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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**

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**FORM F-3**  
**REGISTRATION STATEMENT**  
**UNDER**  
**THE SECURITIES ACT OF 1933**

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**pSivida Limited**

(Exact name of Registrant as specified in its charter)

**Western Australia,**  
**Commonwealth of Australia**  
(State or other jurisdiction of  
incorporation or organization)

**2834**

(Primary Standard Industrial  
Classification Code Number)

**Not Applicable**

(I.R.S. Employer  
Identification No.)

**Level 12 BGC Centre**  
**28 The Esplanade**  
**Perth WA 6000**  
**Australia**  
**61 (8) 9226 5099**

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

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

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.C. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.C. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.

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## CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered (1)	Amount to be Registered (2)	Proposed Maximum Offering Price Per Share	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Ordinary Shares underlying subordinated convertible note	40,453,080	\$0.515(3)	\$20,633,333(4)	\$2,209
Ordinary Shares underlying warrant	8,239,440	\$0.72(4)	\$5,932,397(5)	\$635

- (1) American Depositary Shares (“ADSs”) evidenced by American Depositary Receipts issuable on deposit of the equity shares registered hereby have been registered under a separate statement on Form F-6, Registration No. 333-122158. Each ADS represents ten ordinary shares.
- (2) Please refer to the “Selling Security Holder” section of the prospectus that is a part of this Registration Statement for a description of what comprises the ordinary shares being registered. In accordance with Rule 416(a), the Registrant is also registering hereunder an indeterminate number of ordinary shares that may be issued and resold to prevent dilution resulting from stock splits, stock dividends or similar transactions.
- (3) The average of the high and low prices of the Registrant’s ADSs on March 22, 2006 as reported on the NASDAQ National Market.
- (4) Estimated solely for the purposes of calculating the registration fee pursuant to Rule 475(o) of the Securities Act.
- (5) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g) of the Securities Act, based on the higher of (a) the exercise price of the warrants or (b) the offering price of securities of the same class included in this registration statement.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission acting pursuant to said Section 8(a), may determine.**

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any, jurisdiction where the offer or sale is not permitted.

Preliminary Prospectus, subject to completion, dated March 28, 2006.

## PSIVIDA LIMITED



4,869,252 American Depositary Shares  
representing 48,692,520 Ordinary Shares

The selling security holder of pSivida Limited identified on page 28 of this prospectus may offer and resell up to 4,869,252 of our American Depositary Shares, or ADSs, each of which is evidenced by an American Depositary 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 National 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 National Market under the symbol "PSDV." The last reported sale price of our ADSs on the NASDAQ National Market on March 22, 2006 was US\$5.05.

Our ordinary shares are listed on the Australian Stock Exchange under the symbol "PSD." On March 22, 2006, the closing price of our ordinary shares on the Australian Stock Exchange was A\$0.73, equivalent to a price of approximately US\$5.26 per ADS based on the Federal Reserve Bank of New York noon buying exchange rate on that date of A\$1.00 = US\$0.7204. 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 5.

**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.**

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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.*

*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, 2004, the Federal Reserve Bank of New York Noon Buying Rate was US\$0.6952 = A\$1.00, on June 30, 2005 such exchange rate was US\$0.7618 = A\$1.00 and on December 31, 2005 such exchange rate was US\$0.7342 = A\$1.00.*

### **THE COMPANY**

We are an Australian public company listed on the Australian Stock Exchange, the NASDAQ National 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™, 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 sustained-release drug delivery products. Our two proprietary drug delivery systems, AEON™ and CODRUG™, 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 for treatment of two sight threatening eye diseases. These two products, Vitrasert® and Retisert™, 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 DME, another leading cause of vision loss. Medidur, 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™ 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

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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 re-delivered 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 its 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 US presence, greater access to the US 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.

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 is convertible into ADSs at a conversion price of US\$7.10 per ADS, subject to adjustment

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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 is lower than US\$6.57. We also issued a warrant with a term of six years which entitles the selling shareholder to purchase up to 633,803 ADSs at US\$7.20 per ADS, also subject to adjustment upon specified events. We have 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, pSivida 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.

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.

On March 20, 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 Inc. involving our product Medidur.



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### **Results for the Half Year Ended December 31, 2005**

On March 16, 2006, we announced our unaudited half-year financial report for the half year ended December 31, 2005. The consolidated entity changed its accounting policies on July 1, 2005 to comply with Australian Equivalents to International Financial Reporting Standards, or A-IFRS (effective from July 1, 2005). 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.

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%. This decrease was the result of a reduction in interest received during the period based on lower average cash balances held.

Loss before income tax expense increased to A\$13,070,400 for the half year ended December 31, 2005 from A\$9,598,661 for the half year ended December 31, 2004, an increase of A\$3,471,739 or 36.2%. This increase was the result of an increase in professional fees, employee expenses and general office expenses due to increased corporate activities. These activities included private placements of shares in the form of ADSs and a convertible promissory note and the acquisition of CDS. Employee expenses increased 212% for the half year ended December 31, 2005 compared to the half year ended December 31, 2004 as a result of an increase in staff. Staff numbers, excluding directors, consultants and the staff of CDS, increased by 126% to 52 for the half year ended December 31, 2005 compared to 23 for the half year ended December 31, 2004, as a result of our increased research and development activities related to the applications of BioSilicon.

Research and development expense increased to A\$5,698,842 for the half year ended December 31, 2005 from A\$3,688,062 for the half year ended December 31, 2004, an increase of A\$2,010,780 or 54.5%. This increase is the result of the commencement of Phase IIb clinical trials with our product BrachySil as a potential new brachytherapy treatment for inoperable primary liver cancer.

Loss attributable to our shareholders increased to A\$10,702,745 for the half year ended December 31, 2005 from A\$7,330,165 for the half year ended December 31, 2004, an increase of A\$3,372,580 or 46.0%

Our cash balance increased to A\$27,683,278 for the half year period ended December 31, 2005, compared to A\$12,889,061 for the half year ended December 31, 2004 an increase of A\$14,791,217 or 215%, as a result of additional funding obtained by us in the private placements of ADSs and a convertible promissory note which resulted in gross proceeds of A\$4.3 million and A\$19.7 million respectively.

The half year report takes into account the completion on December 30, 2005 of our acquisition of CDS which is described above.

### **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.psvida.com](http://www.psvida.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.

## 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**

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

We are currently developing products based upon BioSilicon™, 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 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 Australian Equivalents to International Financial Reporting Standards, or 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 accounting principles generally accepted in Australia, or 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. 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.

***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

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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.

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 un-patented 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;

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- 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 diabetic macular edema, or 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. if pSivida Inc. fails to make a development payment or may terminate the agreement with respect to a particular product if pSivida Inc. notifies Alimera 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. Either

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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. Alimera Sciences was only incorporated in June 2003 and has limited resources. 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 entities.

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.

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

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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 (following our acquisition of CDS) the U.S.; BioSilicon is produced for us in Germany and the UK; we are conducting product trials in Singapore; 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;

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- 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 U.S. Food and Drug Administration, or 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 third-party 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.

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 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



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- 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 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.

### **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

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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 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 accounting principles generally accepted in the United States of America, or US 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 US 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.

### **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\$4.15 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;
- 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 National 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

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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 2,112,676 ADSs together with warrants to acquire an additional 633,803 ADSs. 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 U.S. Securities and Exchange Commission, or 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, 2007. We will shortly commence the evaluation and expect to complete it in the first 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 Item 8B, "Significant Changes."*

***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.

***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. Intangible assets are being amortized over a 12 year period on a straight line basis. Based on our preliminary allocation of the purchase price, which is subject to change based on the actual outcome of a third party independent valuation, the amount allocated to goodwill is approximately A\$29.7 million, the amount allocated to identifiable intangible assets is approximately A\$120.0 million, giving rise to a gross deferred tax liability of approximately A\$48.0 million (approximately A\$27.3 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

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goodwill has been allocated exceeds its recoverable value. If identifiable intangible assets 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\$2.5 million per quarter and A\$10.0 million per fiscal year. As a result, purchase accounting treatment of the merger could 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 have 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 are to be expensed in the period in which they are 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 9 months after the closing date of the merger.

### ***If the price of our ADSs does not rise above the conversion price by the time payment on the convertible note becomes due, we may have to repay all or part of the funds received in the convertible note financing.***

On November 16, 2005, we issued a subordinated convertible promissory note in the principal amount of US\$15 million (A\$19.7 million) to an institutional investor. 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 one-third of the principal on each of November 16, 2006, May 16, 2007 and November 16,

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2007 in the event that the average trading price of our ADSs does not exceed the then effective conversion price over the ten trading days leading up to any of those dates. The note is currently convertible at a conversion price of US\$7.10 per ADS, subject to adjustment based on certain events or circumstances, including the market price of ADSs for the ten trading days ended on August 5, 2006. We may make quarterly interest payments on the note 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, the PIPE 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 in certain situations, and our failure to meet this deadline results in monetary penalties against us.

With respect to the PIPE, we were required to complete the registration no later than February 19, 2006. Beginning on March 19, 2006, we may be subject to monthly cash penalties equal to one percent of the PIPE purchase price, or US\$43,225 (A\$59,200), until such registration statement becomes effective. With respect to the convertible note financing, we are required to complete the initial registration no later than 180 days from the date of the applicable agreement, which places the deadline on or about May 15, 2006. Failure to comply with this deadline may result in pSivida having to pay monthly cash penalties equal to one and one-half percent of the convertible note purchase price, or US\$225,000 (A\$308,200), until the registration statement becomes effective. Further, failure to comply with this deadline by in excess of sixty days may result in an event of default under the convertible note. With respect to the acquisition of CDS, we are required to complete the registration no later than 180 days from the closing of the merger, which would be on or about June 30, 2006. Failure to comply with this deadline may result in pSivida having to pay monthly cash penalties equal to one percent of the average closing price of the ADSs during the ten trading days ending on the day that is four trading days prior to the closing of the merger, multiplied by the number of outstanding unregistered ADSs, until the registration statement becomes effective. The average trading price of ADSs during the 10-day period just described was US\$5.087, which indicates that such penalties could amount to US\$813,089 (A\$1,113,700) per month. Each of these registration deadlines is subject to extension in certain circumstances. Once the registrations are completed, we are obligated to keep them effective for specified periods, and failure to do so may subject us to additional penalties.

### **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.

**CAPITALIZATION AND INDEBTEDNESS**

The following table sets forth our capitalization at January 31, 2006 and includes our acquisition of CDS on December 30, 2005. We have not included an “As Adjusted” column because we will receive no proceeds from the sale of ADSs by the selling security holder.

	<b>As of January 31, 2006 Actual (In Australian Dollars)</b>
<b>Indebtedness</b>	
Short-term debt (unsecured)	6,668,445
Long-term debt (unsecured)	11,144,576
<b>Total debt</b>	<b>17,813,021</b>
<b>Stockholders' equity (deficit)</b>	
Share capital	225,110,700
Reserves	3,878,892
Deficit accumulated prior to development stage	(3,813,181)
Deficit accumulated during development stage	(39,391,837)
<b>Total stockholders' equity</b>	<b>185,784,574</b>
<b>Total capitalization and indebtedness in accordance with A-IFRS</b>	<b>203,597,595</b>



**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 financial statements are prepared in accordance with US GAAP, and are derived from, and should be read in conjunction with, the historical 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 the historical consolidated financial statements of CDS which are incorporated by reference to our Supplemental Disclosure submitted on Form 6-K furnished to the SEC on December 22, 2005. Such unaudited pro forma consolidated financial statements are presented as if the acquisition of CDS had occurred on July 1, 2004 for the consolidated statement of operations and June 30, 2005 for the consolidated statement of financial position. 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 financial statements have been made based on available information and assumptions that pSivida's management believes are reasonable. The unaudited pro forma consolidated financial statements are for informational purposes only and do not purport to present what pSivida's results would actually have been had these transactions actually occurred on the dates presented or to project pSivida's results of operations or financial position for any future period. The unaudited pro forma consolidated financial statements 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 fourth quarter of the fiscal year ending June 30, 2006.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**Unaudited Pro Forma Consolidated Statement of Financial Position**  
**As of June 30, 2005**  
**(in Australian dollars)**

	pSivida Historical (3a)	CDS Historical (3b)	Pro Forma Adjustments		Pro Forma
<b>ASSETS</b>					
Current assets:					
Cash and cash equivalents	12,892,061	4,450,442	(5,363,466)	(3c)	11,979,037
Receivables	709,418	44,766			754,184
Receivables, related party		34,647			34,647
Other	322,933	137,450			460,383
<b>Total current assets</b>	<b>13,924,412</b>	<b>4,667,305</b>	<b>(5,363,466)</b>		<b>13,228,251</b>
Non-current assets:					
Property, plant and equipment, net	3,273,663	865,412			4,139,075
Intangible assets, net	61,068,502		120,000,000	(3d)	181,068,502
Goodwill	21,796,699		51,445,237	(3e)	73,241,936
<b>Total assets</b>	<b>100,063,276</b>	<b>5,532,717</b>	<b>166,081,771</b>		<b>271,677,764</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>					
Current liabilities:					
Payables	1,967,718	3,309,413	(676,557)	(3f)	4,635,236
Payables, related party	50,102	34,662			50,102
Deferred revenue		1,864,484			1,864,484
Provisions	29,879				29,879
<b>Total current liabilities</b>	<b>2,047,699</b>	<b>5,208,559</b>	<b>(676,557)</b>		<b>6,579,701</b>
Deferred tax liability, net	10,365,240	—	29,100,000	(3g)	39,465,240
<b>Total liabilities</b>	<b>12,412,939</b>	<b>5,208,559</b>	<b>28,423,443</b>		<b>46,044,941</b>
Commitments and contingencies					
Series A redeemable convertible preferred stock		38,035,845	(38,035,845)	(3h)	—
Stockholders' equity:					
Common stock and additional paid-in capital	117,798,149	16,362,738	124,361,454	(3i)	258,522,341
Deferred stock based compensation		(1,213,574)	1,213,574	(3j)	—
Accumulated other comprehensive loss	(272,067)				(272,067)
Deficit accumulated prior to development stage	(3,813,181)				(3,813,181)
Deficit accumulated during development stage	(26,062,564)	—	(2,741,706)	(3k)	(28,804,270)
Accumulated deficit		(52,860,851)	52,860,851	(3l)	—
<b>Total stockholders' equity (deficit)</b>	<b>87,650,337</b>	<b>(37,711,687)</b>	<b>175,694,173</b>		<b>225,632,823</b>
<b>Total liabilities and stockholders' equity</b>	<b>100,063,276</b>	<b>5,532,717</b>	<b>166,081,771</b>		<b>271,677,764</b>

See accompanying notes to the unaudited pro forma consolidated financial statements.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**Unaudited Pro Forma Consolidated Statement of Operations**  
**Year Ended June 30, 2005**  
**(in Australian dollars except number of shares)**

	pSivida Historical (3m)	CDS Historical (3n)	Pro Forma Adjustments		Pro Forma
<b>Revenues:</b>					
Collaborative research and development – related party		8,626,181			8,626,181
Collaborative research and development – other	161,666	158,385			320,051
Royalties – related party		4,142,445			4,142,445
<b>Total revenues</b>	<b>161,666</b>	<b>12,927,011</b>			<b>13,088,677</b>
<b>Operating expenses:</b>					
Depreciation and amortization expense	(6,207,733)	(495,177)	(10,000,000)	(3o)	(16,702,910)
Research and development expense	(8,287,930)	(2,831,869)	(1,536,555)	(3p)	(12,656,354)
Royalties expense, related party	—	(79,479)			(79,479)
Employee benefits expense	(1,165,025)		(771,528)	(3p)	(1,936,553)
Foreign currency loss	(1,623,484)				(1,623,484)
Corporate office expenses	(4,130,096)	(6,944,035)			(11,074,131)
<b>Total operating expenses</b>	<b>(21,414,268)</b>	<b>(10,350,560)</b>	<b>(12,308,083)</b>		<b>(44,072,911)</b>
Income (loss) from operations	(21,252,602)	2,576,451	(12,308,083)		(30,984,234)
Interest and other income (expense), net	667,310	(213,568)			453,742
Income (loss) before income tax benefit	(20,585,292)	2,362,883	(12,308,083)		(30,530,492)
Income tax benefit	3,645,504	—	3,978,080	(3q)	7,623,584
Income (loss) before outside equity interest	(16,939,788)	2,362,883	(8,330,003)		(22,906,908)
Net loss attributable to outside equity interest	378,276				378,276
Net income (loss)	(16,561,512)	2,362,883	(8,330,003)		(22,528,632)
Accretion of redeemable convertible preferred stock	—	(3,246,135)	3,246,135	(3r)	—
Net loss attributable to common stockholders	(16,561,512)	(883,252)	(5,083,868)		(22,528,632)
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		(5)	358,622,920

See accompanying notes to the unaudited pro forma consolidated financial statements.

**PSIVIDA LIMITED AND SUBSIDIARIES****Notes to Unaudited Pro Forma Consolidated Financial Statements  
(in Australian dollars)****1. Basis of Presentation**

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

**2. Purchase Price Allocation**

The purchase price of \$146,087,658 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 \$133,626,857 (\$0.886 per share, represented by US\$6.762 per ADS);
- § 9,016,230 nonvested ordinary shares of pSivida (represented by 901,623 nonvested ADSs), with an estimated fair value of \$6,411,358, 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;
- § 1,724,460 share options in pSivida (represented by 172,446 warrants over ADSs), with an estimated fair value of \$685,977; and
- § direct acquisition costs of \$5,249,147.

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.

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 and have been made solely for the purposes of developing such pro forma consolidated financial statements.

Following is a preliminary estimate of the allocation of the purchase price as of June 30, 2005:

	<b>Total fair value (in Australian dollars)</b>
Cash	4,450,442
Receivables	79,413
Other	137,450
Patents	120,000,000
In-Process Research and Development	2,741,706
Property, Plant and Equipment	865,412
Payables	(2,667,518)
Deferred Revenue	(1,864,484)
Deferred Tax Liability, Net	(29,100,000)
Total	94,642,421
Purchase price	146,087,658
Goodwill	51,445,237

**PSIVIDA LIMITED AND SUBSIDIARIES****Notes to Unaudited Pro Forma Consolidated Financial Statements  
(in Australian dollars)****3. Pro Forma Adjustments**

## Footnotes to the pro forma statements

- (a) Reflects the historical financial position of pSivida as of June 30, 2005 on a US GAAP basis. Refer to Note 27 of pSivida's audited consolidated financial statements 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, for a description of the differences between A-GAAP and US GAAP as they relate to pSivida and for a reconciliation to US GAAP of equity for the periods indicated therein.
- (b) Reflects the historical financial position of CDS as of June 30, 2005 on a US GAAP basis. The historical statement of financial position data was translated from US dollars to Australian dollars using an exchange rate of \$0.76 as at June 30, 2005.
- (c) Reflects the payment of the \$114,319 cash as partial consideration for the acquisition plus the payment of \$5,249,147 for direct acquisition costs.
- (d) Reflects the fair value of patents acquired (see Note 2). Such amount will be amortized over its estimated useful life which has been assumed to be 12 years for purposes of these pro forma financial statements.
- (e) Reflects the residual value of goodwill attributable to the acquisition. Goodwill is based on a provisional purchase price allocation and is equal to the difference between the purchase consideration and the estimated fair value of identifiable net assets acquired, as set forth above in Note 2. Goodwill is not amortized under US GAAP but is assessed for impairment at least annually.
- (f) Reflects the elimination of CDS' historical liabilities that pSivida did not assume in connection with the acquisition.
- (g) Reflects a deferred tax liability of \$48,000,000 attributable to the difference between the fair value and tax basis of the acquired patents, offset by a deferred tax asset of \$18,900,000 attributable to the acquired net operating loss carryforwards, using the CDS combined federal and state statutory tax rate of 40%. No valuation allowance has been recorded against the deferred tax asset taking into consideration the future reversal of taxable temporary differences. The actual utilization of the acquired net operating loss carryforwards may be subject to limitation due to the "change of ownership" provision of Section 382 of the Internal Revenue Code. The Company has not yet completed the calculation of this annual limitation. See Note 2.
- (h) Reflects the elimination of CDS Series A redeemable preferred stock.
- (i) Reflects the following adjustments (see Note 2):

	\$
Fair value of 150,820,380 pSivida ordinary shares issued	133,626,857
Fair value of 9,016,230 pSivida nonvested ordinary shares issued	7,988,379
Unearned compensation attributable to the above	(1,577,021)
Fair value of 1,211,180 pSivida nonvested ordinary shares issued	846,326
Unearned compensation attributable to the above	(846,326)
Fair value of 1,724,460 pSivida share options issued	685,977
Elimination of CDS common stock and APIC	(16,362,738)
	<u>124,361,454</u>

- (j) Reflects the elimination of CDS deferred stock compensation.

**PSIVIDA LIMITED AND SUBSIDIARIES**

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

- (k) Reflects the estimated write-off of in-process research and development related to the acquisition of CDS (see Note 2).
- (l) Reflects the elimination of CDS accumulated deficit.
- (m) Reflects the historical results of operations of pSivida for the year ended June 30, 2005 on a US GAAP basis. Refer to Note 27 of pSivida's audited consolidated financial statements 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, for a description of the differences between A-GAAP and US GAAP as they relate to pSivida and for a reconciliation to US GAAP of net loss for the periods indicated therein.
- (n) 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 12 months to December 31, 2004 (which are incorporated by reference to our Supplemental Disclosure submitted on Form 6-K furnished to the SEC on December 22, 2005) 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 financial performance 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.
- (o) Reflects the amortization of patents over an estimated useful life of 12 years as described in adjustment (d) above.
- (p) Reflects the amortization of the unearned compensation attributable to the pSivida nonvested shares, described in adjustment (i) above, over the service (vesting) period. The individual awards vest over a minimum service period of six months to a maximum service period of three years from the acquisition date.
- (q) Reflects the deferred tax benefit attributable to the reduction of the gross deferred tax liability described in adjustment (g) above over the 12 year amortization period of acquired patents, 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.
- (r) Reflects the elimination of accretion of the CDS Series A redeemable preferred stock due to the elimination of the stock as described in adjustment (h) above.

**4. In-process research and development**

As indicated in Note 2, pSivida incurred a charge related to this transaction for in-process research and development of \$2,741,706. Such adjustment has been excluded from the pro forma consolidated statement of operations as the charge is a non-recurring charge directly attributable to the acquisition.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**Notes to Unaudited Pro Forma Consolidated Financial Statements**  
**(in Australian dollars)**

**5. 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 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:

	Year ended June 30, 2005
Ordinary shares used to compute pSivida historical basic and diluted loss per share	207,802,540
Ordinary shares issued to former holders of shares of vested CDS common stock	74,307,640
Ordinary shares issued to former holders of shares of CDS convertible redeemable preferred stock	<u>76,512,740</u>
Ordinary shares used to compute pro forma basic and diluted loss per share	<u>358,622,920</u>

Securities that could potentially dilute earnings (loss) per share in the future, including the pSivida nonvested ordinary shares, share options, warrants and the 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.

## 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. The note may be converted into ADSs by the holder at any time prior to November 16, 2008 at a conversion price of US\$7.10 per ADS, subject to adjustment upon specified events, including a price-based weighted average 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 August 5, 2006, if such price is lower than US\$7.10. 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. The note bears interest at a rate of 8% per year, 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 similar to the provisions set forth in the convertible note and further subject to adjustment for stock splits, combinations or similar events. The warrant is exercisable immediately after the closing date of the private placement and expires six years from the date of issuance.

The gross proceeds of the private placement to us were \$15.0 million, or approximately \$19.6 million if the warrant is 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 4,869,252 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 National 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. The warrants are exercisable at any time before November 16, 2011 at a price of US\$7.20 per ADS, subject to adjustment upon specified events. We would use such proceeds for general corporate purposes.



## 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 warrants, 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 March 22, 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 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 a recent market price 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 note is convertible 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 which 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:

<u>Name of Selling Security Holder</u>	<u>Number of Ordinary Shares Owned Prior to Offering (1)</u>	<u>Maximum Number of Ordinary Shares to be Sold Pursuant to this Prospectus (2)(3)</u>	<u>Number of Ordinary Shares Owned After Offering</u>
Castlerigg Master Investments (4)	2,936,621	4,869,252	—

- (1) 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 warrant acquired in November 2005, in each case, which the selling security holder has the right to acquire within 60 days of March 22, 2006 assuming a conversion price of \$7.10. 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 and interest payments due after April 1, 2006 at a conversion price of \$5.15 and the full exercise of the selling security holder's warrant. 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 related warrant (assuming for purposes of such calculation, that the note and warrant were converted or exercised at a conversion price of \$5.15).
- (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.

### **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;

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- 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, broker-dealers 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 reallocated 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 \$292,614 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.

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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.

### 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 December 31, 2005, 387,009,956 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

<u>Fiscal Year Ended</u>	<u>High</u>	<u>Low</u>
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
June 30, 2001	A\$ 0.40	A\$ 0.21

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

<u>Quarter Ended</u>	<u>High</u>	<u>Low</u>
December 31, 2005	A\$ 0.94	A\$ 0.55
September 30, 2005	A\$ 0.945	A\$ 0.75
June 30, 2005	A\$ 0.935	A\$ 0.535
March 31, 2005	A\$ 1.25	A\$ 0.85
December 31, 2004	A\$ 1.43	A\$ 1.02
September 30, 2004	A\$ 1.16	A\$ 0.90
June 30, 2004	A\$ 1.34	A\$ 1.03
March 31, 2004	A\$ 1.44	A\$ 0.52
December 31, 2003	A\$ 0.70	A\$ 0.51
September 30, 2003	A\$ 0.69	A\$ 0.23

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

<u>Month Ended</u>	<u>High</u>	<u>Low</u>
February 28, 2006	A\$ 0.71	A\$ 0.57
January 31, 2006	A\$ 0.73	A\$ 0.60
December 31, 2005	A\$ 0.75	A\$ 0.58
November 30, 2005	A\$ 0.79	A\$ 0.55
October 31, 2005	A\$ 0.94	A\$ 0.72
September 30, 2005	A\$ 0.90	A\$ 0.80

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Our ADSs were listed on the NASDAQ National 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 National Market.

### **Quarterly High and Low Market Price for the Most Recent Fiscal Year and Any Subsequent Period on the NASDAQ National Market**

<b>Quarter Ended</b>	<b>High</b>	<b>Low</b>
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 National Market**

<b>Month Ended</b>	<b>High</b>	<b>Low</b>
February 28, 2006	US\$ 5.46	US\$ 4.40
January 31, 2006	US\$ 5.70	US\$ 4.68
December 31, 2005	US\$ 5.697	US\$ 4.21
November 30, 2005	US\$ 6.00	US\$ 4.21
October 31, 2005	US\$ 7.00	US\$ 5.20
September 30, 2005	US\$ 6.80	US\$ 6.02

## **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 financial statements of CDS for the year ending December 31, 2004, incorporated in this prospectus by reference from our report on Form 6-K furnished to the SEC on December 22, 2005 have been audited by PricewaterhouseCoopers LLP, an independent registered accounting firm, as stated in their report appearing therein, which is incorporated herein by reference, and have been so incorporated in reliance upon said report given upon their authority as experts in accounting and auditing.

## **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 pSivida or its directors, including judgments based on the civil liability provisions of the federal securities laws of the United States.

## 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	\$ 2,844
Transfer Agent Fees	\$ 194,770
Legal Fees and Expenses	\$ 75,000
Accounting Fees	\$ 15,000
Miscellaneous (including EDGAR filing costs)	\$ 5,000
<b>Total</b>	<b><u>\$ 292,614</u></b>

## 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](http://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 180 days 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;
- 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;
- 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;

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- Our report on Form 6-K furnished to the SEC on March 17, 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 for Corporate Affairs, General Counsel and Secretary  
pSivida Inc.  
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](http://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.

**PART II**  
**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 8. Indemnification of Directors and Officers**

**Constitution**

Our constitution states that we must, to the extent the person is not otherwise indemnified, indemnify every officer of pSivida or its wholly-owned subsidiaries and may indemnify our auditors against any liabilities to third parties arising from service to pSivida, except for any liabilities arising out of conduct involving a lack of good faith.

In addition, we may advance funds to cover legal costs incurred by any officer or auditor in defending against liabilities arising from service to pSivida.

The Australian Corporations Act 2001 permits a company to purchase and maintain insurance on behalf of directors, other officers or auditors of pSivida against any liability (other than legal costs) except liability arising out of conduct involving a willful breach of duty, the improper use of information acquired by virtue of his or her position, or the improper use of his or her position to gain an advantage for himself or herself or any other person, or to cause detriment to pSivida. Our constitution authorizes us to purchase and maintain liability insurance, subject to Australian law.

The indemnity in favor of officers is a continuing indemnity which applies in respect of all acts done by a person while an officer of pSivida or one of its wholly owned subsidiaries even though the person is not an officer at the time the claim is made.

Subject to Australian law, we may enter into an indemnification agreement with a person who is or has been an officer of pSivida or any of its subsidiaries, to give effect to the indemnification rights provided for in the Constitution.

**Australian Law**

Section 199A(1) of the Corporations Act 2001 (Commonwealth) provides that a company or a related body corporate must not exempt a person from a liability to the company incurred as an officer of the company. Section 199A(2) of the Corporations Act provides that a company or a related body corporate must not indemnify a person against any of the following liabilities incurred as an officer of the company:

- a liability owed to the company or a related body corporate;
- a liability for a pecuniary penalty order or compensation order under specified provisions of the Corporations Act; or
- a liability that is owed to someone other than the company or a related body corporate that did not arise out of conduct in good faith.

Section 199A(2) does not apply to a liability for legal costs.

Section 199A(3) provides that a company or a related body corporate must not indemnify a person against legal costs incurred in defending an action for a liability incurred as an officer of the company if the costs are incurred:

- in defending or resisting proceedings in which the person is found to have a liability for which they could not be indemnified under

Section 199A(2); or

- in defending or resisting criminal proceedings in which the person is found guilty; or
- in defending or resisting proceedings brought by the Australian Securities and Investments Commission (ASIC) or a liquidator for a court order if the grounds for making the order are found by the court to have been



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established (this does not apply to costs incurred in responding to actions taken by ASIC or a liquidator as part of an investigation before commencing proceedings for the court order); or

- in connection with proceedings for relief to the person under the Corporations Act in which the court denies the relief.

Section 199B of the Corporations Act provides that a company or a related body corporate must not pay, or agree to pay, a premium for a contract insuring a person who is or has been an officer of the company against a liability (other than one for legal costs) arising out of:

- conduct involving a willful breach of any duty in relation to the company; or
- a contravention of the officer's duties under the Corporations Act not to improperly use their position or make improper use of information obtained as an officer.

For the purpose of Sections 199A and 199B, an "officer" of a company includes:

- a director or secretary;
- a person who makes, or participates in making, decisions that affect the whole, or a substantial part, of the business of the company;
- a person who has the capacity to significantly affect the company's financial standing; and
- a person in accordance with whose instructions or wishes the directors of the company are accustomed to act.

### **Item 9. Exhibits**

<b>Exhibit No.</b>	<b>Exhibit Title</b>
2.1	Merger Agreement, dated October 3, 2005, among pSivida Limited, pSivida Inc., and Control Delivery Systems Inc. (c)
4.1	Deposit Agreement, by and among pSivida Limited, Citibank, N.A. and the Holders and Beneficial Owners of American Depositary Shares Evidenced by American Depositary Receipts Issued Thereunder (b)
4.2	Securities Purchase Agreement, dated October 5, 2005, between pSivida Limited and the investor listed on the Schedule of Buyers attached thereto (d)
4.3	Form of Subordinated Convertible Note in the principal amount of US\$15,000,000 (d)(e)
4.4	Form of Warrant to Purchase ADRs for the purchase of up to 633,803 ADRs (d)(e)
4.5	Form of Registration Rights Agreement (d)(e)
4.6	Letter Agreement, dated November 15, 2005, relating to the Securities Purchase Agreement (d)
4.7	Note Amendment Agreement, dated February 22, 2006, between pSivida Limited and Castlerigg Master Investments Ltd. (f)
5.1	Legal Opinion of Blake Dawson Waldron LLP*
23.1	Consent of PricewaterhouseCoopers LLP, dated March 24, 2006 (a)
23.2	Consent of Deloitte Touche Tohmatsu dated, March 27, 2006 (a)
23.3	Consent of Blake Dawson Waldron LLP (to be contained in the opinion filed as Exhibit 5.1 to this Registration Statement)*
24.1	Power of Attorney (included on the signature page of this Registration Statement)

\* To be filed by amendment.

- (a) Filed herewith.
- (b) Incorporated by reference to the registrant's filing on Form F-6 (Commission file number 333-122158) filed on January 19, 2005.
- (c) Incorporated by reference to the registrant's later filing on Form 6-K (Commission file number 000-51122) filed on October 4, 2005. The agreement filed omitted certain schedules containing immaterial information; the registrant agrees to furnish supplemental copies of any omitted schedules to the Commission upon request.
- (d) Incorporated by reference to the registrant's filing on Form 6-K (Commission file number 000-51122) filed on November 15, 2005.
- (e) The final versions of documents denoted as "Form of" have been omitted pursuant to Rule 12b-31. pSivida Limited has entered into such agreements with the participant in the convertible note sale. Such final versions are

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substantially identical in all respects except for the inclusion of the investor's and/or pSivida's signature in the final versions.

(f) Incorporated by reference to the registrant's earlier filing on Form 6-K (Commission file number 000-51122) filed on February 23, 2006.

### **Item 10. Undertakings**

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
  - (i) To include any prospectus required in Section 10(a)(3) of the Securities Act of 1933;
  - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and
  - (iii) To include any material information with respect to the "Plan of Distribution" not previously disclosed in the registration statement or any material change to such information in the registration statement;

*Provided, however, that:*

- (A) Paragraphs (1)(i) and (1)(ii) of this section do not apply if the registration statement is on Form S-8, and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement; and
  - (B) Paragraphs (1)(i), (1)(ii) and (1)(iii) of this section do not apply if the registration statement is on Form S-3 or Form F-3 and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424 (b) that is part of the registration statement.
  - (C) *Provided further, however,* that paragraphs (1)(i) and (1)(ii) do not apply if the registration statement is for an offering of asset-backed securities on Form S-1 or Form S-3, and the information required to be included in a post-effective amendment is provided pursuant to Item 1100(c) of Regulation AB.
- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof;
  - (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering;
  - (4) To file a post-effective amendment to the registration statement to include any financial statements required by Item 8.A of Form 20-F at the start of any delayed offering or throughout a continuous offering. Financial statements and information otherwise required by Section 10(a)(3) of the Securities Act of 1933 need not be furnished, provided, that the registrant includes in the prospectus, by means of a post-effective amendment, financial statements required pursuant to this paragraph (4) and other information necessary to

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ensure that all other information in the prospectus is at least as current as the date of those financial statements. Notwithstanding the foregoing, with respect to registration statements on Form F-3, a post-effective amendment need not be filed to include financial statements and information required by Section 10(a)(3) of the Securities Act or Rule 3-19 if such financial statements and information are contained in periodic reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in Form F-3;

- (5) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:
- (i) If the registrant is relying on Rule 430B:
    - (A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and
    - (B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or
  - (ii) If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.
- (6) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

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Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the provisions described under Item 8 above, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Perth, Western Australia on March 17, 2006.

PSIVIDA LIMITED

By: /s/ Gavin Rezos  
Name: Gavin Rezos  
Title: Chief Executive Officer and Managing Director

By: /s/Aaron Finlay  
Name: Aaron Finlay  
Title: Chief Financial Officer and Company Secretary

Each of the undersigned hereby constitutes and appoints Gavin Rezos and Aaron Finlay, in each case acting individually, his true and lawful attorney-in-fact, with power of substitution and resubstitution, in his name, place and stead, in any and all capacities, to sign any or all amendments, including post-effective amendments, and supplements to this Registration Statement or any related registration statement that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that each said attorney-in-fact, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the U.S. Securities Act of 1933, as amended, this Registration Statement has been signed by or on behalf of the following persons in the capacities indicated as of March 17, 2006.

<u>Name</u>	<u>Title</u>
<u>/s/ Roger Brimblecombe</u> Name: Roger Brimblecombe	Chairman of the Board of Directors, Non-Executive Director
<u>/s/ Gavin Rezos</u> Name: Gavin Rezos	Chief Executive Officer and Managing Director (principal executive officer)
<u>/s/ David Mazzo</u> Name: David Mazzo	Director
<u>/s/Aaron Finlay</u> Name: Aaron Finlay	Chief Financial Officer and Company Secretary (principal accounting officer)
<u>/s/Paul Ashton</u> Name: Paul Ashton	Director; Authorized Representative in the United States
<u>/s/ Stephen Lake</u> Name: Stephen Lake	Director
<u>/s/ Michael W. Rogers</u> Name: Michael W. Rogers	Director
<u>/s/ Heather Zampatti</u> Name: Heather Zampatti	Director

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in this Registration Statement on Form F-3 of our report dated December 2, 2005 relating to the financial statements which appears in pSivida Limited's Form 6-K for the year ended December 31, 2004. We also consent to the references to us under the headings "Experts" in such Registration Statement.

/s/ PricewaterhouseCoopers LLP

PricewaterhouseCoopers LLP  
Boston, Massachusetts  
March 24, 2006

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Registration Statement on Form F-3 of our report dated December 14, 2005 (January 12, 2006 as to Note 19), relating to the financial statements of pSivida Limited appearing in the Annual Report on Form 20-F of pSivida Limited for the year ended June 30, 2005 and to the reference to us under the heading "Experts" in the Prospectus, which is part of this Registration Statement.

/s/ Deloitte Touche Tohmatsu

DELOITTE TOUCHE TOHMATSU  
Perth, Australia  
March 28, 2006

