)
Loss before income tax benefit	(13,070,400)	(13,600,594)	(13,070,400)
Loss for the period	(10,702,745)	(11,232,939)	(10,702,745)
Loss attributable to members of the parent entity	(10,702,745)	(11,232,939)	(10,702,745)
Loss per share — basic and diluted	(0.05)	(0.05)	(0.05)

#### NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

Condensed Consolidated Balance Sheet (A-IFRS)

	As of December 31, 2005		
	As previously reported \$	As restated \$	As further restated \$
Current liabilities:			
Borrowings	6,848,377	12,658,567	6,848,377
Conversion option derivative	—	6,163,539	6,163,539
Total current liabilities	18,562,754	30,536,483	24,726,293
Non-current liabilities:			
Borrowings	11,443,535		5,279,996
Total non-current liabilities (1)	46,493,534	36,877,803	42,157,799
Net assets / total equity (1)	189,230,222	188,700,028	189,230,222

(1) The "as restated" balance as of December 31, 2005 includes an increase in deferred tax liabilities of \$1,827,804 resulting from the refined estimate of the purchase price allocation. This does not constitute a restatement as a final determination of required purchase accounting adjustments, including the allocation of the purchase price, has not yet been made. (Refer to Note 6 above.)

The above restatement resulted in a \$530,194 decrease to the "Deficit accumulated during development stage" as of December 31, 2005.

### 12. Reconciliation to US GAAP

The unaudited consolidated financial statements have been prepared in accordance with A-IFRS, which differ in certain significant respects from accounting principles generally accepted in the United States ("US GAAP"). Following is a summary of the adjustments to net loss and total equity required when reconciling such amounts in the financial statements to the corresponding amounts in accordance with US GAAP, considering the differences between A-IFRS and US GAAP.

#### Restatement of US GAAP amounts

On August 14, 2006, the Company restated the US GAAP amounts previously reported for the intangible assets acquired in the CDS acquisition and the related deferred taxes, as well as for the restricted cash related to the convertible note within the Registration Statement on Amendment No. 2 to Form F-3, as follows:

• Acquired intangible assets and related deferred taxes — Upon further consideration of the guidance in the AICPA Practice Aid: "Assets Acquired in a Business Combination to be Used in Research and Development Activities: A Focus on Software, Electronic Devices and Pharmaceutical Industries," the Company determined that the portion of the CDS acquisition purchase price attributable to Medidur<sup>™</sup> for DME previously allocated to patents (\$31,539,980) meets the definition of IPR&D as the product is currently in Phase III clinical trials and has not been approved by the U.S. Food and Drug Administration. Although the product candidate may have significant future importance, the Company considers that Medidur<sup>™</sup> for DME does not have an alternative future use other than the technological indications for which it is in development. As a result, the Company restated the reconciliation to US GAAP and US GAAP condensed consolidated financial statements as of and for the six months ended December 31, 2005 to write off an additional amount of IPR&D of \$31,539,980, equal to the estimated fair value of the patents and patent applications that relate to Medidur<sup>™</sup> on the acquisition of CDS. The decrease in the amount recognized as patents on the acquisition of CDS also results in a lower deferred tax liability in relation to acquired intangible assets on the basis that US GAAP specifically prohibits the recognition of deferred income tax on IPR&D.



#### NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

Restricted cash — Upon further consideration of the guidance in SEC Regulation S-X, Rule 5-02, which requires separate disclosure of account balances that are restricted as to withdrawal or usage, the Company determined that the terms of the convertible note requiring the Company to hold a net cash balance in excess of 30% of the amount of the note outstanding should be classified as restricted cash. As a result, the Company restated the US GAAP condensed consolidated balance sheet as of December 31, 2005 to separately disclose the restricted cash in the amount of \$6,163,539.

Subsequent to the filing of Amendment No. 2 to the Registration Statement on Form F-3, inquiries by the SEC Staff caused the Company to reconsider the contractual terms of the note in accordance with various accounting literature. Accordingly, on September 15, 2006, the Company restated the US GAAP amounts on Amendment No. 3 to the Registration Statement on Form F-3 related to the current liability classification and debt issuance costs as follows:

- Current liability classification As disclosed within Note 7, the holder of the note could require payment in equal amounts of US\$5.0 million on the 12, 18 and 24 month anniversaries of the note. Upon further consideration of this term, the Company determined that as of the balance sheet date a portion of the note could be due on demand within one-year of the balance sheet date. In accordance with SFAS 6, Classification of Short-Term Obligations Expected to Be Refinanced an amendment of ARB No. 43, Chapter 3A, the repayment due on the 12 month anniversary of the note met the definition of a short-term obligation, and was classified as a current liability, net of related discount and issuance costs, with the remaining balance recorded as a non-current liability. The debt discount and debt issuance costs were allocated proportionately according to the classification of the note.
- Debt issuance costs Upon further consideration of FASB Concepts Statement No. 6: "Elements of Financial Statements", the Company concluded that the debt discount and debt issuance costs should be accounted for in a similar manner. Accordingly, the accounting treatment for the debt issuance costs was modified so that the debt issuance costs are deferred and amortized to each of the earliest redemption dates over the contractual term of the note. The debt issuance costs are recorded as a deferred financing cost within the condensed consolidated balance sheet under US GAAP.

A summary of the significant effects of each of the restatements as of and for the six months ended December 31, 2005 is as follows:

Condensed Consolidated Statement of Operations (US GAAP)

	Six months ended December 31, 2005		
	As previously reported \$	As restated \$	As further restated \$
Write off of in-process research and development	(2,741,706)	(34,281,686)	(34,281,686)
Finance and interest expense	(287,613)	(817,807)	(287,613)
Loss from operations	(15,812,041)	(47,352,021)	(47,352,021)
Loss before income tax benefit	(16,383,659)	(47,923,639)	(47,393,446)
Net loss	(14,003,596)	(45,543,576)	(45,013,382)
Loss per share — basic and diluted	(0.06)	(0.20)	(0.20)

## NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars)

(Unaudited)

Condensed Consolidated Balance Sheet (US GAAP)

		As of December 31, 2005	
	As previously reported \$	As restated \$	As further restated \$
Cash and cash equivalents	27,683,278	21,151,739	21,151,739
Restricted cash		6,163,539	6,163,539
Total current assets	29,436,601	29,436,601	29,436,601
Goodwill	84,150,327	71,534,335	71,534,335
Other intangible assets, net	167,335,328	135,795,348	135,795,348
Deferred financing costs	—	_	8,416,758
Total assets	284,777,237	240,621,265	249,038,023
Borrowings, current	12,658,567	12,658,567	6,848,377
Deferred tax liability	35,232,056	22,616,064	22,616,064
Borrowings, non-current	—	_	13,696,754
Total liabilities	65,768,539	53,152,547	61,039,111
Deficit accumulated during development stage	(40,284,530)	(71,824,510)	(71,294,316)
Total stockholders' equity	219,008,698	187,468,718	187,998,913
Total stockholders' equity	219,008,698	18/,468,/18	187,998,913

## **Reconciliation of net loss**

The following is a reconciliation of net loss as reported in the consolidated statement of operations under A-IFRS to net loss as adjusted for the effects of the application of US GAAP as of December 31, 2005 and June 30, 2005 and for the six months ended December 31, 2005 and 2004:

		Six months en December 31, 2005 (As restated) \$	ded December 31, 2004 \$
Loss for the period in accordance with A-IFRS		(10,702,745)	(7,729,361)
Loss attributable to minority interest			399,196
Loss attributable to members of the parent entity under A-IFRS		(10,702,745)	(7,330,165)
US GAAP adjustments:			
Share-based compensation expense	(a)	—	(41,257)
Fair value of equity instruments issued as consideration — amortization			
expense	(b)	(21,581)	(21,581)
In-process research and development	(C)	(34,281,686)	—
Sales of stock by subsidiaries — amortization expense	(d)	(19,778)	(19,778)
Deferred tax effect of US GAAP adjustments	(b)(c)(d)	12,408	12,408
US GAAP adjustments attributable to minority interest			(20,920)
Net loss in accordance with US GAAP		(45,013,382)	(7,421,294)
Loss per share in accordance with US GAAP			
Basic and diluted loss per share	(e)	(0.20)	(0.04)
Weighted average number of shares — basic and diluted		225,327,359	196,480,572
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## NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

## Reconciliation of total equity

The following is a reconciliation of total equity as reported in the consolidated balance sheet under A-IFRS to total equity as adjusted for the effects of the application of US GAAP as of December 31, 2005 and June 30, 2005:

		As of	
		December 31, 2005 (As restated)	June 30, 2005
Total equity in accordance with A-IFRS		189,230,222	79,695,747
US GAAP adjustments:			
Fair value of equity instruments issued as consideration	(b)	33,513,232	8,410,076
In-process research and development	(c)	(35,316,704)	(1,035,018)
Sales of stock by subsidiaries	(d)	292,557	312,335
Deferred tax impact of US GAAP adjustments	(b)(c)(d)	279,605	267,197
Total equity in accordance with US GAAP		187,998,912	87,650,337

## Roll forward analysis of shareholders' equity under US GAAP

		Six months ended	
		December 31, 2005 (As restated)	December 31, 2004
Balance in accordance with US GAAP at beginning of period		87,650,337	37,794,705
Issuance of shares and options in connection with acquisitions, net of issue			
costs		137,717,687	62,526,881
Issuance of shares in connection with PIPE, net of issue costs		5,167,228	
Issuance of shares in connection with exercise of options			3,666,500
Issuance of options and non-vested shares for services rendered	(a)	797,667	664,679
Warrants attached to convertible loan note		1,719,831	—
Foreign currency translation adjustment		(40,456)	(127,278)
Net loss in accordance with US GAAP		(45,013,382)	(7,421,294)
Balance in accordance with US GAAP at end of period		187,998,912	97,104,193

Note: The above rollforward does not include options and warrants issued as settlement of share issue costs as such issuances do have an impact on net loss or total equity.



#### NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

#### (a) Share-based compensation expense

Under A-IFRS, the Company adopted AASB 2: "Share-Based Payment" effective July 1, 2005. In accordance with the transitional provisions of AASB 2, the standard has been applied retrospectively to all share-based payments granted or issued after November 7, 2002 and that were not yet vested as of January 1, 2005.

Through June 30, 2005, the Company accounted for share-based payments granted to employees and directors under US GAAP using the intrinsic value method in accordance with Accounting Principles Board ("APB") Opinion No. 25: "Accounting for Stock Issued to Employees" ("APB 25") and related interpretations to measure employee stock compensation. Under APB 25, compensation expense was recognized to the extent that the quoted market price of the stock exceeded the exercise price of the equity instrument, if any, at the measurement date, and was charged to earnings ratably over the vesting period. For options that vest upon the achievement of performance conditions beyond the Company's control, compensation expense was recognized when the target was achieved.

The following table illustrates the effect on US GAAP net loss and loss per share if the Company had applied the fair value recognition provisions of Statements of Financial Accounting Standards ("SFAS") No. 123: "Accounting for Stock-Based Compensation" ("SFAS 123") to stock-based employee compensation for the half-year ended December 31, 2004.

	Six months ended December 31, 2004
US GAAP net loss, as reported	(7,421,294)
Add: Stock-based employee compensation expense included in reported US GAAP net loss	77,225
Deduct: Total stock-based employee compensation expense determined under fair value based method	(372,041)
US GAAP pro forma net loss	(7,716,110)
US GAAP basic and diluted loss per share	
As reported	(0.04)
Pro forma	(0.04)

Additionally, through June 30, 2005, the Company accounted for share-based payments granted to consultants under SFAS 123 and EITF Issue No. 96-18: "Accounting for Equity Instruments That Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" ("EITF 96-18") under US GAAP. Under SFAS 123 and EITF 96-18, compensation cost was calculated based on the estimated fair value of the equity instruments measured on the date the services were completed by the respective consultants. For reporting periods prior to the measurement date, interim measures of compensation cost were recognized based on the fair value as of each reporting date and adjusted for changes in fair value between reporting dates.

Effective July 1, 2005, for US GAAP purposes the Company adopted SFAS No. 123R, "Share-Based Payment" ("SFAS 123R") which replaces SFAS 123 and supersedes APB 25. SFAS 123R does not change the measurement guidance of EITF 96-18 for non-employee transactions. Under the modified prospective method of SFAS 123R, the Company applies SFAS 123R for equity-based compensation awards (or portion thereof): (i) granted on or after July 1, 2005; and (iii) not yet vested as of July 1, 2005. Such equity-based compensation awards are measured based on the fair value using the Black-Scholes model. The compensation is recognized as an expense in the statement of operations over the requisite service period. Prior periods have not been restated.

#### NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

Total US GAAP share based compensation costs charged to the statement of operations was \$797,667 and \$77,225 for the half-years ended December 31, 2005 and 2004, respectively. No income tax benefits were recognized and no compensation cost was capitalized as part of property and equipment during the periods presented.

The retrospective transition provisions of AASB 2 and the modified prospective transition provisions of SFAS 123R give rise to GAAP differences in share-based compensation for the six months ended December 31, 2004. There are no US GAAP reconciling items attributable to share-based compensation for the six months ended December 31, 2005 as the impact on compensation cost resulting from differences in the standards, such as the determination of the measurement date for share-based payments made to non-employees, is *de minimis*.

#### (b) Fair value of equity instruments issued as consideration

Under A-IFRS, the fair value of equity instruments issued as consideration in a purchase business combination is based on the quoted market price as of the date of consummation. Under US GAAP, the fair value of the equity instruments issued to effect a purchase business combination is based on the average quoted market price for a period of two days before and two days after the date the terms of the acquisition is agreed to and announced. Accordingly, for US GAAP purposes, the Company has recorded an increase to the value of identifiable intangible assets, the related deferred tax liability and goodwill, as appropriate. The increase in the value of identifiable intangible assets and the related deferred tax liability is amortized over the estimated useful life of the intangible of 12 years.

#### (c) In-process research and development

Under A-IFRS, IPR&D projects acquired in a business combination are capitalized and remain on the balance sheet, subject to any impairment writedowns. Amortization is charged over the estimated useful life from the point when the assets became available for use. Under US GAAP, such assets are recognized in the opening balance sheet but are then written off immediately to the statement of operations, as the technological feasibility of the IPR&D has not yet been established and it has no alternative future use.

Under A-IFRS, deferred tax is provided for IPR&D assets acquired in a business combination. US GAAP does not provide for deferred tax on these assets, resulting in a reconciling adjustment to deferred tax and goodwill.

#### (d) Sales of stock by subsidiaries

In prior periods, certain of the Company's subsidiaries issued additional shares which resulted in a change in pSivida's proportionate interest in the respective subsidiaries. Under A-IFRS, the change in pSivida's proportionate interest in the respective subsidiaries due to share issuances is eliminated on consolidation and therefore is not recognized in the consolidated financial statements. Under US GAAP, the issuance of ordinary shares by a subsidiary is accounted for in accordance with SAB No. 51, "Accounting For Sales Of Stock By A Subsidiary" ("SAB 51") which requires the difference between the carrying amount of the parent's investment in a subsidiary and the underlying net book value of the subsidiary after issuance of ordinary shares by the subsidiary be reflected as either a gain or loss in the statement of operations or reflected as an equity transaction. The Company has elected to account for SAB 51 gains and losses resulting from the sale of a subsidiary's ordinary shares as equity transactions. Accordingly, for US GAAP purposes, the Company has recorded an adjustment to the value of identifiable intangible assets, the related deferred tax liability and additional paid-in capital for the resulting SAB 51 gains and losses. The adjustment to the value of identifiable intangible assets and the related deferred tax liability is amortized over the estimated useful life of 12 years.

### NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

### (e) Loss per share

Under A-IFRS, loss per share is calculated by dividing loss attributable to members of the parent entity by the weighted average number of shares on issue for the period. Methods of computing loss per share in accordance with US GAAP are documented in SFAS No. 128, "Earnings per Share".

For the six months ended December 31, 2005 and 2004, there were no differences in the calculation methodology of loss per share under A-IFRS and US GAAP.

Basic and diluted loss per share are identical for all periods presented as potentially dilutive securities, including options, warrants and convertible debt, have been excluded from the calculation of the diluted net loss per common share because the inclusion of such securities would be antidilutive.

#### (f) Foreign currency translation adjustment

At the date of transition to A-IFRS, the Company elected to reset the foreign currency cumulative translation adjustment to zero under A-IFRS, with the offset recorded against the opening balance of accumulated deficit. US GAAP does not allow the foreign currency cumulative translation adjustment to be reset. This GAAP difference has no impact on net loss or total equity.

#### (g) Convertible note

Upon initial recognition, the proceeds received on the issue of the convertible note with detachable warrants are allocated into liability and equity components. In accordance with A-IFRS, the liability component is measured based on the fair value of a similar liability (including any embedded non-equity derivative features) that does not have an associated equity component. The equity component is determined by deducting the liability component from the proceeds received on the issue of the notes. A portion of the liability proceeds is then allocated to any embedded derivatives that require bifurcation, at an amount equal to fair value. In accordance with US GAAP, the proceeds received are first allocated to the convertible note and the detachable warrants on a relative fair value basis. Then, a portion of convertible note proceeds is allocated to any embedded derivatives, such as the holder's conversion option, that require bifurcation, at an amount equal to fair value. The resulting difference under these recognition methods of the convertible note is de minimis and therefore is not included in the US GAAP reconciliation.

#### (h) Other

Other potential GAAP differences that were considered but not included in the US GAAP reconciliation are as follows:

#### Principles of consolidation / step acquisitions

Under A-IFRS, the minority interest is presented in the balance sheet within equity, separately from the parent shareholders' equity. Under US GAAP, the minority interest is presented outside equity, between liabilities and equity. This did not result in a reconciling item as all subsidiaries are wholly-owned as of December 31, 2005 and June 30, 2005.

A-IFRS does not include prescriptive guidance on accounting for step acquisitions. In the absence of such guidance, the Company applied the partial-step up method in US GAAP for A-IFRS purposes. Other than as detailed in the paragraphs above, there is no difference in the accounting treatment for step acquisitions under US GAAP compared to that under A-IFRS as applied by the Company.

#### Receivables

There is no difference in the accounting treatment of receivables under US GAAP compared to that required under A-IFRS in the Company's circumstances.



#### NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

#### Impairment of goodwill and long-lived assets

Under A-IFRS and US GAAP, goodwill is not amortized but reviewed for impairment annually and when indicators of impairment arise. Under A-IFRS, the impairment test is performed at the cash-generating unit level, being the lowest level to which goodwill can be allocated. The recoverable amount of the cash-generating unit (i.e., the higher of the fair value less costs to sell and value in use) is compared to its carrying amount. The impairment loss is immediately recognized in profit or loss the excess of the carrying amount over the recoverable amount. Under US GAAP, the impairment test is performed at the reporting unit level, being either a business segment or one organization level below. A two step impairment test is performed: (i) the fair value of the reporting unit is compared to the carrying amount of the reporting unit including goodwill; and (ii) the goodwill impairment is measured as the excess of the carrying amount of goodwill over its implied fair value. The impairment loss is immediately recognized in profit or loss. There is no goodwill impairment for the periods presented, and hence no GAAP difference.

Under A-IFRS and US GAAP, long-lived assets are tested for impairment if there is any such indication. Under A-IFRS, impairment is indicated, and a detailed calculation must be performed, if the asset's carrying amount exceeds its recoverable amount. The impairment loss is based on the recoverable amount. Under US GAAP, impairment is indicated, and a detailed calculation must be performed, if the asset's carrying amount exceeds the expected future cash flows to be derived from the asset on an undiscounted basis. The impairment loss is based on the fair value. There were no indicators of impairment during the periods presented, and hence no GAAP difference.

#### Current and deferred income taxes

As applied to the Company, there is no difference in the accounting treatment of current and deferred income taxes other than the deferred tax impact of US GAAP adjustments arising from the differences detailed above.

#### Provisions

Under A-IFRS and US GAAP, provisions relating to present obligations from past events are recorded if the outflow of resources is probable and can be reliably estimated. A-IFRS requires the time value of money to be taken into account when making a provision. In contrast, US GAAP only permits a provision to be discounted where the amount of the liability and timing of payments are fixed or reliably determinable, or where the obligation is a fair value obligation (e.g., asset retirement obligation). Where there is a range of possible outcomes, A-IFRS requires a provision for the expected value to be made. If a range of estimates is predicted and no amount in the range is more likely than any other amount in the range, the 'mid-point' of the range is used to measure the liability Under US GAAP, where the liability is not measured at fair value and there is a range of possible outcomes and no amount in the range, is more likely than any other amount is used to measure the liability. Due to the nature of the provisions recorded by the Company, the difference in accounting policies did not result in a GAAP difference.

#### Registration rights agreement

Under A-IFRS and US GAAP, the Company accounts for the financial instrument and related registration rights agreement separately as freestanding instruments. The Company records a liability for the penalties payable pursuant to the liquidated damages clause per the registration rights agreement in the period in which the penalty is triggered. The Company believes the registration rights agreement does not meet the definition of a derivative in accordance with A-IFRS and US GAAP. Based on the Company's accounting policies, there is no difference in the accounting treatment for a registration rights agreement under US GAAP compared to that under A-IFRS as applied by the Company.

### NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

### Deferred Financing Costs

Under A-IFRS, debt issuance costs are set off directly against the debt, while under US GAAP, the debt issuance costs are included within the balance sheet as a deferred financing cost, resulting in a GAAP difference. This difference was not presented in the US GAAP reconciliation as it represents a balance sheet reclassification with no impact on either net loss or equity for the related periods.

### 13. Additional US GAAP Disclosures - development stage

The Company meets the definition of a development stage enterprise under SFAS No. 7, "Accounting and Reporting by Development Stage Enterprises" ("SFAS 7"). The following additional disclosures, prepared on an A-IFRS basis considering the AASB 1 exemptions, are required in accordance with SFAS 7:

Cumulative consolidated statement of operations from the inception of the development stage (December 1, 2000) to December 31, 2005 – A-IFRS basis

	Period from inception of development stage (Dec 1, 2000 to Dec 31, 2005) \$
Revenue	1,935,521
Research and development	(28,997,615)
Selling, general and administrative	(26,575,241)
Interest and finance expenses	(293,248)
Foreign exchange gain	143,729
Loss before income tax benefit Income tax benefit	(53,786,854) 9,389,099
Loss for the period Loss attributable to minority interest	(44,397,755) 8,745,976
Loss attributable to members of the parent entity	(35,651,779)
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### NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

Cumulative consolidated cash flow statement from the inception of the development stage (December 1, 2000) to December 31, 2005 - A-IFRS basis

	Period from inception of development stage (December 1, 2000 to December 31, 2005) \$
Cash flows from operating activities	
Payments to suppliers, employees and consultants	(13,719,990)
Research and development expenditure	(26,344,846)
Interest received	1,603,934
Other income	233,551
Income received in advance	493,702
Interest expense	(6,782)
Net cash used in operating activities	(37,740,431)
Cash flows from investing activities	
Purchase of property, plant and equipment	(5,681,103)
Proceeds on sale of property, plant and equipment	723,930
Net cash paid for acquisitions of businesses	(5,001,134)
Net cash used in investing activities	(9,958,307)
Cash flows from financing activities	
Proceeds from issue of ordinary shares	52,178,889
Payment of share issue costs	(2,850,342)
Proceeds from convertible loan note	20,500,500
Costs of convertible loan note financing	(607,196)
Equity contributions from minority interest	5,508,030
Net cash provided by financing activities	74,729,881
Net increase in cash and cash equivalents	27,031,143
Cash and cash equivalents at the beginning of the period	597,000
Effects of exchange rate changes on the balance of cash held in foreign currencies	55,135
Cash and cash equivalents at the end of the period	27,683,278

Equity issuances from the inception of the development stage (December 1, 2000) to December 31, 2005 – A-IFRS basis

	Number of shares	Contributed equity \$
Balance at inception of development stage – December 1, 2000	62,329,947	6,060,181
Issue of shares in connection with placement at \$0.30 per share, net of issue costs – December 1, 2000	9,300,000	2,773,709
Non-cash issue of shares as consideration for acquisition at \$0.30 per share, net of issue costs – May 10,		
2001	10,918,535	3,273,959
Balance, June 30, 2001	82,548,482	12,107,849
Issue of shares in connection with placement at \$0.20 per share, net of issue costs – November 22, 2001	12,300,000	2,332,410
Issue of shares in connection with share purchase plan at $0.22$ per share, net of issue costs – May 9,		
2002	998,500	209,357

### NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

	Number of shares	Contributed equity \$
Balance, June 30, 2002	95,846,982	14,649,616
Issue of shares in connection with placement at \$0.12 per share, net of issue costs – October 10, 2002	7,000,000	792,568
Non-cash issue of shares in lieu of director's fees at \$0.13 per share – November 25, 2002	769,231	100,000
Issue of shares pursuant to exercise of stock options at \$0.20 per share – June 19, 2003	300,000	60,000
Balance, June 30, 2003	103,916,213	15,602,184
Issue of shares in connection with share purchase plan at \$0.24 per share, net of issue costs – August 4, 2003	3,891,572	932,297
Issue of shares pursuant to exercise of stock options at \$0.20 per share – August 2003 to May 2004	8,130,000	1,626,000
Non-cash issue of shares as consideration for acquisition at \$0.50 per share, net of issue costs –		
October 6, 2003	13,000,000	6,161,600
Issue of shares in connection with placement at \$1.09 per share, net of issue costs – April 20, 2004	19,375,000	19,308,011
Issue of shares in connection with placement at \$1.16 per share, net of issue costs – April 23, 2004	5,625,000	6,327,890
Balance, June 30, 2004	153,937,785	49,957,982
Non-cash issue of shares as consideration for acquisition at \$1.09 per share, net of issue costs –		
August 5, 2004	49,804,381	54,259,353
Issue of shares pursuant to exercise of stock options at \$0.20 per share – July 2004 to December 2004	13,070,000	2,614,000
Issue of shares pursuant to exercise of stock options at \$0.40 per share – October 2004 to		
December 2004	2,200,000	880,000
Issue of shares pursuant to exercise of stock options at \$0.50 per share – December 14, 2004	150,000	75,000
Issue of shares pursuant to exercise of stock options at \$0.65 per share – December 14, 2004	150,000	97,500
Balance, June 30, 2005	219,312,166	107,883,835
Issue of shares in connection with PIPE at \$0.848 per share, net of issue costs – September 5, 2005	6,650,000	5,158,165
Non-cash issue of shares as consideration for acquisition at \$0.71 per share, net of issue costs –		
December 30, 2005	161,047,790	111,855,860
Balance, December 31, 2005	387,009,956	224,897,860

### 14. US GAAP condensed financial information

The Securities and Exchange Commission has amended Form 20-F to provide four options for foreign private issuers that are first-time adopters of IFRS (or equivalents) and are required to provide interim financial statements in Securities Act or Exchange Act documents used after nine months from the financial year end. pSivida Limited has chosen to use the condensed financial information option, which allows foreign companies to use condensed US GAAP financial information to bridge the gap in interim financial information between previous GAAP and IFRS (or equivalents). The condensed US GAAP financial information provides a level of detail consistent with that required by Article 10 of Regulation S-X for interim financial statements.

The following financial information is the unaudited US GAAP condensed financial information of pSivida Limited for the half-years ended December 31, 2005 (restated) and 2004, for the year ended June 30, 2005 and as of December 31, 2005 (restated), June 30, 2005 and December 31, 2004.

## NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

## CONDENSED CONSOLIDATED BALANCE SHEET (in Australian dollars) (Unaudited)

	Note	December 31, 2005 As restated (Refer Note 12) \$	As of June 30, 2005 \$	December 31, 2004 \$
Current assets				
Cash and cash equivalents		21,519,739	12,892,061	22,000,602
Restricted cash		6,163,539		_
Trade and other receivables		1,238,335	709,418	246,437
Other		8,931,746	322,933	93,310
Total current assets		37,853,359	13,924,412	22,340,349
Non-current assets				
Property, plant and equipment, net		3,854,981	3,273,663	1,756,367
Goodwill		71,534,335	31,840,423	31,840,424
Other intangible assets, net		135,795,348	51,024,779	54,718,665
Other				16,587
Total assets		249,038,023	100,063,277	110,672,392
Current liabilities				
Trade and other payables		9,157,003	2,017,820	1,431,128
Deferred revenue		1,821,445	_	_
Borrowings	(b)	6,848,377	_	_
Conversion option derivative	(b)	6,163,539	_	_
Provisions	. ,	735,929	29,879	8,034
Total current liabilities		24,726,293	2,047,699	1,439,162
Non-current liabilities				
Borrowings		13,696,754	_	_
Deferred tax liability		22,616,064	10,365,240	12,129,037
Total liabilities		61,039,111	12,412,939	13,568,199
Commitments and contingencies	(c)	_	_	_
Stockholders' equity				
Common stock		_	_	
Additional paid-in capital		263,418,932	117,723,693	118,107,148
Accumulated other comprehensive (loss) / income		(312,523)	20,760	(49,058)
Deficit accumulated prior to development stage		(3,813,181)	(3,813,181)	(3,813,181)
Deficit accumulated during development stage		(71,294,316)	(26,280,934)	(17,140,716)
Total stockholders' equity		187,998,912	87,650,338	97,104,193
Total liabilities and stockholders' equity		249,038,023	100,063,277	110,672,392

## NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

### CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS (in Australian dollars, except number of shares) (Unaudited)

	Note	Six months ended December 31, 2005 As restated (Refer Note 12) \$	Twelve months ended June 30, 2005 \$	Six months ended December 31, 2004 \$
Revenue	1.000	50,732	161,666	13,879
Operating expenses:				
Research and development		9,058,338	14,358,160	6,527,591
Selling, general and administrative		4,369,570	5,406,091	2,049,308
Write off of in-process research and development		34,281,686	—	—
Foreign exchange (gain)/loss		(306,841)	1,623,484	1,487,066
Total operating expenses		47,402,753	21,387,735	10,063,965
Loss from operations		(47,352,021)	(21,226,069)	(10,050,086)
Non-operating income (expense): Interest income Interest and finance expenses		246,189 (287,613)	667,310 (1,920)	384,622 (3,406)
Loss before income tax benefit		(47,393,445)	(20,560,679)	(9,668,870)
Income tax benefit		2,380,063	3,620,891	1,869,300
Loss attributable to minority interest			378,276	378,276
Net loss		(45,013,382)	(16,561,512)	(7,421,294)
Loss per share (basic and diluted)		(\$0.20)	(\$0.08)	(\$0.04)
Weighted average number of ordinary shares (basic and diluted)		225,327,359	207,802,540	196,480,572

## (a) Acquisition

As discussed in Note 6, on October 3, 2005, the Company entered into a merger agreement with CDS, a Boston-based company engaged in the design and development of drug delivery products.

The purchase price of the acquisition of \$143,081,155 in accordance with US GAAP consists of:

### NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

- \$114,319 cash;
- 150,820,380 ordinary fully paid shares of pSivida, represented by 15,082,038 ADSs, with an estimated fair value of \$130,610,449 (\$0.866 per share, represented by US\$6.602 per ADS). The fair value of the shares was determined based on the weighted average of the closing share prices of pSivida for the period two days before and two days after October 3, 2005, being the date that the terms of the acquisition were agreed to and announced:
- 9,016,230 non-vested ordinary shares of pSivida, represented by 901,623 non-vested ADSs, with an estimated fair value of \$6,231,034, net of unearned compensation of \$1,577,021. As the holders of the nonvested ADSs have the rights of a normal shareholder, the fair value of these nonvested ADSs was determined based on the fair value of pSivida's ordinary ADSs as stated above;
- 1,724,460 share options in pSivida, represented by 172,446 options over ADSs, with an estimated fair value of \$876,204; and
- direct acquisition costs of \$5,249,149.

A final determination of required purchase accounting adjustments, including the allocation of the purchase price, has not yet been made. The Company believes that the current allocation of the purchase price is reasonable, but is subject to revision upon completion of an independent valuation study, which is expected to be finalized during the first quarter of the fiscal year ending June 30, 2007. In particular, the amounts allocated to intangible assets, being primarily intellectual property in the form of patents acquired and goodwill, and the related deferred tax liabilities, may be revised and may ultimately differ from those used in these consolidated financial statements, either of which could have a material impact on the financial position and results of operations of the Company. Following is an estimate of the preliminary allocation of the US GAAP purchase price as of December 30, 2005, the date of acquisition:

	Total fair value
Cash	228,464
Receivables	460,351
Other	282,588
Property, plant and equipment	624,035
Deferred tax asset	20,705,001
Patents	88,460,020
In-process research and development	34,281,686
Payables	(3,549,399)
Deferred revenue	(1,826,699)
Provisions	(621,399)
Deferred tax liability	(35,384,008)
Total	103,660,640
Purchase price	143,081,155
Goodwill in accordance with US GAAP	39,420,515

The Company determined that the portion of the purchase price attributable to the patents and patent applications relating to Medidur<sup>™</sup> for DME (\$31,539,980) meets the definition of IPR&D as the product is currently in Phase III clinical trials and has not been approved by the FDA. This amount has been determined based on a discounted cash flow analysis of Medidur™ for DME prepared at the time of the acquisition by the Company, considering known royalty rates for the product, standard industry and market discount rates and what the Company considered to be reasonable market penetration rate assumptions. The patents and patent applications that support Medidur™ for DME were evaluated by the Company's investment banker and by management and valued in light of the Phase III stage of product development, nearness to commercialization, a license agreement in place for the use of the technology and an assessment of the risk of failure of the product.

#### NOTES TO THE FINANCIAL STATEMENTS (in Australian dollars) (Unaudited)

As indicated above, the product is currently in a 36 month Phase III clinical trial. Many factors could contribute to the delay or failure of these trials and the Company depends on collaborations with third parties to develop and commercialize this product, and such arrangements may not be available or scientifically or commercially successful, or may be terminated.

Although Medidur<sup>™</sup> for DME may have significant future importance, the Company considers that Medidur<sup>™</sup> for DME does not have an alternative future use other than the technological indications for which it is in development.

Smaller IPR&D projects that have been identified by the Company which were being undertaken by CDS at the time of the acquisition have been determined to have a fair value of \$2,741,706. As these projects are at a very early stage of development, the Company determined the fair value of the projects with reference to the costs incurred by CDS at the time of the acquisition. Such IPR&D projects do not have an alternative future use.

The total amount of IPR&D recognized by the Company on the acquisition of CDS is \$34,281,686 and has been expensed at the date of acquisition under US GAAP.

The following unaudited pro forma financial data presents the combined results of operations of the Company and CDS in accordance with US GAAP as if the acquisition had occurred at the beginning of each period presented.

		Six months ended December 31,	
	2005 \$	2004 \$	
Revenue	686,562	4,195,133	
Loss for the period	(51,358,896)	(9,110,358)	
Basic and diluted loss per share	(0.14)	(0.03)	

The pro forma data is based on historical information and does not necessarily reflect the actual results that would have occurred, nor is it indicative of future results of operations.

Refer to Note 6 for further information on the acquisition of CDS.

(b) Borrowings

In November 2005, the Company issued a subordinated promissory note in the principal amount of US\$15 million (\$20.5 million) to an institutional investor. Refer to Note 7 for further information.

(c) Contingencies

Refer to Note 8 above.

(d) Other

pSivida Limited changed its accounting policies on July 1, 2005 to comply with A-IFRS. Prior to this transition date, the Company's consolidated financial statements were prepared in accordance with accounting principles generally accepted in Australia ("A-GAAP"), which differ in certain respects from US GAAP. Refer to pSivida's Form 20-F Annual Report for the year ended June 30, 2005, filed with the Securities and Exchange Commission, for the Company's consolidated A-GAAP financial statements as of June 30, 2005 and 2004 and for each of the three years in the period ended June 30, 2005, reconciled to US GAAP.