



---

**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 6-K**

**REPORT OF FOREIGN ISSUER  
Pursuant to Rule 13a-16 or 15d-16 of  
the Securities Exchange Act of 1934**

**For the month of December 2005**

**Commission File Number 000-51122**

**pSivida Limited**

(Translation of registrant's name into English)

Level 12 BGC Centre  
28 The Esplanade  
Perth WA 6000

(Address of principal executive offices)

(Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F).

Form 20-F       Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes       No

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82- \_\_\_\_.

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant, pSivida Limited, has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: December 22, 2005

pSivida Limited

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

---

---

**EXHIBIT INDEX**

**EXHIBIT 99.1:** Supplemental Disclosure of pSivida Limited related to its Information Statement, dated December 22, 2005

**EXHIBIT 99.1**

**SUPPLEMENTAL DISCLOSURE OF PSIVIDA LIMITED RELATED TO ITS INFORMATION STATEMENT, DATED DECEMBER 22, 2005**

As previously announced, pSivida Limited (the “Company”) has entered into a definitive agreement and plan of merger, dated October 3, 2005 (the “Merger Agreement”), with Control Delivery Systems, Inc. (“CDS”) and pSivida Inc. (“Acquisition Sub”), a wholly owned subsidiary of the Company, pursuant to which CDS will merge with and into Acquisition Sub and become a wholly owned subsidiary of the Company (the “Merger”). In connection with issuance of the Company’s American Depositary Shares (“ADSs”) in the transactions contemplated by the Merger Agreement, the Company is distributing a confidential information statement to the stockholders of CDS. The Company is furnishing as an exhibit to a Report of Foreign Issuer on Form 6-K this Supplemental Disclosure regarding its business which was contained in the confidential information statement relating to the merger.

**THE ADSs ISSUED IN THE MERGER HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND MAY NOT BE OFFERED OR SOLD IN THE UNITED STATES ABSENT REGISTRATION OR AN APPLICABLE EXEMPTION FROM REGISTRATION REQUIREMENTS.**

**THIS SUPPLEMENTAL DISCLOSURE SHALL NOT CONSTITUTE AN OFFER TO SELL OR A SOLICITATION OF AN OFFER TO BUY ANY SECURITIES.**

Except as otherwise indicated in the supplemental information set forth below, or as the context may otherwise require references to “pSivida “ or like terms refer to pSivida Limited and its subsidiaries and references to “CDS” refer to Control Delivery Systems, Inc.

YOU SHOULD ASSUME THAT THE INFORMATION CONTAINED IN THIS SUPPLEMENTAL DISCLOSURE IS ACCURATE AS OF THE DATE HEREOF ONLY. PSIVIDA’S AND CDS’ BUSINESS, FINANCIAL CONDITION, RESULTS OF OPERATIONS AND PROSPECTS MAY HAVE CHANGED SINCE THAT DATE. THE PARTIES RESERVE THE RIGHT TO, BUT ARE NOT OBLIGATED TO, REVISE THE INFORMATION OR THE MATERIALS CONTAINED THEREIN.

In accordance with General Instruction B of Form 6-K, the information set forth in this Supplemental Disclosure shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing. The information set forth in this Supplemental Disclosure shall not be deemed an admission as to the materiality of any information in this Supplemental Disclosure.

**TABLE OF CONTENTS**

Special Information Regarding Forward-Looking Statements	2
Risk Factors	3
Unaudited Pro Forma Consolidated Financial Information	11
pSivida Information	22
CDS Information	72
Consolidated Statements of Financial Position of pSivida Limited and Subsidiaries	F-1
Consolidated Financial Statements of Control Delivery Systems, Inc	G-2

---

## SPECIAL INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This information statement contains forward-looking statements that involve risks and uncertainties. Words such as “anticipate,” “believe,” “plan,” “expect,” “intend,” “could,” “estimate,” “may,” “should,” “will,” “future,” “potential” and similar expressions to identify such forward-looking statements. There is no assurance that the expectations reflected in such forward-looking statements will prove to be correct. Given these uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. pSivida’s and CDS’ actual results could differ materially from those anticipated in these forward-looking statements due to many important factors some of which are contained in cautionary statements in this information statement, including, without limitation, the forward-looking statements included in this information statement and specifically under “Risk Factors.”

All subsequent written and oral forward-looking statements attributable to pSivida and/or CDS are expressly qualified in their entirety by reference to these cautionary statements.

## RISK FACTORS

*You should carefully read and consider the risks described below, together with all of the information included in this information statement.*

### RISKS RELATING TO pSIVIDA

#### ***Risks Relating to pSivida’s Business***

*All of pSivida’s products and planned products are based upon new and unproven technologies.*

pSivida is currently developing products based upon BioSilicon, a biocompatible and biodegradable form of the element silicon, for multiple applications across many sectors of healthcare. pSivida’s core product focus is on controlled slow release drug delivery and diagnostics. Other potential applications for BioSilicon include uses in 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. pSivida’s failure to develop products based on BioSilicon that overcome these risks would have a material adverse effect on pSivida’s business, financial condition and results of operations.

*pSivida has a history of losses; pSivida expects to continue to incur losses; and pSivida may never become profitable.*

pSivida was formed in 2000. As pSivida is primarily a research and development company, it has incurred operating losses in every year of existence. It has 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 June 30, 2005, it had an accumulated loss of A\$27.9 million. pSivida has not achieved profitability and expects to continue to incur net losses through at least 2007, and it may incur losses beyond that time, particularly if it is not successful in having BrachySil approved and widely marketed by that time. Even if BrachySil is approved and being marketed at some point in 2007 or beyond, pSivida 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 pSivida to achieve profitability are uncertain.

*pSivida relies heavily upon patents, trade secrets and other proprietary technologies and any future claims that its rights to such intellectual property are invalid could seriously harm pSivida’s business.*

Protection of intellectual property rights is crucial to pSivida’s business, since that is how it keeps others from copying the innovations which are central to its proposed products. pSivida’s success is dependent on whether it can obtain patents, defend its existing patents and operate without infringing on the proprietary rights of third parties. pSivida currently has 34 patents and 82 pending patent applications, including patents and pending applications covering BioSilicon and various of its uses. pSivida expects to aggressively patent and protect its proprietary technologies. However, pSivida cannot be sure that any additional patents will be issued as a result of its pending or future patent applications or that any of its patents will withstand challenges by others. If pSivida were determined to be infringing any third party patent, it could be required to pay damages, alter its products or processes, obtain licenses or cease certain operations. pSivida may not be able to obtain any required licenses on commercially favorable terms, if at all. pSivida’s failure to obtain a license for any technology that it may require to commercialize BioSilicon could have a material adverse effect on pSivida’s business, financial condition and results of operations. In addition, many of the laws of foreign countries in which pSivida intends to operate may treat the protection of proprietary rights differently from, and may offer less protection than, the laws in Australia, the United States and other Patent Co-operation Treaty countries.

## Table of Contents

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

pSivida relies, in part, on confidentiality agreements with employees, advisors, vendors and consultants to protect pSivida's proprietary expertise. These agreements may be breached and pSivida may not have adequate remedies in the event of a breach. In addition, pSivida's un-patented proprietary technological expertise may otherwise become known or independently discovered by competitors.

*pSivida has a limited ability to market products itself, and if pSivida is unable to find marketing partners for, or pSivida's marketing partners do not successfully market, its future products, pSivida's business will suffer.*

pSivida presently has no marketing or sales staff. Achieving acceptance for the use of BioSilicon will require extensive and substantial efforts by experienced personnel as well as expenditure of significant funds. pSivida may not be able to establish sufficient capabilities necessary to achieve market penetration.

pSivida intends to license and/or sell BioSilicon to companies that will be responsible in large part for sales, marketing and distribution of products utilizing BioSilicon. The amount and timing of resources that may be devoted to the performance of their contractual responsibilities by these licensees are not expected to be within pSivida's control. These partners may not perform their obligations as expected. pSivida may not derive any revenue from such arrangements from royalties, license or option fees, milestone payments or otherwise.

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

To the extent that pSivida chooses not to or pSivida is unable to enter into future license agreements with marketing and sales partners, it would experience increased capital requirements to develop the ability to market and sell future products. pSivida may not be able to market or sell its technology or future products independently in the absence of such agreements.

*pSivida's markets are competitive, and its competitors could develop more effective products, making pSivida's proposed products uncompetitive, uneconomical or obsolete, thereby impacting its future operations.*

pSivida is or plans to be engaged in the rapidly evolving and competitive fields of drug delivery, tissue engineering, diagnostics and orthopedics technologies. Its competitors include many major pharmaceutical companies and other biotechnology, drug delivery, diagnostics and medical products companies.

Many of pSivida's potential competitors have substantially greater financial, technological, research and development, marketing and personnel resources. pSivida's competitors may succeed in developing

## Table of Contents

alternate technologies and products that are more effective, easier to use, more economical than those that pSivida is seeking to develop or that would render pSivida's technologies and proposed products obsolete, uncompetitive or uneconomical 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 and technologies.

pSivida's competitive position will be based upon its 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 its products and processes;
- obtain required government approvals on a timely basis;
- manufacture products on a cost-effective basis; and
- successfully market products.

If pSivida is not successful in meeting these goals, its business could be adversely affected.

*pSivida faces risks in expanding its efforts beyond its core areas of experience and expertise.*

pSivida plans to expand its focus outside of its areas of experience and expertise to seek to broaden its product pipeline and will require additional internal expertise or external collaborations in areas in which it currently does not have internal resources and expertise. Such expertise and collaborations may be difficult to obtain. pSivida may have to enter into collaboration arrangements with others that may require it to relinquish rights to certain of its technologies or products that pSivida would otherwise pursue independently. pSivida may be unable to acquire the necessary expertise or enter into collaboration agreements on acceptable terms.

*Problems associated with international business operations could adversely affect pSivida's ability to manufacture and sell its products.*

pSivida currently maintains offices in Australia and the UK and, assuming the successful completion of the merger, the U.S.; BioSilicon is produced for pSivida in Germany and the UK; pSivida is conducting product trials in Singapore and intends to seek to license and/or sell products based on BioSilicon in most major world healthcare markets. A number of risks are inherent in pSivida's international strategy. In order for pSivida to license and manufacture products based on BioSilicon, it must obtain country-specific regulatory approvals or clearances or comply with regulations regarding safety and quality in each jurisdiction. pSivida may not be able to obtain or maintain regulatory approvals or clearances in such countries, and it may be required to incur significant costs in obtaining or maintaining foreign regulatory approvals or clearances. In addition, if pSivida obtains such approvals, its international operations will be subject to a number of risks associated with foreign commerce, including the following:

- managing foreign distributors;
- staffing and managing foreign operations;
- political and economic instability;
- foreign currency exchange fluctuations;
- foreign tax laws, tariffs and freight rates and charges;
- timing and availability of export licenses;

## Table of Contents

- 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 pSivida's future profitability.*

pSivida's ability to conduct timely preclinical and clinical research and development programs, obtain regulatory approval, and commercialize its product candidates will depend, in part, upon pSivida's ability to manufacture its products, either directly or through third parties, in accordance with U.S. Food and Drug Administration, or FDA, and other regulatory requirements. pSivida currently has BioSilicon production capability at its own facilities in the UK, which may be augmented where required by QinetiQ's UK production facilities for use in internal and collaborative research. pSivida's lead product candidate, BrachySil, is currently manufactured under contract by Hosokawa Micron Group, Atomising Systems Ltd, HighForce Ltd and AEA Technology QSA GmbH.

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

pSivida's dependence upon third parties for the manufacture of some of its products may adversely affect its profit margins and its ability to develop and deliver products on a timely and competitive basis.

*pSivida's ability to commercialize its proposed products depends on its ability to achieve regulatory approvals.*

pSivida's current and future activities are and will be subject to regulation by governmental authorities in the U.S., Europe, Singapore and other countries. To clinically test, produce and market medical products for human use, pSivida and those that license the use of BioSilicon for such uses must satisfy mandatory procedural, safety and efficacy requirements established by the FDA and comparable state and foreign regulatory agencies. Typically, such rules require that products be approved by the government agency as safe and effective for their intended use prior to being marketed. The approval process is expensive, time consuming and subject to unanticipated delays. BrachySil and other product candidates utilizing BioSilicon may not be approved. In addition, while pSivida intends to apply to have BioSilicon regulated as a device, the FDA may determine to regulate it as a drug, in which case pSivida would incur significant additional cost and time in order to achieve the required regulatory approvals. Any product approvals pSivida achieves could also be withdrawn for failure to comply with regulatory standards or due to unforeseen problems after the product's marketing approval.

Testing is necessary to determine safety and efficacy before a submission may be filed with the FDA to obtain authorization to market regulated products. In addition, 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 pSivida from obtaining, or affect the timing of, future regulatory approvals.



## Table of Contents

*Sivida's proposed products will be subject to the uncertainty of third-party reimbursement and healthcare reform measures which may limit market acceptance.*

In both domestic and foreign markets, pSivida's ability to commercialize its proposed 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 pSivida's 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 pSivida's products, the market acceptance of its 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 healthcare system of the U.S. It is uncertain what legislative proposals will be adopted or what actions federal, state or private payors for healthcare goods and services may take in response to any healthcare reform proposals or legislation. pSivida cannot predict the effect healthcare reforms may have on its business.

*The loss of some or all of pSivida's key personnel could harm its business.*

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

*pSivida may be subject to product liability suits, and it may not have sufficient insurance to cover damages.*

The testing, manufacturing, and future marketing and sale of the products utilizing BioSilicon involves risks that product liability claims may be asserted against pSivida or any future licensees. pSivida's current clinical trial insurance may not be adequate or continue to be available, and pSivida may be unable to obtain adequate product liability insurance, on reasonable commercial terms, if at all. In the event such insurance is not adequate or is not available, pSivida's ability to continue with planned research and development or to market and sell its proposed products could be negatively impacted.

*pSivida will need additional capital to conduct its operations and develop its products, and pSivida's ability to obtain the necessary funding is uncertain.*

pSivida expects to require additional capital resources in order to conduct its operations and develop its proposed products. The timing and degree of any future capital requirements will depend on many factors, including:

- the accuracy of the assumptions underlying pSivida's estimates for its capital needs in the near and long term;
- continued scientific progress in pSivida's research and development programs;
- the magnitude and scope of pSivida's research and development programs;

## Table of Contents

- pSivida's ability to maintain and establish strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- pSivida's progress with preclinical and clinical trials;
- the time and costs of obtaining regulatory approvals; and
- the costs of preparing, filing, prosecuting, maintaining, defending and enforcing patent claims.

If and when required, pSivida will attempt to acquire additional funding through strategic collaborations, public or private equity or debt financings, capital lease transactions or other financing techniques and 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 pSivida to relinquish rights to some of its technologies, product candidates or products that pSivida would otherwise seek to develop and commercialize itself. If sufficient capital is not available, pSivida may be required to delay, reduce the scope of or eliminate one or more of its research or development programs, each of which could have a material adverse effect on its business.

*pSivida has experienced rapid growth and change in its business, and pSivida's failure to manage this and any future growth and change could harm its business.*

As evidenced by pSivida's purchase of the remaining shares of pSiMedica as of August 4, 2004 and the incorporation and potential spin-off of AION Diagnostics, pSivida's business is rapidly changing.

pSivida expects to continue increasing the number of its employees and expanding its business, and pSivida may suffer if it does not manage and train its new employees effectively and operate efficiently. Further, pSivida's efforts span various geographies. Continued rapid growth and operation in multiple geographies may place significant strains on pSivida's managerial, financial and other resources. The rate of any future expansion, in combination with pSivida's complex technologies and products, will demand managerial effectiveness in anticipating, planning, coordinating and meeting pSivida's operational needs which pSivida cannot assure it will provide.

In addition, if pSivida makes acquisitions, such as the merger, or divestitures, it could encounter difficulties that harm its business. pSivida may acquire companies, products or technologies that it believes to be complementary to its business. If it does so, pSivida may have difficulty integrating the acquired personnel, operations, products or technologies. In addition, acquisitions may distract its management and employees and increase pSivida's expenses, which could harm its business. pSivida may also sell businesses or assets as part of its strategy or if it receives offers from third parties. If pSivida does so, it may sell an asset or business for less than its full value or may lose valuable opportunities attendant to such asset or business.

*If pSivida fails to comply with environmental laws and regulations, its 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. pSivida is subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and waste products. pSivida 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 pSivida for injury or contamination that results from its use or the use by third parties of these materials, and pSivida's liability may exceed its total assets. Compliance with environmental laws and regulations is expensive, and current or future environmental regulations may impair pSivida's research, development or production efforts or harm its operating results.

***Risks Relating to pSivida's Location Outside of the United States***

*You may have difficulty in effecting service of legal process and enforcement of judgments against pSivida or its management.*

pSivida is a public company limited by shares, registered and operating under the Australian Corporations Act 2001. Several of pSivida's directors and all of its current 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, substantially all of pSivida's directly owned assets are outside the U.S., and, as such, any judgment obtained in the U.S. against pSivida may not be collectible within the U.S. There is doubt as to the enforceability in the Commonwealth of Australia, in original actions or in actions for enforcement of judgments of U.S. courts, of civil liabilities predicated solely upon federal or state securities laws of the U.S., especially in the case of enforcement of judgments of U.S. courts where the defendant has not been properly served in Australia.

*As a foreign private issuer, pSivida does not have to provide you with the same information as an issuer of securities based in the U.S.*

Because pSivida is a foreign private issuer within the meaning of the rules under the Exchange Act, it is 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 and 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 that would be made available to you by a U.S. public corporation.

In accordance with the requirements of the Australian Stock Exchange, pSivida discloses annual and semi-annual results. pSivida's results are presented in accordance with Australian accounting principles. Its annual results are fully audited with limited reconciliation to U.S. generally accepted accounting principles, and its semi-annual results undergo a limited review by pSivida's independent auditors. Subject to certain exceptions, pSivida is also required to immediately disclose to the Australian Stock Exchange any information concerning it that a reasonable person would expect to have a material effect on the price or value of its shares. This would include matters such as (i) any major new development relating to pSivida's business which are not public knowledge and may lead to a substantial movement in pSivida's share price; (ii) any changes in pSivida's board of directors; (iii) any purchase or redemption by pSivida of pSivida's own equity securities; (iv) interests of directors in pSivida's shares or debentures; and (v) changes in pSivida's capital structure. pSivida is required to provide its semi-annual results and other material information that it discloses in Australia in the U.S. under the cover of SEC Form 6-K. Nevertheless, this information may not be the same or as much information as would be made available to you were you investing in a U.S. public corporation. Further, pSivida is not subject to the requirements of Sarbanes Oxley Act of 2002 to the same extent as U.S. issuers.

***Risks Relating to pSivida's Ordinary Shares and ADSs***

*If pSivida is a passive foreign investment company, holders of pSivida shares and ADSs may suffer adverse tax consequences.*

U.S. holders of pSivida's ADSs can experience unfavorable tax consequences if pSivida is 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 pSivida's ADSs. For example, if a U.S. holder disposes of a pSivida ADS at a gain, and during any year of its holding period pSivida was 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.

## Table of Contents

In general, pSivida will be a PFIC for any taxable year if either (1) 75% or more of its gross income in the taxable year is passive income, or (2) 50% or more of the average value of pSivida's assets in the taxable year produces, or is held for the production of, passive income. pSivida does not yet know whether it 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 this information statement under "Certain Income Tax Consequences of Owning pSivida's ADSs." In the event it is classified as a PFIC, pSivida intends to provide U.S. holders with sufficient information to enable them to make a mitigating election if so desired. However, pSivida may fail to provide such information, and if it does, you may not be aware of its status as a PFIC and may be subject to additional taxes and penalties.

*Holders of ADSs may have limited rights relative to holders of pSivida's ordinary shares in certain circumstances.*

The rights of holders of pSivida 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 pSivida and Citibank, N.A. For example, although pSivida ADS holders are entitled under the deposit agreement, subject to any applicable provisions of Australian law and of pSivida's constitution, to instruct the depository as to the exercise of the voting rights pertaining to the ordinary shares represented by the pSivida ADSs, and the depository has agreed that it will, as far as practical, vote the ordinary shares so represented in accordance with such instructions; pSivida may not provide voting materials to the depository in time for the depository to solicit instructions from ADS holders. This means that holders of pSivida ADSs may not be able to exercise their right to vote. In addition, under the deposit agreement, the depository has the right to restrict distributions to holders of the pSivida ADSs in the event that it is unlawful or impractical to make such distributions. pSivida has no obligation to take any action to permit distributions to holders of its ADSs. As a result, holders of pSivida ADSs may not receive distributions made by pSivida.

*The trading prices of pSivida's ordinary shares and ADSs are volatile and can fluctuate significantly based on events both within and outside pSivida's control including general market and industry conditions.*

Since December 2000, the price of pSivida's ordinary shares has ranged from A\$0.09 to A\$1.44 per share, and since January 27, 2005, the price of pSivida's ADSs has ranged from US\$4.15 to US\$12.14. The price of pSivida's common shares and ADSs may be affected by developments directly affecting pSivida and by developments out of its 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 pSivida's, can swing dramatically, in ways unrelated or that bear a disproportionate relationship to operating performance. pSivida's share and ADS prices and their trading volume may fluctuate based 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 pSivida's 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 pSivida's markets;
- advancements with respect to treatment of the diseases targeted by pSivida's proposed products;
- developments relating to collaborative partners including execution and termination of agreements, achievement of milestones and receipt of payments;

## Table of Contents

- availability and cost of capital and pSivida's financial and operating results;
- changes in reimbursement policies or other practices related to pSivida's 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 pSivida and the biotechnology industry.

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

*The fact that pSivida does not expect to pay cash dividends may lead to decreased prices for its stock.*

pSivida has never paid a cash dividend on its ordinary shares, and it does not anticipate paying any cash dividends as pSivida's future profitability is uncertain. pSivida intends to retain future cash earnings, if any, for reinvestment in the development and expansion of its business. pSivida's convertible note agreement limits pSivida's ability to pay cash dividends.

*Future issuances and sales of pSivida's ordinary shares or ordinary share derivatives could dilute your ownership in pSivida and cause its stock and ADS prices to decline.*

As of September 30, 2005, pSivida has outstanding options to purchase 19,561,713 of its ordinary shares, representing 8.7% of the total outstanding ordinary shares, and has received shareholder approval to grant options with respect to an additional 10,574,790 ordinary shares. In 2005, pSivida raised capital through the issuance of 665,000 pSivida ADSs and warrants to acquire 133,000 pSivida ADSs and issued a convertible note currently convertible into 2,112,676 pSivida ADSs together with warrants to acquire an additional 633,803 pSivida ADSs. In addition, under certain circumstances, the convertible note will become convertible into a larger number of pSivida 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 pSivida ADSs. Exercise and conversion of these options, warrants and convertible securities would dilute existing shareholders. Further, pSivida intends to continue to finance its operations through the issuance of equity securities, if feasible.

*Certain of pSivida's shareholders own a significant percentage of its ordinary shares and therefore may be able to influence its business in ways that are less beneficial to you.*

Excluding QinetiQ Group, pSivida's executive officers, directors and their affiliates beneficially own or control approximately 11.98% of its outstanding ordinary shares (based on the number of pSivida's ordinary shares outstanding on September 30, 2005 and assuming the issuance of ordinary shares upon the exercise of options vested or vesting within 92 days of September 30, 2005). QinetiQ, which independently owns approximately 15.8% of pSivida's outstanding ordinary shares (computed on the same basis), has pledged that, until October 26, 2009, as long as it holds 10% or more of pSivida's outstanding ordinary shares it will vote all of its ordinary shares along with the vote of the majority of the proxy votes exercisable by validly appointed proxies in relation to the relevant resolution. Therefore, QinetiQ's ordinary shares are effectively not counted toward any vote of pSivida's shareholders on a resolution that is required to be passed by a simple majority. As a result, if pSivida's executive officers and directors were all to vote in the same way, their votes would constitute up to approximately 14.0% of the voting power of its

## [Table of Contents](#)

ordinary shares which would give them ability to exert significant influence over pSivida's board of directors and how pSivida operates its business. The concentration of ownership may also have the effect of delaying, deferring or preventing a change in control of pSivida.

### **RISKS RELATING TO CDS AND CDS' BUSINESS**

The following risks relate to CDS and its business on an independent, stand-alone basis and do not reflect any changes that may be effected by the merger, if it is consummated.

*Additional capital, which CDS expects to require, may not be available at the right times, on acceptable terms or at all, and CDS may need to further curtail or cease operations.*

Since 2003, CDS has significantly cut back its research and development program, undertaken two workforce reductions, significantly reduced its operations and sold its real estate to reduce expenditures and conserve cash following Bausch & Lomb's decision to cease funding research and development by CDS. In order to continue, alone or with others, the research, development, clinical testing, manufacturing and commercialization of its proposed products, CDS will require additional funding. CDS expects that royalties from Retisert sales will provide one source of funding but cannot predict the amount or timing of such royalties. If the merger is not completed and additional financing is not available on acceptable terms, or at all, CDS may need to delay, reduce the scope of, or eliminate one or more of its development programs or cease operations altogether.

*CDS has a history of losses and, if CDS does not generate sufficient revenue from licensing and sale of its products and proposed products, CDS may not achieve profitability.*

CDS has incurred net losses in each of its last five fiscal years, and in the nine months ended September 30, 2005. Royalties from sales of CDS' first commercial product, Vitrasert, have declined in each of the past four years, and CDS expects that they will not comprise a significant portion of its future revenue. Although CDS expects to receive royalties from sales of Retisert, CDS is unable to predict the amount or timing of such royalties. CDS' ability to generate net income in the future depends upon its ability to generate revenue through royalties generated by sales of Retisert, collaborative research funding, licensing fees and milestone payments from licensing its proposed products to collaborative partners and its ability, alone or with others, to develop, obtain required regulatory clearances for, and manufacture and market its proposed products. If CDS does not generate sufficient revenue from licensing and sales of its products and proposed products, CDS may not achieve profitability.

*If the clinical trials necessary to obtain regulatory approval of CDS' proposed products are not successful, CDS or any marketing partner will be unable to sell them.*

Vitrasert and Retisert are the only CDS products that have been approved for sale in the U.S. Before CDS or any development partner can obtain approval from the FDA and foreign regulatory authorities to manufacture and sell CDS' proposed products, pre-clinical studies and clinical trials must demonstrate that each of these products is safe for human use and effective for its targeted disease. CDS' 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 CDS' 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;

## Table of Contents

- failure to meet FDA requirements for clinical trial design or for demonstrating efficacy for a particular product;
- inability to follow patients adequately after treatment;
- changes in the design or manufacture of a product;
- inability to manufacture sufficient quantities of materials for use in clinical trials; and
- governmental or regulatory delays.

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

The failure of one of CDS' product candidates to demonstrate safety and efficacy in clinical trials may delay or prevent development or approval of CDS' other product candidates that employ the same delivery technology or deliver the same drug and hinder CDS' ability to conduct related pre-clinical testing and clinical trials.

*Fast track status 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. See "CDS Information — CDS' Business — Government Regulation" for a more detailed description of fast track designation and related approval procedures.

*CDS depends on collaborations with third parties to develop and commercialize its products, and such arrangements may not be available or scientifically or commercially successful or may be terminated.*

CDS' business strategy includes entering into collaborative agreements for the development and commercialization of its product candidates. The curtailment or termination of any of these agreements, such as Bausch & Lomb's 2003 decision to conduct licensed research directly and not to fund such research by CDS, could adversely affect CDS and its ability to develop and commercialize its products and proposed products and fund its operations.

The success of these and future collaboration agreements will depend heavily on the experience, resources efforts and activities of CDS' collaborators. CDS' collaborators have and are expected to have significant discretion in making these decisions. Risks that CDS faces in connection with its 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;
- CDS is required, and expects to be required, under its 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 CDS can pursue;

## Table of Contents

- CDS' collaborators may develop and commercialize, either alone or with others, products that are similar to or competitive with CDS' products;
- CDS' 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 CDS' products to reach their potential could be limited if its collaborators decrease or fail to increase spending related to such products; and
- CDS' collaborators may lack the funding or experience to develop and commercialize CDS products successfully or may otherwise fail to do so.

CDS has exclusively licensed its technology to Bausch & Lomb with respect to Vitrasert, Retisert and certain other ophthalmic uses and to Alimera Sciences with respect to Medidur for DME and certain other ophthalmic uses. Bausch & Lomb is responsible for funding and managing the development and commercialization of all products under its agreement with CDS and can terminate the agreement at any time upon 90 days' written notice. Alimera Sciences and CDS are jointly funding the development of products licensed under that agreement, and Alimera Sciences may terminate its agreement with CDS if CDS fails to make a development payment or may terminate the agreement with respect to a particular product if Alimera Sciences abandons the product or upon 30 days' notice following CDS' failure to make development payments exceeding \$2 million for that product. Either Bausch & Lomb or Alimera Sciences may decide not to continue with or commercialize any or all of the licensed products, change strategic focus, pursue alternative technologies, develop competing products or terminate their agreements with CDS. 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 CDS' technologies. Alimera Sciences was only incorporated in June 2003 and has limited resources. Because CDS does not currently have sufficient funding or internal capabilities to develop and commercialize its 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 CDS products licensed to such entities.

In addition, CDS faces significant competition in seeking additional appropriate collaborators, which generally have substantial opportunities for collaboration. Collaboration arrangements are often complex to negotiate and time consuming to document. CDS may not be successful in establishing additional collaborations or other alternative arrangements, and the terms of any future collaborations may not be favorable to CDS. Moreover, CDS' existing and future collaboration arrangements may not be scientifically or commercially successful.

*CDS is reliant on third parties to manufacture its products, and if they fail to meet FDA and other governmental requirements for the manufacture of CDS' products, sales of CDS products may be limited or stopped.*

CDS 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 CDS and Alimera Sciences, the rights to manufacture Medidur for DME, if approved for marketing, and other products covered by its license agreement with CDS. Although CDS may decide to develop the facilities and capacity to manufacture its products on a commercial scale in the future, its current reliance on third party manufacturers 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;



## Table of Contents

- 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.

The consequence of any disruption to third party manufacturing could negatively impact product development efforts, sales of CDS products and CDS' reputation.

*If users of CDS' proposed products are unable to obtain adequate reimbursement from third-party payors, market acceptance of its proposed products may be limited.*

Successful commercialization of our proposed products will depend in part on the extent to which healthcare providers receive appropriate reimbursement levels from governmental authorities, private health insurers and other organizations for our products and related treatments. Currently, Medicaid and Medicare, most major health maintenance organizations and most health insurance carriers reimburse \$4,240 for the cost of the CDS' Vitrasert implant, and the Centers for Medicare and Medicaid Services recently designated Retisert as eligible for Medicare reimbursement at the rate of \$19,345. Third-party payors are increasingly challenging the prices charged for medical products and services, however. If healthcare providers do not receive adequate reimbursement for CDS' products, they or their patients may not use them.

*If CDS is unable to attract and retain highly qualified personnel, it may hinder its future success.*

Since 2003, CDS terminated most of its highly qualified personnel and is largely reliant on its collaborative partners. CDS' ability to develop future products and achieve future success will depend in part upon its ability to fund, attract and retain highly skilled management, technical and scientific personnel, in addition to its current personnel. Competition for qualified personnel in CDS' industry is intense, and the process of hiring and integrating qualified personnel is often lengthy. CDS may be unable to recruit adequate numbers of qualified personnel on a timely basis, and CDS management and other employees may voluntarily terminate their employment with CDS at any time. The inability to attract and retain qualified personnel could result in delays or failures in product development or approval, loss of sales and diversion of management resources.

*CDS expects intense competition from alternative treatments for its targeted diseases that may reduce or eliminate the demand for CDS' products and proposed products.*

CDS expects that its products and proposed products, if approved, will compete with existing approved and off-label treatments for its targeted diseases as well as new treatments that may be developed to treat these diseases, their symptoms and their underlying causes and off-label use of products approved to treat other diseases. CDS believes 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 CDS' targeted diseases or their underlying causes. For many of its 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 CDS' products and proposed products, may offer therapeutic or cost advantages or may cure CDS' targeted diseases or their underlying causes completely, which could reduce demand for CDS' products and proposed products and could render them noncompetitive or obsolete. For example, sales of CDS' 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.

The financial resources, research and development, clinical trial, regulatory, manufacturing and marketing experience, research and development and manufacturing facilities of many of CDS' competitors

## Table of Contents

and potential competitors are much greater than those of CDS. In addition, they may succeed in obtaining patents that would make it difficult or impossible for CDS to compete with their products.

*Patent protection for CDS' products is important and uncertain. If CDS does not protect its intellectual property, CDS will be subject to increased competition.*

CDS' commercial success will depend in part on its ability to protect its proprietary products and processes from unauthorized use by third parties by obtaining valid and enforceable patents or effectively maintaining them as trade secrets. CDS seeks to obtain and license U.S. and foreign patents related to proprietary technology, inventions and improvements that may be important to the development of its business. However, CDS' patent position, like that of other biotechnology, pharmaceutical and medical device companies, is highly uncertain and involves complex legal and factual questions. The standards that the United States Patent and Trademark Office and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is no uniform worldwide jurisprudence or policy among patent offices regarding the subject matter and scope of claims allowable or granted in medical device or pharmaceutical patents. Consequently, CDS cannot be certain as to the type and scope of patent claims that may be issued to CDS or its licensors, or the extent to which any issued claims may be upheld, may be enforceable or may be substantially narrowed by litigation or government agency actions. In addition, the agreements under which CDS licenses third-party patents require that it meet specified diligence requirements in order to keep its licenses. CDS cannot be certain that it will satisfy these requirements.

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 CDS' licensed or owned patents, or its inability to obtain patents, may enable other companies to develop products that compete with CDS' products and product candidates on the basis of the same or similar technology. As a result, patents of CDS and its licensors may not provide any or sufficient protection against competitors.

CDS also relies on trade secrets, know-how and technology that are not protected by patents to maintain its competitive position. CDS tries to protect this information by entering into confidentiality agreements with parties that have access to it, such as CDS' corporate partners, collaborators, employees, and consultants. Any of these parties could breach these agreements and disclose CDS' confidential information, or CDS' 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, CDS' competitive position could be materially harmed.

*Protecting CDS' proprietary technology is expensive, and if CDS' technology infringes the intellectual property rights of others, CDS may be harmed if it is unable to manufacture and sell its products or it is required to pay substantial damages or license fees.*

Obtaining and protecting patent and proprietary rights is expensive. Patents must be prosecuted and may be challenged, invalidated or circumvented or may interfere with the patents of others. CDS or its licensors may need to participate in proceedings before patent offices or resort to litigation to enforce patents or to determine the scope and validity of CDS', CDS' licensor's or a third party's proprietary rights. CDS could incur substantial costs in connection with any proceeding or litigation, and its management's attention could be diverted, regardless of the results of the proceeding or litigation.

Issued patents or patents that issue may restrict or prevent the manufacture and sale of CDS' products or proposed products, and CDS or its development partners may be subject to infringement claims based on current or later granted patents. An unfavorable decision in any proceeding or litigation could result in significant liabilities, require CDS and its development partners to cease manufacturing or selling the affected products or using the affected processes, prevent CDS from extending its technologies into new products and areas or require CDS to license the disputed rights from third parties. In such an event, CDS' business would be harmed if damages were substantial, if it could not obtain a license on

## Table of Contents

commercially reasonable terms or at all, or if CDS were unable to redesign the affected products or processes to avoid infringement.

*CDS could be exposed to significant product liability claims which could be time-consuming and costly, divert management attention and adversely affect its ability to obtain and maintain insurance coverage or its financial condition.*

CDS' products and product candidates involve an inherent risk of product liability claims against CDS. CDS has insured against claims that may be brought against it in connection with clinical trials and commercial sales of its products. However, this insurance may not fully cover the costs of claims or damages CDS might be required to pay. Product liability claims or other claims related to its products, regardless of their outcome, could require CDS to spend significant time and money in litigation, divert management time and attention, require it to pay significant damages, harm CDS' reputation or hinder acceptance of CDS' products. Any successful product liability claim may prevent CDS from obtaining adequate product liability insurance in the future in sufficient amounts on commercially reasonable terms. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of CDS' products. Product liability claims could also significantly harm CDS' reputation, delay or prevent market acceptance of its products or proposed products and damage its financial condition.

*If they act together, CDS' directors, officers and significant shareholders can control matters requiring stockholder approval because they beneficially own a large percentage of CDS' voting stock, and they may vote in a way with which you do not agree.*

CDS' directors, officers and significant shareholders beneficially own a majority of the outstanding shares of its stock. As a result, if these persons act together, they will have the ability to exercise substantial control over CDS' affairs and corporate actions requiring stockholder approval, including the election of directors, a sale of substantially all CDS' assets, a merger with another entity or an amendment to its certificate of incorporation. If they act together, these stockholders could use their ownership position to delay, deter or prevent a change in control. Also, their aggregate ownership could adversely affect the price that investors might be willing to pay in the future for shares of CDS' common stock.

### **RISKS RELATED TO pSIVIDA'S ACQUISITION OF CDS AND OTHER RECENT TRANSACTIONS**

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

pSivida entered into the merger agreement 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. facilitating 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 the business, financial condition and results of operations of pSivida and its subsidiaries, including CDS. 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;
- persuading employees that pSivida's and CDS' business cultures 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.

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

*pSivida's 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 accounting principles generally accepted in the U.S., pSivida will account for the merger using the purchase method of accounting. Under purchase accounting, pSivida will record the market value of its 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. pSivida will allocate that cost to the individual assets acquired and liabilities assumed, including identifiable intangible assets based on their fair values. Intangible assets generally will be amortized over a twelve year period. The amount of purchase price allocated to goodwill will be approximately A\$55.8 million, the amount allocated to identifiable intangible assets will be approximately A\$120.0 million, giving rise to a gross deferred tax liability of approximately A\$48.0 million (approximately \$29.1 million net of deferred tax assets), and approximately A\$2.7 million will be allocated to in-process research and development. 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 exceeds its implied fair value. If identifiable intangible assets were amortized in equal quarterly amounts over a twelve-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 pSivida's net loss or decrease its net income in the foreseeable future, which could have a material and adverse effect on the market value of pSivida ADSs following completion of the merger.

*pSivida expects to incur significant costs associated with the merger.*

pSivida estimates that it will incur direct transaction costs of approximately \$2.7 million associated with the merger, which will be included as a part of the total purchase consideration for accounting purposes. In addition, CDS estimates that it will incur direct transaction costs for accounting, investment banking and legal services of approximately \$2.5 million, which are in part determined at closing and are expensed in the quarter in which they are incurred. pSivida believes the combined entity may incur charges to operations, which currently are not reasonably estimable, in the quarter in which the merger is completed or the following quarters, to reflect costs associated with integrating the two companies and that such charges may be material.

*Failure to complete the merger could negatively impact pSivida's stock price and its future business and operations.*

If the merger is not completed for any reason, pSivida may be subject to a number of material risks, including the following:

- pSivida would not realize any anticipated benefits from being a part of the anticipated combined company;
- pSivida may be obligated to pay CDS a fee of \$1.05 million in liquidated damages if the merger agreement is terminated in certain circumstances;
- pSivida may experience difficulties in attracting strategic investors, collaborators and partners who were expecting to use the technology proposed to be offered by the combined company; and
- pSivida must pay all or a portion of certain costs relating to the merger, such as legal, accounting, financial advisor and printing fees, even if the merger is not completed, which costs will be substantial.

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

pSivida believes that the merger may 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 or the expiration of any waiting period requirements have been satisfied. However, the FTC and the Antitrust Division frequently scrutinize the legality under the antitrust laws of transactions like the merger, and at any time before or 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 to enjoin the completion of the merger or seeking the divestiture of substantial assets of pSivida or 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 is no mandatory requirement to notify the ACCC of a proposed merger. However, if a proposed merger is likely to give rise to antitrust concerns, or to be perceived by the ACCC as doing so, it is common practice to approach the ACCC to obtain its assurance that it will not oppose the merger. This process is known as seeking informal “clearance”. A formal “authorization” process is also available. pSivida and CDS believe that the merger can be completed without seeking authorization or informal clearance from the ACCC. However, the ACCC may independently scrutinize the merger and could take any action under the Trade Practices Act of 1974 (Cth) it deems necessary or desirable in the public interest, including seeking an injunction or an order for divestment of substantial assets of pSivida or CDS.

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 stockholders sell substantial amounts of ADSs after the merger, the market price of ADSs may decline.*

The resale by CDS stockholders of pSivida ADSs after the merger could cause the market price of pSivida ADSs to decline. In connection with the merger, pSivida expects to issue approximately 16,000,000 ADSs. While the pSivida ADSs will not initially be freely tradable, pSivida has agreed to register their resale within six months for stockholders entering into the registration rights agreement. Therefore, approximately 16,000,000 pSivida ADSs issued in the merger are expected to become freely tradable six months from the closing date.

***If pSivida fails to register the resale of pSivida ADSs by the applicable deadlines, pSivida may be subject to substantial penalties.***

In connection with the acquisition of CDS, pSivida’s recent \$4.2 million private placement structured as a private investment in public equity, referred to herein as the PIPE, and pSivida’s recent issuance to an institutional investor of a \$15 million convertible note, pSivida has entered into agreements to register with the SEC the resale of the pSivida ADSs issued to CDS stockholders and the investors in the PIPE and note issuance. pSivida’s obligation to register ADSs in each of these transactions is subject to deadlines, and our failure to meet any of these deadlines may result in monetary penalties.

pSivida is required to complete the registration no later than one hundred eighty days from the date of the definitive agreements related to the PIPE, or on or about February 23, 2006. If pSivida fails to cause the registration statement registering the resale of pSivida ADSs to become effective beginning one month after this deadline, pSivida may be subject to monthly cash penalties equal to one percent of the PIPE purchase price, or \$42,000 per month, until such registration statement becomes effective. With respect to the convertible note financing, we are required to complete the initial registration no later than one hundred eighty days from the closing date of the issuance, or on or about May 16, 2006. Failure to comply with this deadline will result in pSivida having to pay monthly cash penalties equal to one and one-half percent of the convertible note purchase price, or \$225,000 per month, until the registration statement becomes effective. With respect to the merger, we are required to complete the registration no later than one hundred eighty days from the closing. If the merger closes in early January of 2006 as pSivida expects, the deadline would be on or about early July of 2006. Failure to comply with this deadline will result in pSivida having to pay monthly cash penalties equal to one percent of the average closing price of pSivida 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. Based on a price of \$6.50 per ADS, such penalties could amount to approximately \$1 million per month.

## UNAUDITED PRO FORMA CONSOLIDATED FINANCIAL INFORMATION

In December 2005, pSivida is expected to complete the acquisition of 100% of the issued capital of CDS, an unlisted U.S. company specializing in the development of sustained-release drug delivery products. The acquisition of CDS will be accounted for under the purchase method of accounting.

The unaudited pro forma consolidated financial statements are presented in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP, and are derived from the historical consolidated financial statements of pSivida and CDS included elsewhere in this information statement, 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 present fairly 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 the acquisition 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 and may be adjusted.

The unaudited pro forma consolidated financial statements should be read in conjunction with the audited consolidated financial statements of pSivida and CDS included elsewhere in this information statement.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**UNAUDITED PRO FORMA CONSOLIDATED STATEMENT OF FINANCIAL POSITION**  
**As of June 30, 2005**

	pSivida Historical (3a)	CDS Historical (3b)	Pro Forma Adjustments	Pro Forma
	(In Australian dollars)			
<b>ASSETS</b>				
Current assets:				
Cash and cash equivalents	12,892,061	4,450,442	(7,420,308)(3c)	9,922,195
Receivables	709,418	79,413		788,831
Other	322,933	137,450		460,383
<b>Total current assets</b>	<b>13,924,412</b>	<b>4,667,305</b>	<b>(7,420,308)</b>	<b>11,171,409</b>
Non-current assets:				
Property, plant and equipment, net	3,273,663	865,412		4,139,075
Intangible assets, net	50,703,262		120,000,000(3d)	170,703,262
Goodwill	32,161,939		55,761,654(3e)	87,923,593
<b>Total assets</b>	<b>100,063,276</b>	<b>5,532,717</b>	<b>168,341,346</b>	<b>273,937,339</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>				
Current liabilities:				
Payables	1,967,718	3,344,075		5,311,793
Payables, related party	50,102			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>7,256,258</b>
Deferred tax liability, net	10,365,240	—	29,100,000(3f)	39,465,240
<b>Total liabilities</b>	<b>12,412,939</b>	<b>5,208,559</b>	<b>29,100,000</b>	<b>46,721,498</b>
Commitments and contingencies				
Series A redeemable convertible preferred stock		38,035,845	(38,035,845)(3g)	—
Stockholders' equity:				
Common stock and additional paid-in capital	117,798,149	16,362,738	125,944,472(3h)	260,105,359
Deferred stock based compensation		(1,213,574)	1,213,574(3i)	—
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)(3j)	(28,804,270)
Accumulated deficit		(52,860,851)	52,860,851(3k)	—
<b>Total stockholders' equity (deficit)</b>	<b>87,650,337</b>	<b>(37,711,687)</b>	<b>177,277,191</b>	<b>227,215,841</b>
<b>Total liabilities and stockholders' equity</b>	<b>100,063,276</b>	<b>5,532,717</b>	<b>168,341,346</b>	<b>273,937,339</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**

	<u>pSivida Historical (3l)</u>	<u>CDS Historical (3m)</u> (In Australian dollars except number of shares)	<u>Pro Forma Adjustments</u>	<u>Pro Forma</u>
<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>	<u>161,666</u>	<u>12,927,011</u>		<u>13,088,677</u>
<b>Operating expenses:</b>				
Depreciation and amortization expense	(6,207,733)	(495,177)	(10,000,000)(3n)	(16,702,910)
Research and development expense	(8,287,930)	(2,831,869)		(11,119,799)
Royalties expense	—	(79,479)		(79,479)
Employee benefits expense	(1,165,025)			(1,165,025)
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>	<u>(21,414,268)</u>	<u>(10,350,560)</u>	<u>(10,000,000)</u>	<u>(41,764,828)</u>
<b>Income (Loss) from operations before income tax benefit</b>				
	(21,252,602)	2,576,451	(10,000,000)	(28,676,151)
<b>Interest and other income (expense), net</b>	<u>667,310</u>	<u>(213,568)</u>		<u>453,742</u>
<b>Income (loss) before income tax benefit</b>	<u>(20,585,292)</u>	<u>2,362,883</u>	<u>(10,000,000)</u>	<u>(28,222,409)</u>
<b>Income tax benefit</b>	<u>3,645,504</u>	<u>—</u>	<u>3,055,000(3o)</u>	<u>6,700,504</u>
<b>Income (loss) before outside equity interest</b>	<u>(16,939,788)</u>	<u>2,362,883</u>	<u>(6,945,000)</u>	<u>(21,521,905)</u>
<b>Net loss attributable to outside equity interest</b>	<u>378,276</u>			<u>378,276</u>
<b>Net income (loss)</b>	<u>(16,561,512)</u>	<u>2,362,883</u>	<u>(6,945,000)</u>	<u>(21,143,629)</u>
<b>Accretion of redeemable convertible preferred stock</b>		(3,246,135)	3,246,135(3p)	—
<b>Net loss attributable to common stockholders</b>	<u>(16,561,512)</u>	<u>(883,252)</u>	<u>(3,698,865)</u>	<u>(21,143,629)</u>
<b>Basic and diluted loss per common share</b>	(0.08)	(0.43)		(0.06)
<b>Basic and diluted weighted average number of shares</b>	207,802,540	2,068,990	(5)	367,802,540

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 U.S. GAAP and are presented in Australian dollars.

**2. Purchase Price Allocation**

The estimated purchase price of \$149,727,518 consisted of:

- \$655,308 cash;
- 160,000,000 ordinary full paid shares of pSivida, represented by 16,000,000 American Depositary Shares, or ADSs, with an estimated fair value of \$141,798,165 (\$0.886 per share, represented by US\$6.762 per ADS);
- 1,761,760 share options in pSivida, represented by 176,176 warrants over ADSs with an estimated fair value of \$509,045; and
- direct acquisition costs of \$6,765,000.

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:

	<u>Total Fair Value</u> <u>(In Australian dollars)</u>
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	(3,344,075)
Deferred Revenue	(1,864,484)
Deferred Tax Liability, Net	(29,100,000)
Total	93,965,864
Purchase Price	<u>149,727,518</u>
Goodwill	<u><u>55,761,654</u></u>

**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 U.S. GAAP basis. Refer to Note 27 of pSivida's audited consolidated financial statements included elsewhere in this information statement for a description of the differences between accounting principles



**PSIVIDA LIMITED AND SUBSIDIARIES****NOTES TO UNAUDITED PRO FORMA CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

generally accepted in Australia (A-GAAP) and U.S. GAAP as they relate to pSivida and for a reconciliation to U.S. GAAP of equity for the periods indicated therein.

- (b) Reflects the historical financial position of CDS as of June 30, 2005 on a U.S. GAAP basis. The historical statement of financial position data was translated from U.S. dollars to Australian dollars using an exchange rate of \$0.76 as at June 30, 2005.
- (c) Reflects the payment of the estimated \$655,308 cash as partial consideration for the acquisition plus the payment of \$6,765,000 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 U.S. GAAP but is assessed for impairment at least annually.
- (f) 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 assets 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.
- (g) Reflects the elimination of CDS Series A redeemable preferred stock.
- (h) Reflects the following adjustments:

	\$
Fair value of 160,000,000 pSivida ordinary shares issued (see Note 2)	141,798,165
Fair value of 1,761,760 pSivida share options issued (see Note 2)	509,045
Elimination of CDS common stock and APIC	<u>(16,362,738)</u>
	<u>125,944,472</u>

- (i) Reflects the elimination of CDS deferred stock compensation as all outstanding CDS options will be exchanged for pSivida options.
- (j) Reflects the estimated write-off of in-process research and development related to the acquisition of CDS (see Note 2).
- (k) Reflects the elimination of CDS accumulated deficit.
- (l) Reflects the historical financial results of operations of pSivida for the year ended June 30, 2005 on a U.S. GAAP basis. Refer to Note 27 of pSivida’s audited consolidated financial statements included elsewhere in this information statement for a description of the differences between A-GAAP and U.S. GAAP as they relate to pSivida and for a reconciliation to U.S. GAAP of net loss for the periods indicated therein.
- (m) Reflects the historical results of operations of CDS on a U.S. GAAP basis for the period July 1 2004 to June 30, 2005, which have been derived by combining the U.S. GAAP results of operations for the 12 months to December 31, 2004 (which are included elsewhere in this Information Statement) minus the U.S. GAAP results of operations for the six months to June 30, 2004 plus the U.S. GAAP results of operations for the six months to June 30, 2005. The historical statement of operations data was translated from U.S. dollars to Australian dollars using a weighted average exchange rate of \$0.754 for the year ended June 30, 2005.

**PSIVIDA LIMITED AND SUBSIDIARIES****NOTES TO UNAUDITED PRO FORMA CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

- (n) Reflects the amortization of patents over an estimated useful life of 12 years as described in adjustment (d) above.
- (o) Reflects the tax benefit attributable to the total of the historical CDS income before income tax benefit and the pro forma amortization of intangibles, using the CDS combined federal and state statutory tax rate of 40%. There is no impact on current income taxes due to net operating losses of the combined entity.
- (p) Reflects the elimination of accretion of the CDS Series A redeemable preferred stock due to the elimination of the stock as described in adjustment (g) 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.

**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 earnings 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 shares of pSivida ordinary shares outstanding for the year ended June 30, 2005. Under the terms of the agreement a total of 160 million ordinary shares (represented by 16 million ADSs) will be 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:

	<b>Year Ended June 30, 2005</b>
Ordinary shares used to compute pSivida historical basic and diluted loss per share	207,802,540
Ordinary shares to be issued to former holders of shares of CDS common stock	84,350,410
Ordinary shares to be issued to former holders of shares of CDS convertible redeemable preferred stock	75,649,590
Ordinary shares used to compute pro forma basic and diluted loss per share	<u>367,802,540</u>

Outstanding options and warrants to purchase pSivida ordinary shares 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.

**PSIVIDA INFORMATION**

**SELECTED HISTORICAL FINANCIAL DATA**

The following table presents pSivida's selected historical consolidated financial data as of the dates and for each of the periods indicated. The information set forth below is not necessarily indicative of future results and should be read in conjunction with "pSivida's Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as pSivida's audited consolidated financial statements and the notes thereto appearing elsewhere in this information statement.

The selected consolidated financial data as of June 30, 2005 and 2004 and for each of the three years in the period ended June 30, 2005 have been derived from pSivida's audited consolidated financial statements and the notes thereto included elsewhere in this information statement. The selected consolidated financial data as of June 30, 2003, 2002 and 2001, for the year ended June 30, 2002, and for the period from December 1, 2000 to June 30, 2001 have been derived from pSivida's audited consolidated financial statements and notes thereto which are not included in this information statement.

pSivida prepares its consolidated financial statements in accordance with accounting principles generally accepted in Australia, or A-GAAP, which differ in certain significant respects from accounting principles generally accepted in the United States, or U.S. GAAP. Please refer to Note 27 to the consolidated financial statements for a description of the differences between A-GAAP and U.S. GAAP as they relate to us, and a reconciliation of net loss and total equity to U.S. GAAP for the periods and as of the dates indicated.

	Period from Inception of Development Stage (Dec 1, 2000) to June 30, 2001(1)	Years Ended June 30,			
		2002	2003	2004	2005
(In Australian Dollars except number of shares)					
<b>STATEMENT OF FINANCIAL PERFORMANCE DATA:</b>					
<b>A-GAAP</b>					
Revenues from ordinary activities	113,145	916,600	110,675	381,679	828,976
Depreciation and amortization expense	(11,681)	(38,502)	(37,835)	(39,360)	(1,029,382)
Research and development expense	(226,132)	(3,186,863)	(4,586,182)	(7,011,666)	(8,287,930)
Interest expense	—	—	—	(5,635)	—
Employee benefits expense	(25,486)	(22,999)	(522,977)	(1,238,381)	(1,040,007)
Foreign currency (loss)/ gain	—	(995)	(1,203)	1,461,368	(1,623,484)
Corporate office expenses	(701,576)	(1,664,265)	(318,806)	(1,066,981)	(3,973,892)
Loss from ordinary activities before income tax	(851,730)	(3,997,024)	(5,356,328)	(7,518,976)	(15,125,719)
Income tax expense relating to ordinary activities	—	—	—	—	—
Net loss before outside equity interest	(851,730)	(3,497,024)	(5,356,328)	(7,518,976)	(15,125,719)

[Table of Contents](#)

	Period from Inception of Development Stage (Dec 1, 2000) to June 30, 2001(1)	Years Ended June 30,			
		2002	2003	2004	2005
		(In Australian Dollars except number of shares)			
Net loss attributable to outside equity interest	113,229	1,806,605	2,591,175	3,835,771	399,196
Net loss	(738,501)	(2,190,419)	(2,765,153)	(3,683,205)	(14,726,523)
Loss per share — basic and diluted	(0.01)	(0.02)	(0.03)	(0.03)	(0.07)
Weighted average number of ordinary shares outstanding — basic and diluted	69,053,359	89,834,844	101,281,292	126,990,066	207,802,540
<b>US GAAP</b>					
Revenue from ordinary activities	N/A	N/A	—	56,200	161,666
Net loss (restated(2))	N/A	N/A	(2,268,603)	(5,019,974)	(16,561,512)
Loss per share — basic and diluted (restated(2))	N/A	N/A	(0.02)	(0.04)	(0.08)
Weighted average number of ordinary shares outstanding — basic and diluted	N/A	N/A	101,281,292	126,990,066	207,802,540

	As of June 30,				
	2001(1)	2002	2003	2004	2005
<b>STATEMENT OF FINANCIAL POSITION DATA:</b>					
<b>A-GAAP</b>					
Cash assets	3,270,093	5,051,509	1,180,134	31,350,656	12,892,061
Working capital	3,107,966	4,643,187	433,609	29,791,981	11,876,713
Total assets	9,247,729	11,273,860	7,175,342	40,367,058	82,035,313
Contributed equity	12,107,849	14,649,616	15,602,184	49,957,982	107,883,835
Deficit accumulated prior to development stage	(3,813,181)	(3,813,181)	(3,813,181)	(3,813,181)	(3,813,181)
Deficit accumulated during development stage	(738,501)	(2,928,920)	(5,694,073)	(9,377,278)	(24,103,801)
Total parent entity interest in equity	7,585,467	7,939,515	6,095,165	36,845,743	79,987,614
Total outside equity interest	1,376,663	2,773,306	204,354	1,583,200	—
Total equity	8,962,180	10,712,821	6,299,519	38,428,943	79,987,614
<b>U.S. GAAP</b>					
Total assets (restated (2))	N/A	N/A	8,220,492	41,295,099	100,063,276
Total equity (restated(2))	N/A	N/A	7,140,316	37,794,705	87,650,337
Contributed equity	N/A	N/A	15,434,340	51,030,718	117,798,149

(1) The legal entity that became pSivida was incorporated as the Sumich Group Ltd in April 1987. The Sumich Group operated an agriculture business which was placed into administration or receivership

## Table of Contents

on September 30, 1998. pSivida was subsequently formed on December 1, 2000 following upon entering into a court-approved arrangement with Sumich Group's creditors which fully extinguished all prior liabilities as of that time. pSivida then appointed new directors and officers and re-listed on the Australian Stock Exchange under its new name.

- (2) The U.S. GAAP financial information as of and for the years ended June 30, 2004 and 2003 has been restated. Refer to Note 27 to the Company's audited consolidated financial statements included elsewhere herein for a description and summary of the significant effects of the restatement.

### **Exchange Rates**

The following tables set forth for the periods and dates indicated certain information concerning the rates of exchange of A\$1.00 into U.S.\$ based on the noon market buying rate in New York City for cable transfers in Australian dollars as certified for customs purposes by the Federal Reserve Bank of New York, which pSivida refers to as the noon buying rate.

<u>Month</u>	<u>High</u>	<u>Low</u>
June 2005	0.7792	0.7498
July 2005	0.7661	0.7403
August 2005	0.7739	0.7469
September 2005	0.7731	0.7537
October 2005	0.7644	0.7436
November 2005	0.7451	0.7267

The noon buying rate on December 20, 2005 was \$0.7328 = A\$1.00.

<u>Year Ended June 30,</u>	<u>At Period End</u>	<u>Average Rate</u>	<u>High</u>	<u>Low</u>
2001	0.5100	0.5320	0.5996	0.4828
2002	0.5628	0.5682	0.5748	0.4841
2003	0.6713	0.5884	0.6729	0.5280
2004	0.6952	0.7155	0.7979	0.6390
2005	0.7618	0.7568	0.7974	0.6880

### **pSIVIDA'S MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The following discussion of pSivida's financial condition and results of operations is presented in A-GAAP and should be read in conjunction with "Selected Historical Financial Data of pSivida" and the audited consolidated financial statements and other financial information appearing elsewhere in this information statement. In addition to historical consolidated financial information, the following discussion and analysis contains forward-looking statements that reflect pSivida's plans, estimates, intentions, expectations and beliefs. pSivida's actual results could differ materially from those anticipated in the forward-looking statements as a result of many factors, including those discussed under "Risk Factors" and elsewhere in this information statement.

#### **Overview**

pSivida is a development stage enterprise at an early stage in the development of BioSilicon. It has incurred net losses since inception and expects to incur substantial and increasing losses for the next few years as pSivida expands its research and development activities and moves its product candidates into later stages of development. All of pSivida's product candidates are in early stages of development and it faces the risks of failure inherent in developing drugs based on new technologies. The process of carrying out the development of its products to later stages of development may require significant additional research and development expenditures, including pre-clinical testing and clinical trials, as well as for obtaining regulatory approval. To date, pSivida has funded its operations primarily through private placements of equity securities, the exercise of options and share purchase plans.

## Table of Contents

pSivida's revenues are generated in both Australian dollars and Pounds Sterling, and a majority of its expenses are incurred in either Australian dollars, Pounds Sterling or U.S. dollars.

### **Results of Operations**

The following table is intended to illustrate a tabular analysis of certain consolidated statement of financial performance data as a percentage of net loss before outside equity interest for all periods presented.

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Net loss before outside equity interest	100%	100%	100%
Revenue from ordinary activities	(5.5)%	(5.1)%	(2.0)%
Depreciation and amortization expense	6.8%	0.5%	0.7%
Research and development expense	54.8%	93.2%	85.6%
Interest expense	—	0.1%	—
Employee benefits expense	6.9%	16.5%	9.8%
Foreign currency (loss)/gain	10.7%	(19.4)%	—
Corporate office expenses	26.3%	14.2%	5.9%

The level of research and development expenditure has increased during the past three years. This is a direct result of the continued development of the BioSilicon technology and its applications such as the human trials of BrachySil which are being undertaken in Singapore. The increasing level of general corporate activity has also led to an increase in corporate costs over the three years.

It should be noted, when considering the above table that other income/(expenses) from ordinary activities, net for the years ended June 30, 2005 and 2004 include an amount of unrealized foreign exchange gain/(loss) on deposits held in U.S. dollars and Pounds Sterling equal to A\$(1.6) million and A\$1.5 million respectively. No such amount arose in prior periods as prior to April 2004, no material cash deposits were held by pSivida other than in Australian dollars.

### **Results of Operations For the Year Ended June 30, 2005 Compared to the Year Ended June 30, 2004**

#### *Net Loss*

For reasons described further below, pSivida's net loss increased to A\$14.7 million for the year ended June 30, 2005 from A\$3.7 million for the year ended June 30, 2004, an increase of A\$11.0 million, or 299.8%. The increase in net loss in 2005 is primarily attributable to pSivida's acquisition of the remaining outside equity interest in pSiMedica in August 2004, resulting in the consolidated group recognizing the full costs of pSiMedica. Other causes include pSivida's NASDAQ listing in January 2005 and the associated increased US regulation, an increase in all areas of corporate administration including consultants, rent and travel due to the increased levels of activity.

#### *Revenue from Ordinary Activities*

Revenue from ordinary activities increased to A\$828,976 for the year ended June 30, 2005 from A\$381,679 for the year ended June 30, 2004, an increase of A\$447,297 or 117.2%. Revenue in the 2005 period consisted of A\$667,310 interest income compared to A\$325,479 in interest income in the 2004 period. The increase in interest income in the 2005 period primarily relates to interest income earned on pSivida's higher balances of cash from previous capital raisings. Additionally, pSivida recognized A\$161,666 as other income in the 2005 period in connection with the research being undertaken by EpiTan and pSivida's top 5 global pharmaceutical company collaboration partner (see "pSivida's Business").

## Table of Contents

### *Depreciation and Amortization Expense*

Depreciation and amortization expense (excluding depreciation of plant and equipment used in research and development activities) increased to A\$1,029,382 for the year ended June 30, 2005 from A\$39,360 for the year ended June 30, 2004, an increase of A\$990,022, or 2515.3%. The level of depreciation expense increased only slightly through the year as capital expenditure on plant and equipment for other than research and development activities also increased slightly. No amount of amortization of intellectual property was recognized by pSivida because its intangible assets have not led to a product at a commercial production stage of development. pSivida recognized a goodwill amortization expense of \$973,923 for the year, representing most of the increase in the depreciation and amortization expense.

### *Research and Development Expense*

Research and development expense increased to A\$8.3 million for the year ended June 30, 2005 from A\$7.0 million for the year ended June 30, 2004, an increase of A\$1.3 million, or 18.2%. This increase is primarily attributable to an increase in pSivida's expenditure on the research and development into the drug delivery platform and preparations for the planned undertaking of clinical trials in relation to pancreatic application of BrachySil. (Refer to "pSivida's Business" for a detailed description of pSivida's research and development activities).

### *Employee Benefits Expense*

Employee benefits expense decreased to A\$1.0 million for the year ended June 30, 2005 from A\$1.2 million for the year ended June 30, 2004, a decrease of A\$198,374, or 16.0%. This decrease is attributable to a decrease in employee bonuses during the full year of operations.

### *Corporate Office Expenses*

Corporate office expenses increased to A\$3,973,892 for the year ended June 30, 2005 from A\$1,066,981 for the year ended June 30, 2004, an increase of A\$2,906,911, or 272.4%. This increase is primarily due to pSivida's NASDAQ listing during the year, increased U.S. regulation requirements and an increase in all areas of corporate administration including consultants, rent and travel due to the increased levels of activity during the year.

### ***Results of Operations For the Year Ended June 30, 2004 Compared to the Year Ended June 30, 2003***

#### *Net Loss*

For reasons described further below, pSivida's net loss increased to A\$3.7 million for the year ended June 30, 2004 from A\$2.8 million for the year ended June 30, 2003, an increase of A\$918,052, or 33.2%. The increase in net loss in 2004 is primarily attributable to the increase in research and development expenditure with the commencement of human clinical trials of BrachySil in Singapore.

#### *Revenue from Ordinary Activities*

Revenue from ordinary activities increased to A\$381,679 for the year ended June 30, 2004 from A\$110,675 for the year ended June 30, 2003, an increase of A\$271,004, or 244.9%. Revenue in the 2004 period consisted of A\$325,479 interest income compared to A\$110,675 in interest income in the 2003 period. The increase in interest income in the 2004 period primarily relates to interest income earned on the A\$25.6 million net proceeds received in the private placement of ordinary shares during April 2004 (Refer to Note 10 of the consolidated financial statements). Additionally, pSivida recognized A\$56,200 as other income in the 2004 period in connection with the research being undertaken by EpiTan (see "pSivida's Business").

## Table of Contents

### *Depreciation and Amortization Expense*

Depreciation and amortization expense (excluding depreciation of plant and equipment used in research and development activities) increased to A\$39,360 for the year ended June 30, 2004 from A\$37,835 for the year ended June 30, 2003, an increase of A\$1,525, or 4.0%. The level of depreciation and amortization expense remained constant through the year as capital expenditure on plant and equipment for other than research and development activities was similar in amount to the prior year. No amount of amortization of intangible assets was recognized by pSivida because its intangible assets have not led to a product at a commercial production stage of development.

### *Research and Development Expense*

Research and development expense increased to A\$7.0 million for the year ended June 30, 2004 from A\$4.6 million for the year ended June 30, 2003, an increase of A\$2.4 million, or 52.9%. This increase is attributable to an increase in pSivida's expenditure on the completion of pre-clinical trials of BrachySil and human clinical trials of BrachySil which commenced during 2004 in Singapore. (Refer to "pSivida's Business" for a detailed description of pSivida's research and development activities).

### *Employee Benefits Expense*

Employee benefits expense increased to A\$1.2 million for the year ended June 30, 2004 from A\$522,977 for the year ended June 30, 2003, an increase of A\$715,404, or 136.8%. This increase is attributable to the increase in full and part time permanent staff employed during the year which pSivida required as a result of increased levels of research and development activity and additional finance and administration resource requirements.

### *Other Income/ Expenses from Ordinary Activities, Net*

Other income/(expenses) from ordinary activities, net increased to A\$394,387 for the year ended June 30, 2004 from A\$320,009 for the year ended June 30, 2003, an increase of A\$74,378, or 23.2%. This increase is primarily due to the recognition of a significant unrealized foreign exchange gain of A\$1.5 million in 2004 due to favorable movements in the Pound Sterling and U.S. dollar against Australian dollar foreign exchange rates on significant cash deposits held in foreign currencies comprising proceeds of pSivida's private placement of ordinary shares during April 2004. Prior to April 2004, pSivida did not hold material cash deposits in foreign currency. In addition, corporate administration expenses increased to A\$1.1 million from the year ended June 30, 2004 from A\$318,806 for the year ended June 30, 2003, an increase of A\$748,175, or 234.7%. This increase is due to an increase in all areas of corporate administration including consultants, rent and travel due to the increased levels of activity and pSivida's further development during the year.

### *Foreign Currency*

During the year ended June 30, 2005 an unrealized foreign exchange loss was recognized of A\$1.6 million which arose entirely due to unfavorable movements in the Pound Sterling and U.S. dollar against Australian dollar foreign exchange rates. During the year ended June 30, 2004 an unrealized foreign exchange gain of A\$1.5 million was recognized. Prior to April 2004, no material cash deposits were held by pSivida other than in Australian dollars.

pSivida does not utilize financial derivatives instruments or other financial instruments subject to market risk.

### *Conditions in Australia*

pSivida is incorporated under the laws of, and its principal offices are located in the Commonwealth of Australia. Therefore, it is directly affected by political and economic conditions in Australia.



**Quantitative and Qualitative Disclosures About Market Risk**

pSivida has exposure to changes in foreign currency exchange rates and interest rates. It does not utilize derivative financial instruments or other financial instruments subject to market risk.

**Foreign Currency Exchange Rates**

pSivida conducts operations in two principal currencies, the Pound Sterling and the Australian dollar. These two currencies operate as the two functional currencies for pSivida's United Kingdom and Australian operations respectively. Cash to fund working capital requirements is managed centrally within each of the two countries with cash deposits managed in Australia and held in Pounds Sterling, Australian dollars and U.S. dollars.

During the year ended June 30, 2005 an unrealized foreign exchange loss on cash held in currencies other than the reporting currency was recognized of A\$1.6 million which arose due to unfavorable movements in the Pound Sterling and U.S. dollar against Australian dollar foreign exchange rates. Prior to April 2004, no material cash deposits were held by pSivida in foreign currencies other than Australian dollars.

Based on Pounds Sterling and U.S. dollar account balances at June 30, 2005, the following table shows the sensitivity of pSivida's consolidated financial performance as a result of an appreciation or depreciation in the value of the Australian dollar against the Pounds Sterling and U.S. dollar.

	A\$ Depreciation			Current Rate	A\$ Appreciation		
	-15%	-10%	-5%		5%	10%	15%
	(In thousands of Australian dollars)						
£	703	469	234	—	(234)	(469)	(703)
US\$	818	546	273	—	(273)	(546)	(818)
Total	1,521	1,015	507	—	(507)	(1,015)	(1,521)

**Interest Rates**

Cash deposits are held in call and deposit accounts and are subject to variable interest rates. pSivida does not consider its exposure to interest rates to be significant.

**Recently Issued Accounting Pronouncements Applicable to pSivida***Australian Pronouncements*

Impacts of adopting Australian Equivalents to International Financial Reporting Standards

**(a) Management of the transition to AIFRS**

pSivida will be required to prepare financial statements that comply with Australian Equivalents to International Financial Reporting Standards, or AIFRS, as adopted by the Australian Accounting Standards Board for annual reporting periods beginning on or after January 1, 2005. Accordingly, pSivida's first half-year report prepared under AIFRS will be for the half-year reporting period ended December 31, 2005, and its first annual financial report prepared under AIFRS will be for the year ended June 30, 2006.

The transitional rules for first time adoption of AIFRS require that the Company restate its comparative financial statements using AIFRS, except for AASB 132: "Financial Instruments: Disclosure and Presentation" and AASB 139: "Financial Instruments: Recognition and Measurement" where comparative information is not required to be restated. Currently, the Company provides two years of comparative financial information in its financial statements to comply with applicable SEC requirements. The SEC has granted a one-time relief from this requirement for foreign registered companies preparing their first set of financial statements in compliance with International Financial Reporting Standards. The Company has elected to apply this relief and will only provide one year of comparative information in the 30 June 2006 financial statements. For reporting in the 2006 fiscal year, comparatives will be remeasured

## [Table of Contents](#)

and restated for the half-year ended 31 December 2004 and the financial year ended 30 June 2005. Most of the adjustments on transition are required to be made to opening retained profits at the beginning of the first comparative period (i.e., at 1 July 2004).

In 2004, pSivida commenced a review of accounting policies in preparation for managing the transition to AIFRS. Priority has been given to considering the preparation of an opening balance sheet in accordance with AIFRS as at July 1, 2004, pSivida's transition date to AIFRS. This will form the basis of accounting for AIFRS in the future and is required when pSivida prepares its first fully AIFRS-compliant financial report for the year ended June 30, 2006.

### **(b) The likely impacts of AIFRS on the results and financial position of pSivida and the consolidated entity**

Set out below are the known key differences in accounting policy and our known estimable transitional differences identified as of 30 June 2005, where accounting policies are expected to change on adoption of AIFRS and the likely impacts on the current year operating results and financial position of the Company, had the financial statements been prepared using AIFRS, based on the directors' accounting policy decisions current at the date of this financial report. The adjustments included are based on the AIFRS standards released as at June 30, 2005. These are subject to ongoing review and any amendments by the AASB, or by interpretative guidance from the International Accounting Standards Board or AASB, could change the adjustments included. The AIFRS standards and interpretations that will apply to the Company will be those released as at December 31, 2005 being the date of the first half year financial statements that the Company has to publish under AIFRS. The disclosures below represent the Company's current best estimate of the quantitative impact of the AIFRS implementation at the date of this report and accordingly they remain subject to change.

There are certain items that still require resolution and additional differences in accounting policy that may be identified. The directors may, at any time until the completion of the Company's first AIFRS compliant financial report, elect to revisit, and where considered necessary, revise the accounting policies applied in preparing the disclosures below.

### **(c) Adjustments to balance sheet items under AIFRS (net of tax)**

#### **(i) Intangibles**

Under Australian Accounting Standards AASB 3 Business Combinations, goodwill will not be permitted to be amortized but instead is subject to impairment testing on an annual basis or upon triggers which may indicate a potential impairment. As a result accumulated amortization of \$973,923 (all expensed during the 2005 year) would be added back to the value of intangibles.

#### **(ii) Share-based payments**

Under AASB 2 Share-Based Payment, equity-settled share-based payments in respect of equity instruments issued after November 7, 2002 that were unvested as at January 1, 2005 are measured at fair value at grant date. The fair value determined at grant date of equity-settled share-based payments is expensed on a straight-line basis over the vesting period, based on the estimated number of equity instruments that will vest. As a consequence, contributed equity will increase by \$591,900 for the financial year ended June 30, 2005.

#### **(iii) Foreign currency translation reserve**

The directors have elected to set the translation reserve to zero as at AIFRS transition as permitted under AASB 1 First-Time Adoption of Australian Equivalents to International Financial Reporting Standards. This results in the transfer of \$78,220 from the foreign currency translation reserve to retained earnings as at AIFRS transition.

**(iv) Accumulated losses**

With limited exceptions, adjustments required on first-time adoption of AIFRS are recognized directly in accumulated losses at the date of transition to AIFRS. The cumulative effect of these adjustments for the consolidated entity will be an increase in opening accumulated losses of \$78,220.

**(d) Adjustments to current year loss under AIFRS (net of tax)**

**(i) Intangibles**

Under AASB 3 Business Combinations, goodwill would not be permitted to be amortized but instead is subject to impairment testing on an annual basis or upon triggers which may indicate a potential impairment. As a result goodwill amortization expense of \$973,923 recorded in the year ended 30 June 2005 would be added back to the net loss for the year. There is no goodwill amortization required to be added back to the net loss upon the transition date of 1 July 2004.

**(ii) Share-based payments**

Under AASB 2 Share-Based Payment, equity-settled share-based payments in respect of equity instruments issued after November 7, 2002 that were unvested as at January 1, 2005 are measured at fair value at grant date. The fair value determined at grant date of equity-settled share-based payments is expensed on a straight-line basis over the vesting period, based on the estimated number of equity instruments that will vest. As a consequence, an additional employee benefit expense of \$508,613 and consultancy fees expense of \$83,287 will be recognized in the profit and loss for the financial year ended June 30, 2005.

**(e) Other impacts**

(i) Management has decided to apply the exemption provided in *AASB 1 First-Time Adoption of Australian Equivalents to International Financial Reporting Standards* which permits entities not to restate business combinations that occurred prior to the date of transition to AIFRS. Business combinations occurring after the date of transition (i.e. 1 July 2004) will be subject to the provisions of *AASB 3 Business Combinations*.

(ii) Management has decided to apply the exemption provided in *AASB 1 First-Time Adoption of Australian Equivalents to International Financial Reporting Standards* which permits entities not to apply the requirements of *AASB 132 Financial Instruments: Presentation and Disclosures* and *AASB 139 Financial Instruments: Recognition and Measurement* for the financial year ended June 30, 2005. The standards will be applied from July 1, 2005. Management is in the process of determining the impact that adopting the standards would have on the financial statements of the Company.

(iii) Under *AASB 136 Impairment of Assets*, the consolidated entity's assets, including goodwill would be tested for impairment as part of the cash generating unit to which they belong, and any impairment losses recognized in the income statement. At this stage in pSivida's review process pSivida is not aware of any impairment issues that would result in a material adjustment to the financial statements.

(iv) No material impacts are expected to the cash flows presented under current A-GAAP on adoption of AIFRS.

**(f) Acquisition of minority interest**

During the year pSivida purchased minority interests in controlled entity pSiMedica. Under current A-GAAP this acquisition has been accounted for separately from other acquisitions (that is, as a step acquisition, which involved the separate determination and recognition of the fair values of the net assets of the subsidiary and any goodwill arising on the acquisition).

*AASB 127 Consolidated and Separate Financial Statements* requires minority interests to be classified as equity. Consequently the acquisition by pSivida of additional ownership interests in pSiMedica Limited

## [Table of Contents](#)

represents an equity transaction. As such, accounting for the transaction as a step acquisition is inappropriate. The financial effect of the adjustment required on the restatement of the June 30, 2005 accounts is yet to be determined.

### **U.S. Pronouncements**

In December 2004, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or SFAS, No. 123 (revised 2004): Share-Based Payments, or SFAS 123R. This statement eliminates the option to apply the intrinsic value measurement provisions of Accounting Principles Board, or APB, Opinion No. 25 to stock compensation awards issued to directors and employees. Rather, SFAS 123R requires companies to measure the cost of director and employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost will be recognized over the period during which the director, executive or employee is required to provide services in exchange for the award — the requisite service period (usually the vesting period). SFAS 123R applies to all awards granted after the required effective date (July 1, 2005 for pSivida) and to awards modified, repurchased, or cancelled after that date. As permitted by SFAS 123, pSivida accounted for share-based payments to directors, executives and employees using APB 25, the intrinsic value method through June 30, 2005. Accordingly, the adoption of the SFAS 123R fair value method may have a significant impact on pSivida's results of operations, although it will have no impact on its overall financial position. The full impact of the adoption of SFAS 123R cannot be predicted at this time, as it depends on levels of share-based payments for future grants. However, had the Company adopted SFAS 123R for director, executive and employee options in prior periods, the impact of that standard would have approximated the pro forma impact of SFAS 123, as disclosed in Note 27(a), Share-based compensation — Options issued to directors and employees for services rendered.

In December 2004, the FASB issued SFAS No. 153: "Exchanges of Nonmonetary Assets" — an amendment of APB Opinion No. 29, or SFAS 153, which amends APB Opinion No. 29: Accounting for Nonmonetary Transactions to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. SFAS 153 is effective for nonmonetary assets exchanges occurring in fiscal periods beginning after June 15, 2005 (fiscal 2006 for pSivida). At this time, management reasonably believes that the adoption of SFAS 153 will not have a material effect on pSivida's financial position or results of operations.

In May 2005, the FASB issued SFAS No. 154: "Accounting Changes and Error Corrections," or SFAS 154, a replacement of APB Opinion No. 20: "Accounting Changes" and SFAS No. 3: "Reporting Accounting Changes in Interim Financial Statements," effective for fiscal years beginning after December 15, 2005 (fiscal 2007 for pSivida). SFAS 154 changes the requirements for the accounting for and reporting of a voluntary change in accounting principle as well as the changes required by an accounting pronouncement which does not include specific transition provisions. At this time management reasonably believes that the adoption of SFAS 154 will not have a material effect on pSivida's financial position or results of operations.

### **Differences between Australian Accounting Standards and U.S. Accounting Standards**

pSivida's prepares its audited consolidated financial statements in accordance with A-GAAP, which differ in certain significant respects from U.S. GAAP. The following table sets forth a comparison of pSivida's net loss and total equity in accordance with A-GAAP and U.S. GAAP as of the dates and for the periods indicated:

	<b>Years Ended June 30,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Net loss in accordance with A-GAAP	(14,726,523)	(3,683,205)	(2,765,153)
Net loss in accordance with US GAAP (restated(1))	(16,561,512)	(5,019,974)	(2,268,603)

## Table of Contents

- (1) Subsequent to the issuance of June 30, 2004 consolidated financial statements pSivida changed the amounts previously reported in the US GAAP reconciliation for the accounting for deferred income taxes as described in Note 27 to the consolidated financial statements.

	As at June 30,		
	2005	2004	2003
Total equity in accordance with A-GAAP	79,987,614	38,428,943	6,299,519
Total equity in accordance with US GAAP (restated)(1)	87,650,337	37,794,705	7,140,316

See Note 27 to pSivida's audited consolidated financial statements for a description of the differences between A-GAAP and U.S. GAAP as they relate to it, and a reconciliation to U.S. GAAP of net loss and total equity for the dates and periods indicated therein. Differences between A-GAAP and U.S. GAAP that have a material effect on net loss and total equity primarily relate to share-based compensation and purchase accounting.

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

Subsequent to the issuance of the June 30, 2004 consolidated financial statements, the Company changed the amounts previously reported in the U.S. GAAP reconciliation for the accounting for deferred income taxes as follows:

- Deferred tax liability for acquired intangible assets — Previously, deferred taxes were not recorded on the intangible assets acquired in connection with the step acquisition of pSiMedica as the book to tax basis differences were deemed to be permanent as the amortization of the related intangibles is not deductible for income tax purposes. The Company has subsequently concluded that, although under tax law, it will not receive a tax deduction in the future for recovery of the intangible assets, recognition of a deferred tax liability on the acquired intangibles is nevertheless required under U.S. GAAP because it is assumed for financial reporting purposes that the Company will generate future revenues at least equal to the recorded amount of the investment, and recovery will result in future taxable amounts.
- Valuation allowance for deferred income tax assets — Previously in establishing a valuation allowance, the Company fully reserved the total balance of the deferred income tax assets related to tax loss carryforwards as it was deemed more likely than not that the deferred tax assets would not be realized. As a result of the recognition of the U.S. GAAP deferred tax liabilities in connection with the step acquisition of pSiMedica as per the above, the Company has reevaluated the recoverability of the deferred income tax assets, taking into consideration the reversal of taxable temporary differences under U.S. GAAP.
- Amortization of intangible assets — Where the recognition of a deferred tax liability for acquired intangible assets as per the above resulted in additional basis of the related intangible, the additional basis is being amortized over the remaining estimated useful life of the intangible asset for U.S. GAAP purposes.

Refer to Note 27 to the Company's audited consolidated financial statements included elsewhere herein for a summary of the significant effects of the restatement.

### **Critical Accounting Policies**

pSivida prepares its audited consolidated financial statements in accordance with A-GAAP. As such, pSivida is required to make certain estimates, judgments, and assumptions that management believes are reasonable based upon the information available. These estimates, judgments and assumptions affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the periods presented. The significant accounting policies listed in Note 1 of the consolidated financial statements that management believes are the most critical to aid in fully understanding and evaluating pSivida's financial condition and results of operations under A-GAAP are discussed below.

#### **Valuation of intangible assets**

Other than cash deposits held, the value recognized in intangible assets on the consolidated statement of financial position is the most significant asset held by pSivida and the accounting principles adopted and estimated by management in recognizing these assets are therefore considered critical.

Intellectual property principally represents the license granted to pSiMedica from QinetiQ (formerly the Defense Evaluation and Research Agency in the United Kingdom) and patents granted. The QinetiQ license is an exclusive worldwide royalty-free license to the BioSilicon technology in the field of human and animal healthcare and in vivo diagnostic applications.

pSivida consolidated the results of pSiMedica upon the acquisition of a controlling economic interest in pSiMedica on May 10, 2001. Prior to this date, pSiMedica had undertaken little research and development activities and the cost of any research and development that had been undertaken was expensed in the accounts of pSiMedica. Upon the acquisition of additional share capital in pSiMedica in May 2001, it was considered reasonable to assume that the majority of the value paid by pSivida at this time should be attributable to the value of the license. The remainder was attributable to receivables, plant, property and equipment and payables. Attributing the bulk of the value paid by pSivida to the license was also considered reasonable on the basis that prior to acquisition of the additional share capital in pSiMedica there had not been any material patent grants.

Therefore, pSivida considered that it was reasonable that the value of A\$5.1 million, being the bulk of the value of the consideration paid on May 10, 2001 in acquiring the additional pSiMedica shares, should be primarily attributable to the value of the license and represented a reasonable fair value of the license at the time of the transaction.

On August 4, 2004 pSivida completed the acquisition of the pSiMedica shares that it did not already hold such that it now holds 100% of the issued capital in pSiMedica. Prior to acquiring 100% of the issued capital in pSiMedica, the most recent step in the acquisition of pSiMedica took place on October 13,

## Table of Contents

2003. At this point in time, management ascribed no value to the patent portfolio of pSiMedica and as a result the value acquired was recognized purely as the QinetiQ license. However, since this time, the company has been granted significant patents and it was thought appropriate that this position be reviewed. Based on management's assessment, the total amount of the incremental increase in the value of intangible assets of A\$25,000,000 should be attributed to the patents granted since October 2003. Consequently, based on management's assessment pSivida recognizes the intangible assets in the form of the license at the value of A\$64.4 million and patents at the value of A\$25 million.

In pSivida's A-GAAP consolidated financial statements, recognition of the value of intangible assets acquired has been made with reference to the actual cost of the investment made by it in acquiring pSiMedica shares. More specifically, the bulk of this value is attributed to the fair value of the license granted to pSiMedica by QinetiQ amounting to \$35.6 million and patents granted in relation to the BioSilicon technology of approximately \$13.8 million and goodwill of approximately \$9.9 million. The remainder was attributable to receivables, plant, property and equipment and payables. Other than the intangible assets, the value of assets acquired was considered nominal in value, particularly on the basis that the costs of research and development were expensed and no significant patents had been granted at May 10, 2001, when pSiMedica was first recognized in the consolidated financial statements.

Intellectual property is recorded at the cost of acquisition and is carried forward as an asset on the expectation that it will lead to commercialization. The carrying value of intangibles is reviewed by pSivida's board of directors at each reporting date.

### ***Estimated Useful Economic Life***

Based on the level of development of BioSilicon products, the competitive nature of the drug delivery industry and what is considered industry practice, a period of 12 years is considered by management to be a reasonable estimation of the expected useful economic life of the license.

The pSivida directors gave due consideration to the technical and commercial life of the intellectual property (being patents and licenses) concluding that a 12 year useful life was appropriate to determine their useful economic life to be the lesser of 12 years or the average remaining life of the intellectual property. Amortization will be recognized on the commencement of commercial production of products calculated on a straight-line basis over the remaining balance of the estimated useful life. pSivida reviews the commercial status of products on at least an annual basis and it is expected that amortization of intellectual property will commence during the year ending June 30, 2007.

Depreciation of plant and equipment is recognized on a straight-line basis over the estimated useful lives of three years. As pSivida's business is competitive and developmental in nature, plant and equipment is required to be regularly updated due to technological advancements and three years therefore is considered by management to be a reasonable estimation of the expected useful economic life of its plant and equipment.

### ***Realization of Deferred Tax Assets***

The recognition of deferred tax assets is based upon the likelihood of recoverability from future taxable income will be available, against which the reversal of timing differences can be deducted. To the extent that recovery is not likely, a valuation allowance is established. (Refer to Note 5 of the consolidated financial statements.) The recognition of deferred tax balances therefore involves judgment regarding pSivida's future financial performance in which the deferred tax asset is recognized. On this basis pSivida has not achieved profitability and expects to continue to incur net losses through to 2007. As pSivida does not expect BrachySil to be widely marketed before then, no tax asset has been recognized.

### ***Liquidity and Capital Resources***

Cash and cash equivalents totaled A\$12.9 million at June 30, 2005 compared to A\$31.4 million at June 30, 2004. pSivida has financed its operations primarily through private placements of equity

## Table of Contents

securities, the exercise of options and share purchase plans. In Australia, a share purchase plan is a limited offer to a company's existing shareholders to acquire a limited number of previously unissued ordinary shares with a maximum value of A\$5,000 per shareholder at a discount of 12.5% to the market value of pSivida's stock. Since December 1, 2000, the date it commenced business as pSivida, pSivida has not utilized borrowings and pSivida does not anticipate that borrowings will be required in the short term, with the exception of a convertible note entered into by pSivida on November 16, 2005. pSivida has no off-balance sheet financing and pSivida expects that its current cash levels will be sufficient to support current levels of research and development until the second quarter of calendar year 2007.

However, pSivida may increase its level of research and development activity which will directly increase its need for cash reserves as research and development is pSivida's most significant cost driver.

On April 20, 2004, pSivida raised A\$19.4 million, net of issue costs through a private placement of 19,375,000 ordinary shares to institutional and accredited investors at a subscription price of US\$0.80 and on April 23, 2004, it raised an additional A\$6.2 million net of issue costs through a private placement of 5,625,000 ordinary shares to institutional and accredited investors at a subscription price of US\$0.85.

On August 23, 2005 pSivida raised US\$4.2 million (A\$5.6 million) before costs via the private placement of 665,000 ADRs to predominantly US investors at US\$6.50 (A\$8.61) each, pursuant to a PIPE.

On November 16, 2005 pSivida issued a convertible note to a New York based institutional accredited investor, pursuant to which the investor purchased US\$15 million (A\$19.7 million) subordinated convertible debentures, convertible into pSivida ADSs at an initial conversion price of US\$7.10 (A\$9.50).

Net cash used in operating activities totaled A\$12.3 million for the year ended June 30, 2005 compared to A\$7.8 million for the year ended June 30, 2004 and A\$4.6 million for the year ended June 30, 2003. Research and development expenditure is the most significant expenditure item resulting in increased cash flows during the years ended June 30, 2005, 2004 and 2003 and amounted to A\$8.3 million, A\$6.1 million and A\$3.9 million respectively. (Refer to "pSivida's Business" for a detailed description of pSivida's research and development activities). Payments to suppliers and employees during the years ended June 30, 2005, 2004 and 2003 were A\$4.8 million, A\$2.0 million and A\$787,216, respectively. The increase in payments from the year ended June 30, 2003 to the year ended June 30, 2005 consisted of increased expenses relating to additional administrative activities and the timing of cash payments related to these activities.

Net cash used in investing activities totaled A\$8.1 million for the year ended June 30, 2005 compared to A\$527,168 for the year ended June 30, 2004 and A\$51,948 for the year ended June 30, 2003 principally for the cash paid for the acquisition of the remaining outside equity interest in pSiMedica, the construction of a cleanroom facility in Germany and the purchase of laboratory and computer equipment in Malvern, United Kingdom and in Perth, Western Australia.

Net cash flows from financing activities totaled A\$3.6 million for the year ended June 30, 2005 compared to A\$37.0 million for the year ended June 30, 2004 and A\$852,567 for the year ended June 30, 2003.

Cash flows from financing activities during the year ended June 30, 2005 reflected the following:

- During the year ended June 30, 2005 pSivida raised A\$3.6 million on the issue of additional share capital upon the exercise of options previously issued. At various times during the year, a total of 13,070,000 options were exercised at a price of A\$0.20, 2,200,000 options were exercised at a price of A\$0.40, 150,000 were exercised at a price of A\$0.50 and 150,000 options were exercised at a price of A\$0.65.
- During the year pSivida incurred \$27,422 in issue costs in relation to the acquisition of the remaining outside equity interest in pSiMedica in August 2004.

## Table of Contents

Cash flows from financing activities during the year ended June 30, 2004 reflected the following:

- On August 4, 2003, pSivida issued 3,891,572 ordinary shares at A\$0.24 per share, raising A\$932,298 net of issue costs. On October 6, 2003, pSivida issued additional share capital through a placement of 13,000,000 ordinary shares at A\$0.50 per share to investors, raising A\$6.2 million net of issue costs;
- On April 20, 2004, pSivida issued additional share capital through a placement of 19,375,000 ordinary shares at US\$0.80 per share to investors, raising A\$19.4 million net of issue costs, and on April 23, 2004, pSivida raised an additional A\$6.2 million net of issue costs through the issue of additional share capital with a further placement of 5,625,000 ordinary shares at US\$0.85 per share to investors;
- On October 13, 2003, pSivida subscribed for additional share capital in pSiMedica, increasing its direct ownership by 3.4% to 46.25% with indirect effective control over 53.05%. The consideration paid by pSivida in relation to this additional investment amounted to £2 million (A\$4.84 million). This transaction had no impact on the consolidated statement of cash flows. Additional equity contributions received by the subsidiary totaled A\$2.6 million;
- During the year a total of 8,130,000 options were exercised raising A\$1.6 million.

Cash flows from financing activities during the year ended June 30, 2003 reflected the following:

- On October 14, 2002, pSivida issued additional share capital through a placement of 7,000,000 ordinary shares at A\$0.12 per share raising A\$792,567 net of issue costs; and
- During the year a total of 300,000 options were exercised raising A\$60,000.

Cash flows from financing activities during the year ended June 30, 2002 reflected the following:

- On November 21, 2001, pSivida issued additional share capital through a placement of 12,300,000 ordinary shares at A\$0.20 per share to investors, raising A\$2.3 million net of issue costs;
- On March 7, 2002, pSivida subscribed for additional shares issued by pSiMedica. This had the effect of increasing pSivida's direct percentage ownership by 2.3% to 42.85% and indirect effective control to 50.79%. The consideration paid by pSivida in relation to this additional investment amounted to £1 million (A\$2.74 million). This transaction had no impact on the consolidated statement of cash flows. Additional equity contributions received by the subsidiary totaled A\$2.9 million;
- On May 9, 2002, pSivida issued 998,500 ordinary shares at A\$0.22 per share under a share purchase plan, raising A\$209,357 net of issue costs.

On September 12, 2002, pSivida entered into an agreement for a fully underwritten A\$7.5 million equity line of credit with Global Emerging Markets, also known as GEM, a New York based private equity group. A commitment fee equivalent to 1.67% of the total value of the facility is payable by pSivida to GEM on the proceeds of drawdowns. In addition, GEM was issued options to acquire 2,000,000 of pSivida's ordinary shares at A\$0.20 per share, expiring on December 31, 2004. These options were exercised by GEM on February 4, 2004. This agreement has now been terminated and no drawdowns were made by pSivida on this facility.

From commencing business as a development stage enterprise to June 30, 2005, pSivida's capital expenditures have totaled A\$4.8 million consisting of computer equipment and laboratory equipment that is being used in connection with its research and development activities undertaken in Malvern, United Kingdom and administration in Perth, Western Australia. Capital expenditures for plant and equipment and leasehold improvements are being depreciated on a straight line basis over the estimated useful lives of three years, with a net balance at June 30, 2005 of A\$3,273,663. pSivida does not have significant capital spending requirements, but expects to continue to engage in capital spending consistent with anticipated



## [Table of Contents](#)

growth in operations and personnel. Capital expenditure has been funded largely through the private placement of ordinary share capital.

pSivida believes that pSivida's existing cash and cash equivalents as well as anticipated cash flow from the exercise of options will be sufficient to support its current operating plan until the second quarter of calendar year 2007. However, pSivida has based this expectation on assumptions that may prove to be incorrect. pSivida's future funding requirements will depend upon many factors, including, but not limited to:

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

The following table outlines pSivida's contractual obligations as of June 30, 2005 for payments under its indebtedness (including capital leases), purchase obligations, operating leases and other obligations and the effects such obligations are expected to have on pSivida's liquidity and cash flows in future periods:

	Payments Due by Period				
	<u>Total</u>	<u>Less than 1 Year</u>	<u>1- 3 Years</u>	<u>3- 5 Years</u>	<u>More than 5 Years</u>
Contractual Obligations					
Long-Term Debt Obligations	—	—	—	—	—
Capital (Finance) Lease Obligations	—	—	—	—	—
Operating Lease Obligations	448	326	122	—	—
Purchase Obligations	—	—	—	—	—
Other Long-Term Liabilities	—	—	—	—	—
<b>Total</b>	<u>448</u>	<u>326</u>	<u>122</u>	<u>—</u>	<u>—</u>

## [Table of Contents](#)

### CAPITALIZATION AND INDEBTEDNESS

The following table sets forth pSivida's unaudited actual and as adjusted capitalization at September 30, 2005. The as adjusted column gives effect to the issuance of 16 million pSivida ADSs (representing 160 million ordinary shares) in the merger, based on an assumed price of US\$6.76 per share (taking into account the cash/stock combination in the merger, and the relevance of additional funding in the adjusted price) after deducting estimated merger and other expenses payable by pSivida. The actual number of pSivida ADSs issued, and the amount of cash paid, pursuant to the merger may be more or less than that estimated and such variation would affect portions of the as adjusted column of the following table. Depending on the extent of such variation, the effect on the as adjusted column could be material.

	As of September 30, 2005	
	Actual	As Adjusted
	(In Australian Dollars)	
<b>Indebtedness</b>		
Long-term debt	—	—
<b>Total Debt</b>	—	—
<b>Stockholders' equity (deficit)</b>		
Contributed equity	113,661,678	255,968,888
Reserves	(187,966)	321,079
Deficit accumulated prior to development stage	(3,813,181)	(3,813,181)
Deficit accumulated during development stage	(27,181,298)	(27,181,298)
<b>Total stockholders' equity</b>	<b>82,479,233</b>	<b>225,295,488</b>
<b>Total capitalization in accordance with A-GAAP</b>	<b>82,479,233</b>	<b>225,295,488</b>

### DIVIDEND POLICY

pSivida currently intends to retain any future earnings to finance the growth, development and expansion of its business. Accordingly, it does not intend to declare or pay any dividends on pSivida's ordinary shares for the foreseeable future. The declaration, payment and amount of future dividends, if any, will be at the sole discretion of pSivida's board of directors after taking into account various factors, including its financial condition, results of operations, cash flow from operations, current and anticipated capital requirements and expansion plans, the income tax laws then in effect and the requirements of applicable corporate law.

### PSIVIDA'S BUSINESS

#### Overview

pSivida is 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. pSivida is working toward developing applications for controlled slow release drug delivery and diagnostics. Initially, pSivida is using BioSilicon to target primary liver cancer, but it intends 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. pSivida is currently conducting a Phase IIb dose optimization BioSilicon trial in inoperable primary liver cancer patients at Singapore General Hospital. Other potential applications for BioSilicon may include tissue engineering, orthopedics and food science.

pSivida is a public company limited by shares. The legal entity that became pSivida was incorporated as the Sumich Group Ltd on April 28, 1987. The Sumich Group listed on the ASX on September 17,

## [Table of Contents](#)

1987 and operated an agriculture business which was placed into administration or receivership on September 30, 1998. pSivida was subsequently formed on December 1, 2000 upon entering into a court-approved arrangement with Sumich Group's creditors which fully extinguished all prior liabilities as of that time. pSivida then appointed new directors and officers and re-listed on the ASX under its new name. pSivida was then recapitalized through a placement to investors of 9,300,000 ordinary shares at A\$0.30 per share, raising A\$2.8 million.

pSivida's ordinary shares are also listed on the Frankfurt, Berlin, Munich and Stuttgart exchanges under the symbol "PSI." pSivida's ordinary shares also trade in the United Kingdom on the OFEX International market Service (IMS) under the symbol "PSD."

### **Strategy**

pSivida's commercialization strategy is to concentrate on internal product development; the licensing of the BioSilicon technology platform; and the potential sale of non-core intellectual property.

### **Internal Product Development**

The focus of pSivida's 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). pSivida has established detailed commercialization plans for BrachySil, pSivida's lead product, bearing in mind market sizes, benefits offered to patients and alternative competitive therapies. The first step in pSivida's commercialization strategy for BrachySil was a validation of human safety and efficacy through human clinical trials, which was completed in early 2005. Currently underway is pSivida's Phase IIb dose optimization trial with the first patients now having been treated in Singapore. It is expected that these trials will be followed directly by registration trials. pSivida also intends to open up dialogue with the FDA, the EU regulatory authorities and government regulators in various other jurisdictions in order to establish that BrachySil may appropriately be regulated as a device rather than as a drug. If BrachySil becomes registered as anticipated in 2007, pSivida intends to investigate BrachySil's use as a treatment for other inoperable tumors such as pancreatic, metastatic ovarian and tumors within the peritoneum, brain and lung.

### **Licensing of Core and Non-Core Intellectual Property**

pSivida believes that potential range of applications for BioSilicon will permit early stage licensing for non-core applications such as biomaterial in orthopedics, tissue engineering and regenerative medicine. Furthermore, 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 being explored. For example, pSivida recently entered a license agreement with Beijing Med-Pharm pursuant to which Beijing Med-Pharm will be responsible for the clinical development, marketing and distribution of BrachySil in China. pSivida also intends to license diagnostic and sensor applications of the BioSilicon platform technology developed by its subsidiary, AION Diagnostics. In addition to licensing, pSivida may also consider opportunities for collaborations.

On October 27, 2005 pSivida signed a license with Beijing Med-Pharm Corporation (BJGP: PK) for the clinical development, marketing and distribution of BrachySil, in China.

Under the terms of the license, pSivida 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. It is a condition of the license that a manufacturing and supply agreement for pSivida to supply BrachySil to Beijing Med-Pharm is concluded within 90 days.

The license includes upfront and milestone payments in excess of US\$2 million and royalties ranging up to 30%, depending upon level of sales, payable to pSivida by Beijing Med-Pharm.

## [Table of Contents](#)

Beijing Med-Pharm is a US-based company with Chinese subsidiaries that offers an end-to-end solution to primarily Western pharmaceutical companies who wish to sell their products into the Chinese marketplace. In December 2004, Beijing Med-Pharm initiated the first ever purchase of a Chinese pharmaceutical distribution company by a foreign entity after it signed an agreement to purchase Beijing Wanwei Pharmaceutical Ltd., a pharmaceutical distributor covering the bulk of Beijing's hospitals.

BrachySil (32-P BioSilicon) will enter a Phase IIb dose-profiling study shortly as a potential new treatment for primary liver cancer (also called hepatocellular carcinoma or HCC). China has the highest incidence of HCC in the world, with over 345,000 estimated new cases per annum (Globocan), representing 55% of total worldwide cases. Focused programs are being prepared to seek to exploit its potentially broader utility in other significant cancer indications, including inoperable pancreatic and secondary liver disease.

### ***Sale of Non-Core Applications***

pSivida is also exploring sales of early stage non-core applications. Such applications include biomaterial in orthopedics, tissue engineering and regenerative medicine producing.

### ***BioSilicon™***

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. These pores can be formed into a diverse array of shapes and sizes and can be filled with various drugs, genes and proteins. pSivida believes that BioSilicon's features include:

- **Biocompatibility** — BioSilicon is biocompatible, meaning that it is not injurious and does not cause immunological rejection within the body. pSivida has assessed the biocompatibility of BioSilicon as follows:
  - BioSilicon wafers implanted in animals for a period of up to 6 months performed similarly to medical grade titanium, a well-known biocompatible material, in terms of biocompatibility.
  - Toxicology studies performed for pSivida by Quintiles Transnational and Huntingdon Life Sciences Group in the UK have shown that the maximum tolerated dose of BioSilicon is ten to one hundred times the dose expected to be used in pSivida's clinical trials in Singapore.
  - To date, pSivida's human trials have produced no apparent product-related adverse events.
- **Non-toxicity** — pSivida's 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. pSivida has undertaken both pre-clinical studies and clinical trials testing the toxicology of BioSilicon. pSivida's pre-clinical toxicology studies have demonstrated a minimum tolerated dose which is substantially in excess of the doses expected to be used in initial clinical applications. Also, comparative toxicology studies in animals comparing BioSilicon and titanium have shown no significant differences in toxicology.
- **Biodegradability** — pSivida believes that BioSilicon can be made biodegradable *in vivo* and *in vitro* (in animals and humans and in solution). The rate of biodegradation depends on the degree of nanostructuring that is imparted on the material. pSivida believes that, as a result, BioSilicon can be made to dissolve in suitable environments in days, weeks or months, depending upon the size and nature of the BioSilicon implanted. This has been demonstrated in various models:
  - BioSilicon has been shown to dissolve in synthetic body fluids such as serum, plasma and gastric juices.
  - While a similar test has not been performed in humans, BioSilicon has been shown to dissolve when placed subcutaneously in guinea pigs.
  - pSivida has tested BioSilicon in a variety of buffered solutions (salty waters).

## [Table of Contents](#)

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. It believes that other potential applications may include tissue engineering, orthopedics and food science (food sensors and nutraceutical products).

### **Core Markets**

#### *Brachytherapy*

Brachytherapy is a relatively new form of treatment for cancer involving the localized delivery of radioactive agents directly into a tumor. The market is currently dominated by the use of radioactive 'seeds' for the treatment of hormone non-responsive prostate cancer. These are mainly used for the treatment of prostate cancer and can cause trauma on application. Current mainline brachytherapy implants are relatively large, causing trauma and hemorrhaging in tumors. Such seeds also carry comparatively long-range radio emitters that cause normal tissue damage and other quality of life problems to the patient. Other products in this area such as Yttrium 90 (Y90) ceramic spheres are not generally administered directly into tumors but into the vasculature feeding tumor-bearing organs such as the liver. The latter approach causes a significant degree of healthy tissue damage. These current therapeutic regimens have limited value for inoperable liver cancer. Liver cancer is currently one of the world's major causes of cancer-based mortality.

#### *Drug Delivery*

The market for new drug delivery formulations is rapidly growing. The value of the global drug delivery market is currently in excess of US\$66 billion, and is estimated to grow to US\$114 billion by 2007. Drug delivery has proved to be a critical element in the drug development process, resulting in enhanced safety and efficacy of many medicines. Improvement of drug delivery is important for better patient safety and drug bioavailability. Furthermore, the use of novel drug delivery systems is an increasingly important strategy for major pharmaceutical and biotechnology companies as they recognize the benefits of forging relationships with drug delivery companies to enable the delivery of new drugs and extend the commercial life of their current drugs.

### **Core BioSilicon Applications**

#### *Brachytherapy*

Brachytherapy is a relatively new form of treatment for cancer and involves the delivery of radioisotopes directly into the tumor. With improved tumor location and mapping, this approach to cancer therapy has grown substantially in recent years allowing the physician/surgeon/radiologist to specifically expose tumor tissue to radioisotopes in a targeted manner.

For brachytherapy treatment, pSivida believes BioSilicon has many significant advantages:

- Short range — 32-P isotope has a short active range resulting in less damage to healthy tissue
- Range of tumors — fine gauge needle delivery allows potential application to all solid tumors, unlike current brachytherapy products
- Direct delivery — injection via fine gauge needle minimizes side effects and tissue trauma
- Inexpensive device — low cost, abundant availability of silicon, with scale up proven
- Distribution — 32-P half-life of 14 days allows more convenient distribution to hospitals and application in the patient
- Immobilization — 32-P device is immobilized in the tumor, significantly reducing risk of leakage or systemic side effects

*BrachySil™*

BrachySil, pSivida's lead product candidate, is a brachytherapy product that pSivida believes has the potential to significantly expand the current brachytherapy market size. BrachySil consists of an injectable BioSilicon structure that carries 32-phosphorus, or 32P, a radioactive isotope which has been shown to shrink tumors. The isotope 32P emits beta or electron radiation which has been shown to be effective at shrinking tumors. However, this radiation is harmful to healthy tissue. Therefore, the 32P and its radiation must be confined to the area of the tumor and not allowed to travel within the body. Existing 32P-based products do not fully immobilize 32P, allowing the isotope to dissolve, enter the bloodstream and harm healthy tissue in other parts of the body. pSivida has engineered BrachySil to ensure that the 32P is unable to escape the BioSilicon particle. Therefore, the 32P is in effect "locked" into BrachySil by producing an amalgam of phosphorus and silicon. The BrachySil treatment is delivered, without surgery, via injection through the abdomen using a fine gauge needle, allowing the clinician to administer a single dose of BrachySil directly into the tumor site. 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 and precise product for both patient and physician.

pSivida is developing products in this growing area through its wholly-owned, Singapore-based subsidiary pSiOncology in conjunction with Singapore General Hospital. pSiOncology is also developing localized chemotherapy products.

Phase IIB clinical trials commenced with BrachySil (32-P BioSilicon) as a potential new brachytherapy treatment for inoperable primary liver cancer (hepatocellular carcinoma, HCC). The first patient has successfully received treatment at Singapore General Hospital using a new fine-gauge needle multi-injection device which will enable for the first time, larger and also multiple tumors to be treated. A total of 50 patients will be entered into this multi-centre trial which will be conducted in Singapore, Malaysia and Vietnam. BrachySil trials for pancreatic cancer are expected to commence in the first quarter of 2006.

The study, which was designed in collaboration with Singapore General Hospital and approved by the Singaporean regulatory authority (Health Sciences Authority) will determine the optimal dose of BrachySil in treating inoperable HCC. Patients will be evaluated up to 12 months after treatment, and the endpoints are based on evaluations of patient safety and target tumor responses, as well as overall survival.

The study is intended to provide pivotal efficacy and safety data to support future product registration and approval of BrachySil as an effective treatment for primary liver cancer. These results are expected to build on the findings of a Phase IIA study concluded earlier this year on patients with advanced liver cancer. In this trial, which was also conducted at Singapore General Hospital, BrachySil was found to be both safe and well tolerated. It was also found to reduce significantly the size of some tumors treated even on a lower dose as used in the earlier trials.

In addition, the Phase IIB trial will include a clinical evaluation of pSivida's proprietary SIMPL™ implantation system. SIMPL™ is a fine-gauge needle, multi-injection device, through which BrachySil is injected as a liquid suspension directly into tumors under local anesthetic. The device has been designed to distribute the implanted dose from a single entry point and to enable physicians to treat larger tumors. This device is expected to be a further significant advantage of BrachySil over existing brachytherapies as well as assist in expanding the application of BrachySil to other solid tumor cancers.

Assuming that trials are successful and an optimal dose is established, pSivida intends to undertake larger multi-center clinical trials involving patients in both Asia and Europe to produce data sufficient to register BrachySil for use as an approved treatment for primary liver cancer. pSivida expects completion of its optimization dose study during early 2006, followed by initiation of regulatory studies, thus registration could potentially be completed in mid 2007. Following BrachySil's registration, pSivida anticipates rapid adoption of the treatment because it is delivered by means of a fine gauge direct needle without surgery under local anesthetic and patients are able to be discharged the following day. If BrachySil becomes registered as anticipated in 2007, pSivida intends to investigate BrachySil's use as a treatment for other

inoperable tumors such as pancreatic, metastatic ovarian and tumors within the peritoneum, brain and lung. pSivida believes that such approvals may expand the market for brachytherapy.

During late 2005, pSivida also intends to open up dialogue with the FDA in order to establish that BrachySil may appropriately be regulated as a device rather than as a drug. pSivida is pursuing a similar strategy with respect to EU regulatory authorities to qualify for device registration in Europe under the auspices of a CE mark application. Generally speaking, obtaining regulatory approval to market a medical device is much less expensive and time consuming than the process required for a drug. pSivida also intends to consult with government regulators in various other jurisdictions to promote this strategy.

#### *Drug Delivery*

pSivida is also strongly focused on the application of BioSilicon technology to a controlled, slow release drug delivery product. pSivida intends to achieve this through the development of pSivida's own products such as BrachySil; the delivery of generic or "off patent" drugs utilizing new delivery methods comprised of BioSilicon; and licensing the use of BioSilicon to pharmaceutical companies for delivery of their patented drugs.

The following properties make BioSilicon a potentially effective drug delivery platform:

- high drug loading rates (up to 95.0%);
- ability to control release timing (hours/days/weeks/months);
- ability to vary pore size to accommodate different drug sizes;
- ability to serve as a conductor of electrical charge which can be altered to regulate drug delivery rate; and
- potential incorporation of diagnostics and delivery intelligence.

BioSilicon functions as a "honeycomb" structure to retain drugs within the 'cells' within the nanometer scale structure. In contrast, many polymers cause toxicity and inflammation and can actually chemically react with the pharmaceutical being delivered. BioSilicon's biodegradability and solubility can be finely tuned without changing the chemical nature of the material itself. Thus, unlike polymer-based systems, BioSilicon's composition is identical for all potential products whether they are implants for drug delivery or biodegradable orthopedic devices (pins, screws, braces, etc.). The only characteristic that is varied is the level of engineering and shape of the silicon device. Computer model systems have shown that the rate at which the BioSilicon structure degrades in the body can be precisely regulated in order to release a drug over a period of time.

pSivida also plans to develop "smart" drug delivery devices making use of the semi-conductor properties of silicon. BioSilicon can potentially perform in the same manner as a silicon chip, thus providing the opportunity to marry the electronic potential of the material with healthcare applications. Utilizing these properties may enable processors, sensors and telemetry to be incorporated into a biodegradable drug delivery structure. This combination may provide for a more powerful delivery system than conventional polymer-based systems which must rely on their natural rate of biodegradation. With a biodegradable BioSilicon chip, the drug release might be made 'intelligent' through microprocessor control.

pSivida has an agreement with an undisclosed top 5 global pharmaceutical company for the staged evaluation of BioSilicon for drug delivery. The agreement covers the evaluation of BioSilicon for the controlled release of a number of selected compounds. The pharmaceutical company will fund the direct costs of the program.

## ***Non-Core Applications***

### *Diagnostics*

pSivida recently incorporated AION Diagnostics in Australia to develop diagnostic applications for BioSilicon. pSivida intends to license diagnostic and sensor applications of the BioSilicon platform technology.

Through AION Diagnostics, pSivida seeks to develop diagnostic applications using the biodegradable, optical, semiconductor and micro machining properties of BioSilicon. AION Diagnostics will look to develop products through strategic collaborations with universities, research institutions and industry partners. AION Diagnostics will also seek grant funding in Australia and the United States. Research currently being undertaken is at a preliminary stage only and there is no guarantee that BioSilicon will ultimately be used in the commercialization of a product in this area.

pSivida has assigned to AION Diagnostics its licensing agreement with Forschungszentrum Jülich for the use of its porous silicon optical mirror technology. Forschungszentrum Jülich is a science and engineering research institution funded jointly by the Federal Republic of Germany and the State of Nordrhein Westfalen.

### *Orthopedics*

pSivida believes that BioSilicon also has potential to be used as a biodegradable scaffold for orthopedic tissue engineering. A porous silicon structure could be deliberately sculpted to provide bone-building cells with a scaffold that the cells can penetrate and to which cells can anchor. As the bone tissue deposits itself onto the scaffold, the silicon would slowly dissolve away, eventually leaving just the new bone. Silicon's ability to carry an electrical current charge bias may also give BioSilicon an advantage in the treatment of bone conditions, promote bone growth and may have other orthopedic applications. Data gathered to date in preclinical studies indicate that cells will grow and divide in BioSilicon substrates and that BioSilicon can be osteo-conductive, promoting bone growth and deposition. In July 2003, pSiMedica entered into a shared revenue agreement with Texas Christian University, for which Texas Christian University will receive 10.0% of patent royalties for any joint intellectual property developed in the areas of tissue engineering and orthopedic applications. Research being undertaken in the orthopedics field is still at a preliminary stage, and there is no guarantee that BioSilicon will ultimately lead to a commercializable product in this area.

### *Tissue Engineering*

pSivida believes that BioSilicon also has potential uses in tissue engineering as a biodegradable scaffold or framework. U.S.-based Cytomatrix is evaluating BioSilicon for the expansion of stem cells for the treatment of a variety of diseases. Singapore General Hospital is assessing the use of BioSilicon as a scaffold to assist the growth of tissue cells for applications in areas such as craniofacial and reconstructive surgery. The McComb Foundation, an Australian company, together with its commercialization partner, Clinical Cell Culture, Ltd., is evaluating the use of BioSilicon as a scaffold to assist in the growth of various cells for application in future tissue engineering products including in the wound healing and burns area. Depending on results and compatibility with Clinical Cell Culture's products, Clinical Cell Culture will have the right to commercialize products combining its proprietary technology with BioSilicon. pSivida is also examining the use of growth and disease inhibiting factors within the BioSilicon scaffold to assist with tissue regeneration. pSivida is also active in the area of wound management products, including research into the development of potentially novel biodegradable sutures. All of these research initiatives involving the use of BioSilicon in the area of tissue engineering are at a preliminary stage only and there is no guarantee that BioSilicon will ultimately be used in the commercialization of any products in this area.



*Food Technology*

pSivida has entered into an agreement with ITOCHU Corporation to explore the development and commercialization of new ingestible BioSilicon products in the rapidly growing area of food technology. ITOCHU is a large multinational corporation headquartered in Japan with considerable experience in the food industry and interests ranging from technology development and production through to distribution and retail. Further international collaborations and licensing opportunities are anticipated in the food industry. pSivida's research in the area of food technology is at a preliminary stage only and there is no guarantee that BioSilicon will ultimately be used in the commercialization of a product in this area.

**Subsidiary Companies**

*pSiMedica*

In December 2000, pSivida co-founded pSiMedica Ltd, a company incorporated in the United Kingdom. pSiMedica was formed with QinetiQ Group plc and several individuals and privately held investment companies. pSivida invested A\$1.0 million to acquire an 11.1% interest in pSiMedica. QinetiQ, which was formerly part of the Defense Evaluation and Research Agency, or DERA, an agency of the government of the UK, is currently one of Europe's largest science and technology solutions companies. QinetiQ remains 56.0% owned by the UK Ministry of Defense on behalf of the Government of the United Kingdom, but has sold interests of 30.5% to the Carlyle Group, one of the world's leading private equity firms, and 13.0% to QinetiQ's employees.

Further significant events in pSiMedica's history are as follows:

- In May 2001, pSivida increased its ownership in pSiMedica from 11.1% to 40.1% by acquiring 28.9% of pSiMedica's outstanding ordinary shares from other minority shareholders. This acquisition of shares in pSiMedica was made in consideration for A\$1.8 million in cash and the issuance of 10,918,535 of pSivida's ordinary shares at a value of A\$0.30 per share, or a total consideration value of A\$5.1 million. At the same time, pSivida also received powers of attorney over the pSiMedica shareholdings of Viaticus Capital Pty Ltd, representing 1.5%; Mr. Sam Giacomo, representing 1.4%; Mr. David McAuliffe, representing 1.4%; and Dr. Aston, representing 7.0%. These transactions resulted in pSivida's holding an indirect 51.4% controlling interest in pSiMedica, and thereafter, pSivida began to consolidate pSiMedica in pSivida's consolidated financial statements.
- On March 7, 2002, pSivida subscribed for additional shares issued by pSiMedica. This had the effect of increasing pSivida's direct percentage ownership by 2.8% to 42.9% and indirect effective control to 50.8%. The consideration paid by pSivida in relation to this additional investment amounted to £1 million (approximately A\$2.7 million). This investment was required to fund continued research and development by pSiMedica.
- On October 13, 2003, pSivida again subscribed for additional convertible preference share capital in pSiMedica, increasing pSivida's direct ownership by 3.4% to 46.3% with indirect effective control over 53.1%. The consideration paid by pSivida in relation to this additional investment amounted to £2.0 million (approximately A\$4.8 million). This investment was required to fund continued research and development by pSiMedica.
- On August 4, 2004, pSivida acquired the remaining shares in pSiMedica that it did not already own. The consideration paid was \$59,224,568 which comprised of \$4,323,622 in cash, a total of 49,804,381 ordinary shares of pSivida issued at a value of \$1.09 for A-GAAP purposes, 638,537 pSivida options with an estimated fair value of \$292,828 (issued to employees of pSiMedica in exchange for their rights being waived in relation to options previously issued by pSiMedica) and direct acquisition costs totalling \$321,342. As a result of this transaction QinetiQ became pSivida's largest shareholder holding 17.5% of its issued capital at that time.

## Table of Contents

### *pSiOncology*

On July 24, 2002, pSiOncology Pte Ltd. was formed in Singapore by pSiMedica, Singapore General Hospital and Biotech Research Ventures Pte Ltd to develop BioSilicon brachytherapy products for the treatment of operable and inoperable cancer tumors.

In May 2004, the minority shareholders in pSiOncology, Singapore General Hospital Technology Ventures Pte Ltd and Biotech Research Ventures Pte Ltd, exchanged their pSiOncology shares for newly issued shares in pSiMedica. Since that time, pSiMedica has been the holder of 100.0% of the issued share capital of pSiOncology.

### *AION Diagnostics*

On August 24, 2004, pSivida incorporated AION Diagnostics Limited in Australia to develop and commercialize diagnostic applications of BioSilicon. pSivida has licensed diagnostic and sensor applications of the BioSilicon platform technology to AION Diagnostics. pSivida capitalized AION Diagnostics with A\$1.2 million. In addition, zero exercise price options have been created over 20.0% of the fully diluted issued capital to be awarded to directors, staff and consultants of AION Diagnostics, subject to the achievement of milestones. By exploiting both the biocompatible and biodegradable properties of BioSilicon, AION Diagnostics will be seeking to commercialize diagnostic products that will provide real time continuous measurement of important diagnostic markers. The move to spin out AION Diagnostics will enable a separate team to focus on leveraging the technological opportunities in BioSilicon to develop and commercialize a diagnostics product portfolio, while pSivida and its staff remain focused on the core areas of slow release drug delivery and brachytherapy.

Both QinetiQ and pSivida act as strategic partners of AION Diagnostics as AION Diagnostics looks to develop products through strategic collaborations with universities, research institutions and industry partners and seeks grant funding in Australia and the U.S.

### **Collaborations**

#### *QinetiQ*

In connection with the organization of pSivida and pSiMedica, in December 2000, pSiMedica entered into a technology license agreement with the Defense Evaluation and Research Agency, or DERA, an instrumentality of the UK government. The technology license gave pSiMedica the right to use intellectual property associated with BioSilicon to develop, manufacture and sell products for uses on or in the human and animal body. The intellectual property included patents, patent applications, various research reports, trademarks, know-how and other materials. The license was granted on a worldwide, royalty free basis in exchange for shares in pSiMedica. DERA retained the right to use the intellectual property in connection with defense-related, noncommercial purposes. The license provided that DERA would later assign the intellectual property outright upon the fulfillment of certain conditions, including pSiMedica successfully raising additional funds.

In March 2002, subsequent to pSivida's making an additional investment in pSiMedica funded by its November 2001 placement of ordinary shares, pSiMedica entered into an assignment agreement with QinetiQ. Pursuant to the assignment agreement, QinetiQ, the successor to DERA's rights to the intellectual property, assigned the outright ownership of the intellectual property to pSiMedica with QinetiQ retain only the right to sublicense the intellectual property to DERA for noncommercial, defense-related uses and, subject to reasonable terms, in connection with purposes outside of pSiMedica's original field of use. pSiMedica gave only nominal consideration for assignment, as the obligation to assign the intellectual property was pursuant to the earlier license agreement. Pursuant to the assignment agreement, pSiMedica became the owner of all the relevant patents, patent applications, research reports, trademarks, know-how and other materials associated with BioSilicon.

## Table of Contents

### *Singapore General Hospital*

During July 2002, pSiMedica entered into an agreement with Singapore General Hospital related to the incorporation of pSiOncology Pte Ltd., now an indirect wholly-owned subsidiary of pSivida and a direct wholly-owned subsidiary of pSiMedica. The agreement involves the licensing of intellectual property pertaining to BioSilicon from pSiMedica to explore its potential as a platform for brachytherapy. During May 2004 pSiMedica issued shares to Singapore General Hospital in exchange for the outside equity interest in pSiOncology Pte Ltd and subsequently as a result of the transaction whereby pSivida acquired the outside equity interest in pSiMedica, Singapore General Hospital exchanged its pSiMedica shares for pSivida ordinary shares.

### *AEA Technology QSA GmbH*

During March 2004 pSiMedica entered into a three year agreement with AEA Technology QSA GmbH for the construction of a facility for the production and manufacture of radioactive <sup>32</sup>P-BioSilicon nano-structured micro particles to meet pSiMedica's commercial supply requirements. This facility was completed in September 2005.

pSivida's broader commercialization strategy involves a high degree of partnering at various levels to lower the costs to pSivida of the development process. The research and development process is conducted and coordinated through pSiMedica as well as through collaborative partnerships. pSivida anticipates licensing and assigning rights pertaining to non-core applications, providing pSivida with cash flow and allowing pSivida to focus on commercialization of core products strategy. While continuing to develop pSivida's existing collaborative partnerships pSivida entered into eight new arrangements during 2004 and 2005.

Descriptions of several of pSivida's main collaborations are included below. pSivida has entered into written agreements with each of the identified third parties. These agreements provide for the study and evaluation of potential uses for BioSilicon in conjunction such third party's products and inventions. To date, no specific products have been identified or marketed pursuant to these collaborations, and in each case research being undertaken is at a preliminary stage only and there is no guarantee that BioSilicon will ultimately be used in the commercialization of a product in the area of the collaboration. In most instances, the collaboration agreement provides that pSivida will retain the rights to any discoveries relating to BioSilicon and the third party will retain the right to discoveries relating to its product. Where discoveries involve a combination of both products, generally any rights or intellectual property arising as a result of that combination will be shared equally, with the third party having the right to market the combination product. In connection with collaborations with universities, pSivida retains the right to market and commercialize all discoveries, and in some instances, the university will be granted the right to receive a royalty.

### *Top Five Global Pharma*

The evaluation of selected compounds from an undisclosed top five global pharmaceutical company has progressed successfully. The collaboration agreement covers a staged evaluation of the pharmaceutical company's proprietary compounds in pSivida's porous silicon, controlled release platform (BioSilicon). The initial stage of the planned 12 month program has concluded, meeting the agreed technical success criteria, and in turn triggering the next payment to pSivida under the terms of the agreement.

### *ITOCHU Corporation — Japan, Asia and Food Technology*

A non-exclusive agreement was signed with ITOCHU Corporation for the development and commercialization of BioSilicon in Japan and Asia and food applications. ITOCHU, one of the world's largest corporations is engaged in development of commercial opportunities and products for BioSilicon in Japan and other significant markets in Asia. ITOCHU also has significant experience and expertise in the food industry and is engaged in the development and commercialization of new products utilizing BioSilicon technology in the rapidly growing area of food technology and nutraceuticals.

## [Table of Contents](#)

### *Cirrus Pharmaceuticals*

pSivida recently entered into a contract with U.S.-based Cirrus Pharmaceuticals, Inc., an independent R&D organization based in Research Triangle Park, North Carolina, to accelerate and expand development of a number of specific drug candidates formulated in BioSilicon to expand a BioSilicon product pipeline of reformulated drugs. The development contract has an initial extendable term of one year and provides a dedicated team of scientists from Cirrus Pharmaceuticals. The relationship has been established to seek to generate new products based on reformulating existing specific generic and proprietary drugs and their delivery utilizing BioSilicon. To the extent that such new reformulations or delivery demonstrate improved efficacy, safety and/or compliance as compared to the original product, then pSivida will be able to claim patent protection on its new products. All intellectual property developed through this collaboration relating to BioSilicon will be wholly-owned by pSivida.

### *EPITAN — Completion of Proof of Concept Study*

pSivida has entered into an agreement with the Institute of Medical and Veterinary Science in Adelaide, South Australia, pursuant to which an in vivo study was conducted that indicated that a single injection of pSivida's porous BioSilicon technology successfully released MELANOTAN™ over a sustained period. The outcome of this collaboration may lead to a second-generation liquid-based injectable MELANOTAN™ product.

### *Forschungszentrum — Porous Silicon Mirror Technology*

pSivida's subsidiary, AION Diagnostics, entered into a licensing agreement with Forschungszentrum Julich GmbH, part of Germany's largest research institute, to acquire rights in the use of Forschungszentrum's porous silicon mirror technology. Combining this technology with its recently acquired BioSilicon diagnostics platform, AION Diagnostics intends to examine the development of BioSilicon optical mirrors as an in vivo diagnostic device, with the ability to provide early diagnosis and continual monitoring of patients.

### *Flinders University/ ARC Grant*

pSivida together with the Flinders University of South Australia was awarded an ARC Industry Linkage Grant. Flinders University plans to develop a novel ophthalmic bioimplant from BioSilicon. The project is intended to result in biomaterials for the treatment of blinding diseases of the eye. Implanted into the limbus, bioimplants may ameliorate some common corneal diseases.

### *University of South Australia — Evaluation of Protein & Peptide Delivery*

pSivida entered into a research and development collaboration with the University of South Australia to evaluate the potential of the BioSilicon platform for the delivery of protein and peptide-based therapeutics (or biopharmaceuticals) including antibodies, hormones and growth factors that account for a substantial and increasing segment of the pharmaceutical market. Preliminary investigations using BioSilicon have indicated its utility for the delivery of biopharmaceuticals, including its potential for the development of new controlled release formulations of existing marketed therapeutics.

### *University of Pittsburgh (U.S.) — DNA vaccine delivery*

pSivida's collaboration with the University of Pittsburgh is exploring the use of BioSilicon in binding and protecting DNA during vaccine therapy in model systems. pSiMedica has developed the technology to load and release DNA from BioSilicon matrices resulting in effective production of immunogen (the antigen for which the DNA codes). The ability to load and protect DNA during vaccine regimens is vital to the production of DNA vaccine products.

## [Table of Contents](#)

### *McComb Foundation/ Clinical Cell Culture Ltd (Australia) — tissue engineering products*

The McComb Foundation is a research organization established in 1999 to conduct research into tissue engineering. Clinical Cell Culture, an ASX listed biomedical company, is the McComb Foundation's commercialization partner which develops and distributes tissue-engineered cellular products for autologous skin replacement. Clinical Cell Culture's products are based in part on technologies licensed from the McComb Foundation. The McComb Foundation and Clinical Cell Culture are evaluating the use of BioSilicon as a scaffold device to assist in the growth of various cells for application in future tissue engineering products including in the wound healing and burns area. Depending on results and compatibility with Clinical Cell Culture's products, Clinical Cell Culture will have the right to commercialize products combining its proprietary technology with BioSilicon. The collaboration agreement was entered into in August 2003.

### *Singapore General Hospital (Singapore) — tissue engineering*

In addition to Singapore General Hospital's work with BrachySil, other research programs being conducted at SGH's Department of Plastic Surgery are assessing the use of BioSilicon as a scaffold to assist in the growth of tissue cells for applications in areas such as craniofacial and reconstructive surgery.

## **Manufacturing**

pSivida currently acquires BioSilicon from QinetiQ in the UK for use in internal and collaborative research. pSivida's lead product, BrachySil, is currently manufactured in accordance with FDA guidelines by Hosokawa Micron Group, Atomising Systems Ltd, HighForce Ltd and AEA Technology QSA GmbH. pSivida requires that BrachySil be manufactured in accordance with FDA guidelines because, in the U.S., the FDA regulates the manufacturing processes used to produce products such as pSivida's, and the U.S. is the largest market into which pSivida hopes to be able to market BrachySil in the future. pSivida intends to apply to the FDA to market BrachySil in the U.S., which will require FDA certification of pSivida's compliance with its regulations., pSivida believes that its experience in manufacturing in compliance with FDA guidelines should facilitate the application process. To date, pSivida has not sought nor has pSivida received approval from the FDA of its manufacturing processes.

BioSilicon is manufactured through the controlled nano-structuring of elemental silicon. This process consists of the acid etching of elemental silicon which results in the creation of interconnected nanowire structures that resemble a honeycomb. This structure allows elemental silicon to become biodegradable while also allowing the retention of therapeutic substances within the honeycomb matrix. In order to produce suitable drug delivery devices, pSivida has sought to engineer products that fulfill particular clinical requirements. For example, in order to administer therapies using fine bore needles of 18 gauge or smaller, the delivery device must be no larger than 1.2 millimeters in diameter. The manufacture of BrachySil requires several steps. These steps include:

- The production of a fine powder of silicon;
- Measurement and separation of suitably-sized silicon particles for clinical application;
- Acid etching to produce biodegradable silicon particles; and
- Phosphorus coating and neutron transmutation to produce particles coated with <sup>32</sup>P.

In order to achieve the four steps above, pSivida has sought to contract with four separate companies, each an expert in one of the above manufacturing processes.

pSivida has developed BioSilicon production capability at pSivida's own facilities in the UK.

During March 2004 pSiMedica entered into a three year agreement with AEA Technology QSA for the construction of a facility for the production and manufacture of radioactive <sup>32</sup>P-BioSilicon nano-structured microparticles to meet pSiMedica's commercial supply requirements. This facility was completed in September 2005.

**Intellectual Property**

pSivida believes that it enjoys a strong intellectual property position, with core biomaterial patents granted in the valuable United States and European markets. pSivida owns all intellectual property rights in relation to BioSilicon for which there are as at September 2005, 34 granted patents, 29 patent families and over 80 patent applications. The core patent, which recognizes BioSilicon as a biomaterial, was granted in the United Kingdom in 2000 and the United States in 2001.

Product candidates and component materials protected by patents and patent applications owned by pSiMedica include materials comprising bioactive, resorbable and biocompatible silicon that are of value in the fabrication of new generations of intelligent drug delivery devices, orthopedic implants and intelligent diagnostic tools.

In December 2000, QinetiQ granted pSiMedica an exclusive, worldwide, royalty free license to the BioSilicon technology in the field of human and animal healthcare and diagnostic applications on or in the body. This license includes rights of first refusal over technologies developed by QinetiQ related to this field. QinetiQ was granted 41.7% of the issued share capital on the founding of pSiMedica in exchange for this license. In March 2002, after pSivida achieved certain milestones, including the successful completion of its second round funding and the investment of an additional one million pounds in pSiMedica, the license from QinetiQ was converted into an assignment of such rights, including ownership of patents and other intellectual property. On August 4, 2004 pSivida acquired the remaining shares QinetiQ held in pSiMedica. The consideration paid was A\$4.3 million together with a total of 49,804,381 ordinary shares of pSivida issued at a value of A\$1.09 per share.

pSivida's patent portfolio currently consists of 24 granted patents and 82 patent applications relating to the use of BioSilicon on or in the body. All intellectual property rights for BioSilicon are owned royalty free. pSiMedica holds granted patents that cover the broad use of BioSilicon in healthcare applications and patents that relate more specifically to pSivida's core focus of specialized drug delivery, targeted internal cancer therapy and diagnostics. The core patent, which recognizes BioSilicon as a biomaterial, was granted in the UK in 2000 and in the U.S. in 2001.

Potential products protected by patents and patent applications owned by pSiMedica include materials comprising bioactive, resorbable and biocompatible silicon that are of value in the fabrication of new generations of intelligent drug delivery devices, orthopedic implants and intelligent diagnostic tools.

pSivida currently has 34 granted patents, together with one application that has been accepted, and which should be granted within the next few months.

The following table provides general details relating to pSivida's patents and patent applications; it is based on information available on September 21, 2005.

<u>Priority Number</u>	<u>Status</u>	<u>Subject Matter</u>
9515956.2	National applications (EP, JP, CA, KR1) <b>Granted (GB1, GB2, US1, US2, KR2)</b> Divisional (US3)	The claims relate to resorbable, bioactive, and biocompatible forms of silicon. Further claims relate to electronic devices and composites comprising bioactive silicon.
9808052.6	National applications (CA, JP, KR, US) <b>Granted (AU, NZ, EP1, CN1)</b> Divisional (EP2, CN2)	The claims relate to resorbable and biocompatible silicon implants for the delivery of beneficial substances to animals or humans.
9815819.9	National applications (CA, CN, HK, JP, KR) <b>Granted (US1, AU1, AU2, EP1, NZ)</b> Divisionals (US2, EP3)	The claims relate to the transfer of material (such as, but not limited to, genetic material) into cells using porous or polycrystalline silicon. The claims also specifically relate to biolistic (also known as microprojectile) delivery.

## [Table of Contents](#)

<b>Priority Number</b>	<b>Status</b>	<b>Subject Matter</b>
9909996.2	National applications (CA, CN, JP, KR, US) <b>Granted (AU, EP, NZ)</b>	The claims relate to the use of derivatised porous silicon as a biomaterial and to devices, including electronic devices, comprising derivatised porous silicon.
9924334.7	National applications (CA, JP, US) <b>Granted (SG, AU, EP)</b>	The claims relate to orally administrable pharmaceutical products, including products comprising electronic circuitry, comprising porous or polycrystalline silicon.
9928511.6	National applications (CA, JP, US) <b>Granted (EP, NZ, AU, SG)</b>	The claims relate to an invention which is of value in the treatment of patients that have taken an overdose.
9929521.4	National applications (CA, EP, JP, SG) <b>Granted (NZ, AU, US1)</b>	The claims relate to a method of fabricating hermetically sealed silicon capsules suitable for drug delivery, and for the packaging of electronic implants.
0008494.7	Divisional (US2) National applications (EU, JP) <b>Granted (US) or shape)</b>	The claims relate to substantially monodispersed (having the same size porous silicon particles.
0014079.8	National applications (US, JP, SG, EP) <b>Granted (AU1) Divisional (AU2)</b>	The claims relate to a silicon composite material, suitable for use in bone repair and bone replacement, comprising silicon and a carrier material.
0020276.2	National applications (US, CA, JP) <b>Granted (EP, NZ, AU)</b>	The claims relate to dermatological compositions comprising porous and/or polycrystalline silicon.
0104383.5	National applications (US, AU, CA, JP, EP, SG) <b>Granted (NZ, SGW)</b>	The claims relate to products comprising silicon for the treatment of cancer.
0118689.9	National applications (US, AU, CA, JP, EP, SG)	The claims relate to the use of silicon for the pulmonary delivery of drugs to human or animal patients.
0120202.7	National applications (AU, JP, EP, SG) <b>Accepted (US)</b>	The claims relate to sweat patches, including patches comprising electronic circuitry, for the collection and detection of sweat components.
0130608.3	Divisional (US1) National applications (US, EP, JP, AU, SG, CN, KR)	The claims relate to silicon fibers or fabrics for medical use.
0212667.0	National applications (US, CA, JP, EP, AU, NZ)	A novel orthopaedic scaffold, and a self-assembly process for fabrication of such a scaffold.
0302283.7	National applications (US, EP, JP, CN)	The claims relate to the use of silicon for boron neutron capture therapy.
0307453.1	International application (All PCT states)	The claims relate to the use of silicon devices, including electronic devices, for the collection and assay of cancer markers.
0324483.7	International application (All PCT states)	The claims relate to porous silicon compositions having high levels of loading, and to methods of loading.
0324482.9	International application (All PCT states)	The claims relate to chlorambucil/porous silicon and taxol/porous silicon compositions for brachytherapy.
0400149.1	International application (All PCT states)	The claims relate a method of fabricating a phosphorous containing silicon material.

## Table of Contents

<u>Priority Number</u>	<u>Status</u>	<u>Subject Matter</u>
0411358.5	International application (All PCT states)	The claims relate to the fabrication of a consolidated silicon particulate product. The method is of particular value in the fabrication of inexpensive anodised porous silicon.
0419653.1	International application (All PCT states)	The claims relate to a syringe having a curved flexible needle for introducing BrachySil into a tumor.
0420676.9	Priority Application	The claims relate to a chronotherapeutic device.
0423383.9	Priority Application	The claims relate to ductile silicon structures, and medical use of such structures.
0504657.8	Priority Application	The claims relate to a new treatment for osteoporosis.
0508174.0	Priority Application	The claims relate to Oral hygiene compositions.
0515357.2	Priority Application	The claims relate to a silicon packaging material.
0515353.1	Priority Application	The claims relate to the use of silicon in food products.
Not yet known	Priority Application	The claims relate to an analytical device for testing body fluids.

### *Notes:*

- (a) Each invention group is identified by the earliest priority patent application number. Each priority application is filed at the GB Patent Office, and hence the priority numbers are GB application numbers.
- (b) The table shows the status of each invention group. For example a case will typically be filed as a priority GB application, it will then go on to be filed as an international patent application. The final stages are national filing (for example in U.S., Europe, etc) and grant.
- (c) The nature of the protection provided by the claims is given in the "Subject Matter" part of the table.
- (d) Abbreviations are used to indicate the states in which national applications have been filed. These abbreviations are as follows: AU = Australia, GB = Great Britain, CA = Canada, CN = China, EP = Europe, HK = Hong Kong, JP = Japan, KR = Korea, NZ = New Zealand, SG = Singapore, US = United States.
- (e) Divisional applications are indicated by "1", "2", "3" etc, for example GB1, GB2, EP1, EP2, US1, US2, US3.
- (f) For NZ and AU applications the term "accepted" means that a Notice of Acceptance has been received. For the EP applications, the term "accepted" means that a Rule 51(4) EPC Communication, in which the Applicant is informed of the intention to grant a patent, has been received. For US applications the term "accepted" means that the Notice of Allowance has been received. For China the term "accepted" means that a Decision on Granting of Patent Right has been issued.

pSivida has strengthened its intellectual property portfolio with the granting of an additional 13 patents during the past year. In August 2005, pSivida was granted its fifth patent in the important United States market which provides for the classification of porous silicon into monodispersed particles with a tight size distribution. The classification into tight sized distributions is a key attribute of many micro-engineered particle products.

pSivida was also granted its first patents in China and Korea. pSivida believes that obtaining patent coverage in China is important as China has the highest incidence of primary liver cancer in the world with approximately 350,000 cases in 2002. The potential lower cost of the Chinese registration pathway and the vast need of products treating liver cancer make China an important commercial target.



## Table of Contents

The Korean patent covers the electronic-based properties of BioSilicon in the stimulation of orthopedic tissue repair and re-engineering where scaffolds are required to support new bone growth. The technology also has application for treatment of fractures that do not heal, such as “bone non-union”. pSivida believes that Korea’s recognized strength in the design and manufacture of micro-components for the electronics industry makes it an important jurisdiction for this technology pSivida hopes to capitalize on Korea’s technology strengths as well as the higher margins associated with healthcare products.

### ***Sales and Marketing***

pSivida has no experience in the sales, marketing and distribution of healthcare products. If in the future pSivida fails to reach or elects not to enter into an arrangement with a collaborative partner with respect to the sales and marketing of any of pSivida’s future products, pSivida would need to develop a sales and marketing organization with supporting distribution capability in order to market such products directly. Significant additional expenditures would be required for pSivida to develop such a sales and marketing organization.

### ***Competition***

pSivida is engaged in healthcare product development, an industry that is characterized by extensive research efforts and rapid technological progress. Many established biotechnology companies, universities and other research institutions with financial, scientific and other resources significantly greater than pSivida’s are marketing or may develop products that directly compete with any products pSivida may develop. These entities may succeed in developing products that are safer, more effective or less costly than products pSivida may develop. Even if pSivida can develop products which should prove to be more effective than those developed by other companies, other companies may be more successful than pSivida because of greater financial resources, greater experience in conducting preclinical studies and clinical trials and in obtaining regulatory approval, stronger sales and marketing efforts, earlier receipt of approval for competing products and other factors. If pSivida commences significant commercial sales of any products, it or its collaborators will compete in areas in which pSivida has no experience, such as marketing. There can be no assurance that pSivida’s products, if commercialized, will be accepted and prescribed by healthcare professionals.

pSivida’s principal competitors in this market are the numerous drug delivery and pharmaceuticals companies that are attempting to improve the safety and efficiency of pharmaceuticals by developing and introducing novel delivery methods. Most of these companies aim to deliver drugs with polymer-based systems, some of which are not biodegradable. pSivida does not know of any other company that is developing a non-polymer — i.e., pure element — drug delivery system.

### ***Employees***

As of September 30, 2005, pSivida had 53 employees, excluding directors and consultants. Of such employees, 39 were employed in research and development, 12 in management and administration and two in operations; 36 employees are located in Malvern, United Kingdom, three in Singapore and 14 in Perth, Western Australia.

Australian and UK labor laws and regulations are applicable to all of pSivida’s employees depending upon their location of employment. The laws concern various matters, including severance pay rights at termination, retirement or death, length of work day and work week, minimum wage, overtime payments and insurance for work related accidents.

### ***Facilities***

Facilities pSivida leases approximately 223 square meters of laboratory space and 449 square meters of office space in Malvern, United Kingdom and approximately 305 square meters of office space in Perth, Western Australia.

### ***Property, Plant and Equipment***

pSivida's manufacturing partner QSA, has completed the construction and validation of a state-of-the-art cleanroom facility, dedicated to the supply of pSivida's lead cancer therapy BrachySil, at QSA's Auriga Medical™ facility in Braunschweig, Germany. This GMP facility will fulfill the final process in the manufacture of BrachySil for future clinical and commercial use, and represents the crucial final stage in establishing the manufacturing and supply infrastructure to support BrachySil as it advances through clinical trials towards the market.

pSivida owns computer equipment, office furniture and lab equipment, the majority of which are used in its Malvern laboratory facilities. pSivida leases approximately 223 square meters of laboratory space and 449 square meters of office space in Malvern, United Kingdom and approximately 305 square meters of office space in Perth, Western Australia.

### ***Legal Proceedings***

pSivida is not presently involved in any legal proceedings nor has there been any proceeding entered into by pSivida or on pSivida's behalf since December 1, 2000.

### **pSIVIDA'S MANAGEMENT**

#### ***Directors and Senior Management***

The members of the board of directors and senior management of pSivida and its subsidiaries are listed below. The business address of pSivida's directors and senior management is: c/o pSivida Limited, Level 12 BGC Centre, 28 The Esplanade, Perth WA 6000, Australia.

#### ***Director Appointments***

pSivida has recently appointed two non-executive directors to its board in Dr. David J Mazzo and Mr. Michael W. Rogers.

The members of the board of directors of pSivida and their principal occupations are as follows:

<b>Name</b>	<b>Date of Appointment</b>	<b>Principal Occupation</b>
Dr. Roger Brimblecombe	March 5, 2002	Independent Consultant
Dr. Roger Aston*	December 1, 2000	Independent Consultant
Mr. Gavin Rezos	December 1, 2000	Managing Director, pSivida Limited
Ms. Alison Ledger	July 30, 2004	Independent Consultant
Mr. Stephen Lake	July 30, 2004	Investment Director, QinetiQ
Dr. David Mazzo	July 25, 2005	Non-Executive Director, pSivida Limited; President and Chief Executive Officer, Chugai Pharma U.S.A
Mr. Michael Rogers	July 27, 2005	Non-Executive Director, pSivida Limited; Vice President, Chief Financial Officer and Treasurer of Indevus Pharmaceuticals Incorporated

\* Dr Roger Aston retired from pSivida's board on November 15, 2005.

#### ***Dr. Roger Brimblecombe***

Dr. Brimblecombe, Ph.D., D.Sc., F.R.C.Path., C.Biol., F.I.Biol., is a former chairman of SmithKline and French Research Ltd. He is currently chairman of MVM Ltd, the venture capital arm of the UK Medical Research Council. He is also non-executive chairman of Oxxon Therapeutics, Inc (U.S.), DanioLabs Ltd, and a non-executive director of Vertex Pharmaceuticals Inc (U.S.A), Tissue Science Laboratories Ltd, and GenPat77 Phamacogenetics AG (Germany). He has provided strategic consultancy services to research and development companies in Europe, the U.S. and Japan. He is a fellow of the

## Table of Contents

Royal Society of Medicine, the Royal College of Pathologists and the Institute of Biology. He is consultant editor of Drug Discovery World magazine. Dr. Brimblecombe is also chairman of pSiMedica and pSiOncology.

### *Gavin Rezos*

Mr. Rezos, B.Juris., LL.B., B.A., earned a law degree from the University of Western Australia and has been admitted as a barrister and solicitor in Western Australia, England and New South Wales. He practiced law in London in corporate finance before joining Midland Montagu, an investment bank now known as HSBC Investment Bank plc, in 1990. He was an investment banking director at HSBC in positions based in London, Sydney and Dubai. Mr. Rezos is currently principal of Viaticus Capital Pty Ltd, a biotechnology venture capital and corporate advisory company. He has investment banking experience in a variety of industries and geographical locations including Europe, Latin America, the Middle East and Asia. Mr. Rezos is also a director of pSiMedica, pSiOncology and AiMedics Pty Ltd (Australia) and non-executive chairman of AION Diagnostics.

### *Dr. Roger Aston*

Dr. Aston has more than 20 years experience in the pharmaceutical and biotechnology industries. His previous positions have included CEO of Peptech Limited (Australia), director of Cambridge Antibody Technology Limited (UK) and chairman of Cambridge Drug Discovery Limited — now BioFocus plc (UK). Dr. Aston was also founder and CEO of Biokine Technology Ltd (UK) prior to its acquisition by the Peptech Group. He was a founder and is the former CEO of pSiMedica and pSiOncology. Dr. Roger Aston is also chairman of Australian Cancer Technology Limited (Australia). Dr Roger Aston retired as a director and executive officer of pSivida and pSiOncology at the pSivida annual general meeting held on November 15, 2005.

### *Alison Ledger*

Ms. Ledger was most recently a principal at McKinsey & Co both in Sydney and London specializing in financial institutions including banking, asset management, stock exchanges, insurance and regulatory compliance. She joined McKinsey in 1995 after holding positions with Bankers Trust in London marketing investment funds to European corporate and institutional clients. Ms. Ledger has extensive financial experience and knowledge of international capital markets with a breadth of knowledge in strategy, operations, performance improvement, cost management, new business building and geographic expansion. She has a Harvard MBA and has lived and worked in numerous countries including the UK, Australia and the U.S.

### *Stephen Lake*

Mr. Lake, BA (Jt. Hons), MBA, ACA, is Investment Director, QinetiQ Limited. He has over 20 years of experience in the high technology sector as a senior executive in both large multi-national and early stage venture backed companies. He was a founding executive of Reuters venture capital arm Greenhouse. He has extensive international experience having worked in the U.S. for 10 years, as well as in France and the Nordic countries. Mr. Lake is a UK-qualified chartered accountant and has an MBA in technology and strategy from the Theseus Institut (France). He is a non-executive director of Quintel Technology Limited and QS4 Group Limited, a joint venture between Rotch and QinetiQ.

### *Dr. David Mazzo*

Dr. Mazzo, BA (Hons), BSc (Hons), MSc, PhD, is President and Chief Executive Officer of Chugai Pharma U.S.A, and is based in New Jersey, U.S.A. Chugai Pharma U.S.A is part of the Roche group of companies and is a subsidiary of Chugai Pharmaceutical Company Limited (Japan), a global research-based pharmaceutical company. Dr Mazzo holds a Bachelor of Arts with Honors (Interdisciplinary Humanities) and a Bachelor of Science with

## Table of Contents

Honors in Chemistry from Villanova University, and a Master of Science in Chemistry and a PhD in Analytical Chemistry from the University of Massachusetts. He complemented his American education as a Research Fellow at the ecole Polytechnique Federale de Lausanne, Switzerland. Dr Mazzo is also a director of AMEX-listed Avair Pharmaceuticals (appointed 1 August 2005).

### *Michael Rogers*

Mr. Michael Rogers, BA, MBA, is Executive Vice President, Chief Financial Officer and Treasurer of Indevus Pharmaceuticals Incorporated, a biopharmaceutical company based in Lexington, Massachusetts, U.S.A. Mr. Rogers received an MBA from the Darden School of Business, University of Virginia and a BA, Political Science from Union College, and brings significant financing, acquisition, investment banking and partnering experience relating to pharmaceutical and biotechnology companies to the pSivida board. He will chair the Audit Committee and is the designated “audit committee financial expert.”

From January 7, 2003 until July 30, 2004, Nadine Donovan was a member of pSivida’s board of directors. Following Mrs. Donovan’s resignation to concentrate on personal endeavors, Mr. Lake and Ms. Ledger were appointed directors by a resolution of shareholders at a general meeting of shareholders held on July 30, 2004. Mrs. Donovan joined pSivida in March 2001 as Company Secretary/ Financial Controller.

The current executive officers of pSivida and their titles are as follows:

<u>Name</u>	<u>Title</u>
Mr. Gavin Rezos	Managing Director
Mr. Aaron Finlay	Chief Financial Officer and Company Secretary
Dr. Anna Kluczevska	Head of Diagnostics
Mr. Brian Leedman	Investor Relations Manager

### *Aaron Finlay*

Mr. Finlay joined pSivida as of May 17, 2004, as CFO and Company Secretary. His most recent role was as INVESCO Australia’s Chief Financial Officer where he had responsibility for the operations of finance, as well as the compliance, legal, and human resources functions. Prior to that position, Mr. Finlay was head of group tax and treasury for INVESCO’s global operations in London. Prior to joining INVESCO, Mr. Finlay worked for PricewaterhouseCoopers (then Price Waterhouse) in London and Perth. Mr. Finlay is also chief financial officer and company secretary of AION Diagnostics.

### *Dr. Anna Kluczevska*

Dr. Kluczevska held the position of global product manager for Baxter Healthcare’s BioSurgery division. At Baxter, she oversaw the management of Baxter BioSurgery’s products in over 50 countries focusing on registration, product launch and global product management. Dr. Kluczevska is also managing director of AION Diagnostics.

### *Brian Leedman*

Mr. Leedman is a marketing and communications specialist with more than 10 years’ experience at Westpac Banking Corporation and Ernst & Young. As the former Group Marketing Manager of Ernst & Young in Perth, Western Australia, Mr. Leedman was responsible for building industry relationships, public relations and brand management. Mr. Leedman holds a Bachelor of Economics and a Master of Business Administration from the University of Western Australia.

## [Table of Contents](#)

### ***pSiMedica Limited***

The members of the board of directors of pSiMedica and their principal occupations are as follows:

<b>Name</b>	<b>Principal Occupation</b>
Dr. Roger Brimblecombe	Independent Consultant
Mr. Gavin Rezos	Managing Director, pSivida
Dr. Mark Parry-Billings	Research & Development Director

The executive officers of pSiMedica and their titles are as follows:

<b>Name</b>	<b>Title</b>
Prof. Leigh Canham	Chief Scientific Officer
Mr. Stephen Connor	Director of Development
Dr. Jill Ogden	Commercial Director
Dr. David Petty	Intellectual Property Manager

#### *Prof. Leigh Canham*

Prof. Canham has 25 years of research experience related to silicon technology. He was awarded an honorary chair at the University of Birmingham in 1999 for his work on the optoelectronic properties of nano-structured silicon. Trained at University College (BSc physics) and Kings College (PhD solid state physics) in London, Prof. Canham then conducted research at QinetiQ (formerly, RSRE, DERA) in Malvern UK from 1986 to 2000. In December 2000, he co-founded pSiMedica with Dr. Aston to develop the BioSilicon technology platform invented in QinetiQ. He is a frequent speaker on the subject of the medical applications of silicon technology and is member of the editorial board of international journal *Biomedical Microdevices*.

#### *Dr. Mark Parry-Billings*

Dr. Parry-Billings joined pSiMedica in November 2004. Dr. Parry-Billings earned a BS with first class honors from the University of Loughborough and subsequently earned a DPhil from the Department of Biochemistry, University of Oxford where he conducted post-graduate work before joining Schering Healthcare. For the six years prior to joining pSiMedica, Dr. Parry-Billings was Director of Research & Development at Innovata Biomed Ltd. He joined Innovata BioMed in 1994 from Schering Healthcare Ltd where he was a Senior Clinical Research Associate.

#### *Stephen Connor*

Mr. Connor joined pSiMedica in November 2001. Previously, he held increasingly senior positions in Cambridge at Murex Medical Research Ltd, Quantum Biosystems Ltd, Cantab Pharmaceuticals Research Ltd, Chiroscience R&D Ltd, and most recently, Imutran Ltd — a Novartis Pharma company. From 1978 to 1985, he worked at the Withington Hospital, Manchester.

#### *Dr. Jill Ogden*

Dr. Ogden joined pSiMedica in November 2003. She has 18 years of commercial and R&D experience in the biotechnology, healthcare and drug delivery industries. She graduated with a BSc and PhD in Genetics from the University of Sheffield. Following her postdoctoral research at the Universities of Edinburgh and Oxford, she joined Delta Biotechnology Ltd. In 1993, Dr. Ogden co-founded and was principal of Propharma Consultants, a consultancy specializing in the biopharmaceutical industry. Between 1996 and 2000, she was business development manager of Andaris Ltd and the Quadrant Healthcare plc. Following the acquisition of Quadrant by Elan Corporation, she became director of business development for Elan Drug Delivery Ltd.

## [Table of Contents](#)

### *Dr. David Petty*

Dr. Petty joined pSiMedica in July 2002. Dr. Petty graduated in chemistry and subsequently obtained a PhD in organic semiconductors in 1991 at the University of Nottingham. After a one year fellowship at The Institute for Molecular Science, Okazaki, Japan he earned an MSc in intellectual property management at the University of London and then worked for a database company specializing in pharmaceutical patents. Dr. Petty subsequently worked for Fisons Instruments' patent department from 1994 before joining the Ministry of Defense IP department in 1996. Over the last five years, he has been responsible for managing the BioSilicon portfolio of patents at both DERA/ QinetiQ and pSiMedica.

### *pSiOncology Pte Ltd.*

The members of the board of directors of pSiOncology and their principal occupations are as follows:

<u>Name</u>	<u>Principal Occupation</u>
Dr. Roger Brimblecombe	Independent Consultant
Mr. Gavin Rezos	Managing Director, pSivida
Dr. Beng Choo Lim	Clinical Director
Mr. Stephen Lake	Investment Director, QinetiQ

### *Dr. Beng Choo Lim*

Dr. Lim has worked with multinational pharmaceutical corporations such as Pharmacia (now Pfizer), Glaxo and Smith Kline Beecham and several start up companies. Dr. Lim received her doctorate in pharmacology from the National University of Singapore and is registered with the Singapore Board of Pharmacy. Her clinical research experience includes initiation and project management of all phases of clinical trials to support registration in the U.S., Europe and Asia in the therapeutic areas of naso-pharyngeal cancer, vitreous hemorrhage, Hepatitis B, peptic ulcer, respiratory, dermatology and anti-infectives.

The executive officers of pSiOncology and their titles are as follows:

<u>Name</u>	<u>Title</u>
Dr. Beng Choo Lim	Clinical Project Manager

### *AION Diagnostics Limited*

Wholly-owned subsidiary AION Diagnostics Limited appointed Dr Jorg Schreiber PhD as a non-executive director in May 2005. Dr Schreiber has over 20 years' experience in the diagnostics industry, principally with Roche Diagnostics and Boehringer Mannheim in Germany and brings with him leadership and expertise in the commercialization of world class diagnostic products.

The members of the board of directors of AION Diagnostics and their principal occupations are as follows:

<u>Name</u>	<u>Principal Occupation</u>
Mr. Gavin Rezos	Managing Director, pSivida
Prof. Leigh Canham	Chief Scientific Officer, pSiMedica; Director, AION Diagnostics
Dr. Anna Kluczevska	Head of Diagnostics, pSivida; Managing Director, AION Diagnostics
Dr. Jörg Schreiber PhD	Non-executive Director

## Table of Contents

The executive officers of AION Diagnostics and their titles are as follows:

<u>Name</u>	<u>Title</u>
Dr. Anna Kluczevska	Managing Director
Mr. Aaron Finlay	Chief Financial Officer and Company Secretary
Mr. Brian Leedman	Investor Relations Manager

### ***Board Practices***

The business of pSivida is managed by its directors. The directors exercise all of the powers that pSivida's constitution, the Corporations Act 2001, the Australian Stock Exchange or the Australian Stock Exchange Listing Rules do not reserve to the shareholders in general meeting.

The directors exercise their powers and discharge their duties as a board.

The board's policies and practices exist within a framework of:

- the Corporations Act 2001;
- the general law, including the law relating to directors' duties;
- the Australian Stock Exchange Corporate Governance Council's Principles of Good Corporate Governance and Best Practice Recommendations; and
- the Australian Stock Exchange Listing Rules.

The overall role of the board, as set out in its charter, includes:

- setting pSivida's strategic direction;
- identifying the expectations of pSivida's shareholders;
- identifying regulatory and ethical expectations and obligations; and
- identifying areas of significant business risk and ensuring arrangements are in place to adequately manage those risks.

The board delegates responsibility for the operation and administration of pSivida's company and its subsidiaries to the Managing Director.

The board ensures management's objectives and activities are aligned with those expectations and risks identified by the board through the mechanisms set out below:

- oversight of pSivida's business, including its control and accountability systems;
- appointing and removing the chief executive officer (or equivalent);
- ratifying the appointment and, where appropriate, the removal of the chief financial officer and the company secretary;
- input into and final approval of corporate strategy and performance objectives;
- reviewing and ratifying systems of risk management and internal compliance and control, codes of conduct and legal compliance;
- monitoring senior management's performance and implementation of strategy, and ensuring appropriate resources are available;
- approving and monitoring the progress of major capital expenditure, capital management, and acquisitions and divestitures;

## Table of Contents

- approving and monitoring financial and other reporting; and
- monitoring compliance of tax processes.

### COMPOSITION OF THE BOARD

The composition of the board is determined in accordance with the following principles and guidelines:

- the board must comprise at least three directors;
- the board must comprise directors with an appropriate range of qualifications and expertise; and
- the board must meet regularly and follow meeting guidelines set down to ensure all directors are made aware of, and have available, all necessary information, to participate in an informed discussion of all agenda items.

The performance of all directors is reviewed annually by the chairman of the board in order to ensure that the board continues to discharge its responsibilities in an appropriate manner.

pSivida's constitution provides that the board may appoint a director at any time other than during a general meeting. However, any director so appointed automatically retires at the next general meeting and must seek re-election at that general meeting. Otherwise, pSivida's constitution permits the election of a director at general meeting and by ordinary resolution and both Mr. Lake and Ms. Ledger were appointed directors by a resolution of shareholders at a general meeting of shareholders held on July 30, 2004. Dr Mazzo and Mr Rogers were appointed by the board and were re-elected at the pSivida annual general meeting held on November 15, 2005.

One third of directors other than the director who is the Managing Director (or is one of the Managing Directors and has been nominated by the board as exempt from retirement) must retire at each Annual General Meeting. If the applicable number of directors is not a multiple of three, the nearest whole number to one third is applied in determining how many directors must retire from office. This will mean that for the year ending June 30, 2006, (subject to the appointment of any new directors by pSivida in general meeting prior to the 2006 Annual General Meeting), two of the current seven directors must retire and will be eligible for re-election. The directors chosen to retire will be the directors who have held office the longest since last being elected or appointed. If additional directors are appointed and more than two directors are required to retire, then where two or more directors have held office for the same amount of time, they may agree which of them will retire and if they cannot decide they will draw lots. Dr. Brimblecombe was appointed a director on March 5, 2002 and was re-elected at the general meeting held on November 17, 2004. Both Mr. Rezos and Dr. Aston were appointed directors by a resolution of shareholders at a general meeting of shareholders on November 24, 2000 becoming effective on December 1, 2000 and Dr. Aston was most recently re-elected at a general meeting by ordinary resolution on October 21, 2003.

Furthermore, any director who is not a Managing Director must retire from office at the conclusion of the third annual general meeting after which they were elected and are eligible for re-election.

pSivida's constitution does not prescribe any maximum age limit for directors. This means that automatic retirement from office is not imposed upon reaching a certain age.

Whether or not a director's appointment is expressed to be for a specified period, pSivida's constitution permits:

- members by ordinary resolution; or
- members holding a majority of pSivida's issued, voting shares by written notice to pSivida,

to remove any director from office. The Corporations Act 2001 supports and supplements these members' powers to remove directors from office.



***Compliance with U.S. Law and NASDAQ Rules Regarding Director Independence, Etc.***

*General*

Pursuant to the Sarbanes-Oxley Act of 2002, the SEC has issued new rules that, among other things, require NASDAQ to impose independence requirements on each member of the audit committee. The new NASDAQ rules implement two basic criteria for determining independence: (i) audit committee members would be barred from accepting any consulting, advisory or other compensatory fee from the issuer or an affiliate of the issuer, other than in the member's capacity as a member of the board of directors and any board committee, and (ii) audit committee members of an issuer that is not an investment company may not be an "affiliated person" of the issuer or any subsidiary of the issuer apart from his or her capacity as a member of the board and any board committee.

The SEC defines "affiliate" for non-investment companies as "a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the person specified." The term "control" is proposed to be consistent with the other definitions of this term under the Exchange Act, as "the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise." A safe harbor has been proposed by the SEC, under which a person who is not an executive officer, director or 10% shareholder of the issuer would be deemed not to have control of the issuer.

For purposes of NASDAQ, an "independent director" is a person who is not an officer or employee of pSivida or any of its subsidiaries and who does not have a relationship that, in the opinion of the board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Recently-adopted SEC and NASDAQ rules have applied to pSivida since July 31, 2005. pSivida has taken appropriate steps with respect to pSivida's corporate governance system so that its board of directors satisfies provisions of Rule 10A-3 under the Exchange Act and the amended corporate governance standards of NASDAQ implementing the requirements of Rule 10A-3, including the requirements relating to the independence of the audit committee members and responsibilities of the audit committee. For so long as pSivida is listed on NASDAQ and rules applicable to pSivida so require:

- pSivida will continue to have a board of directors consisting of a majority of independent directors, as defined under NASDAQ's corporate governance rules;
- pSivida will continue to have an audit committee of at least three members, comprised solely of directors each of whom: (1) meets NASDAQ's definition of independence; (2) meets the SEC's definition of independence; (3) has not participated in the preparation of pSivida's financial statements or any of its current subsidiaries at any time during the past three years; and (4) is able to read and understand fundamental financial statements, including a balance sheet, income statement, and cash flow statement;
- pSivida will continue to have at least one member of the audit committee who has past employment experience in finance or accounting, requisite professional certification in accounting, or any other comparable experience or background which results in the individual's financial sophistication, including being or having been a chief executive officer, chief financial officer or other senior officer with financial oversight responsibilities;
- pSivida will have adopted a formal written audit committee charter that complies with NASDAQ's rules, and that the audit committee will, among other things, review and assess the adequacy of the charter on an annual basis;
- pSivida will either ensure that pSivida's nomination committee and remuneration committee have only independent directors or that all decisions made by the board in respect of compensation of officers and nomination of directors are approved by a majority of pSivida's independent directors;

## Table of Contents

- pSivida will have adopted a code of conduct applicable to all directors, officers and employees which complies with NASDAQ and SEC rules, and such code will be publicly available;
- pSivida will hold regularly scheduled meetings at which only independent directors are present.

pSivida has been granted an exemption from the quorum requirement under NASDAQ rules which requires each issuer to provide for a quorum as specified in its by-laws for any meeting of the holders of common stock, which shall in no case be less than 33<sup>1</sup>/<sub>3</sub>% of the outstanding shares of a company's common voting stock. pSivida's constitution provides for a quorum requirement of two members at general meetings of pSivida's shareholders. This quorum requirement is in accordance with Australian law and generally accepted business practices in Australia.

### ***Independence of Directors***

The board of directors considers Ms. Ledger to be an independent director. She has an indirect interest in 1,900,000 ordinary shares held by her spouse representing 0.84% of the outstanding ordinary shares as of September 30, 2005.

The board of directors considers Messrs. Mazzo and Rogers to be independent directors. pSivida has recently granted Dr. Mazzo 200,000 options, and Mr. Rogers 200,000 options. The board of directors considers Mr. Lake to be an independent director. Mr. Lake was separately recommended by the nomination committee of the board on the basis of his extensive experience in building and developing growth technology businesses. Mr. Lake is currently employed by and responsible for managing and developing the QinetiQ Ventures portfolio of spin-out companies. QinetiQ, immediately after the completion of the transaction whereby pSivida acquired the remaining shares in pSiMedica that it did not already own, held approximately 17.5% of pSivida's issued share capital. The board does not consider this holding of its ordinary shares to affect Mr. Lake's independence on the basis that QinetiQ has pledged that, until October 26, 2009, as long as it holds 10% or more of pSivida's outstanding ordinary shares that it will exercise its voting rights in line with the majority of proxy votes exercisable by validly appointed proxies in relation to any resolution of pSivida's shareholders. In addition, the board considers there are sufficient and suitably documented policies and procedures in place at QinetiQ separating Mr. Lake and the corporate department of QinetiQ responsible for all dealing in relation to their interest in pSivida's ordinary shares.

### ***Existing board committees***

To assist in the execution of its responsibilities, the board has established a number of committees including a nomination committee, a remuneration committee and an audit and compliance committee.

#### *Nomination Committee*

The primary purpose of the nomination committee is to ensure that the board is comprised of individuals who are best able to discharge the responsibilities of directors having regard to the law and the highest standards of corporate governance.

The nomination committee meets this mandate by:

- assessing the skills required on the board and from time to time considering the extent to which the required skills are represented on the board;
- establishing processes for the review of the performance of individual directors and the board as a whole; and
- establishing processes for the identification of suitable candidates for appointment to the board.

The duties and responsibilities of the nomination committee are:

- to periodically assess the skills required to competently discharge the board's duties, having regard to pSivida's strategic direction, and report the outcome of that assessment to the board;

## Table of Contents

- to assess the skills represented on the board by the directors and determine whether those skills meet the required skills as identified, as and when it considers appropriate but in any event on each occasion on which an existing director retires;
- to make recommendations to the chairman of the board on means by which skill levels of existing directors can be enhanced;
- to implement a process for the identification of suitable candidates for appointment to the board;
- to make recommendations to the board on candidates it considers appropriate for appointment;
- to inform the board of the names of directors who are retiring in accordance with pSivida's constitution and make recommendations to the board as to whether the board should support the re-nomination of that retiring director; and
- to undertake a process of review of the retiring director's performance during the period in which the director has been a member of the board and conduct that review by whatever means it considers appropriate including assessment of performance by peers and self. However, a member of the nomination committee must not participate in the review of his or her own performance.

The decisions of the nomination committee, as contained in its minutes, constitute recommendations to the full board. The board has adopted procedures whereby any action taken after July 31, 2005 based on a recommendation of the nomination committee must be ratified by a majority of the independent directors.

The nomination committee must be comprised of at least two members of the board. The terms of appointment to the nomination committee are at the discretion of the board and vacancies may be filled as they arise. From August 2, 2004 until November 15, 2005, the members of the nomination committee were Dr. Brimblecombe (Chairperson), Ms. Ledger and Dr. Aston. Since November 15, 2005, the members of the nomination committee have been: Dr. Brimblecombe (Chairperson) and Ms. Ledger.

### *Remuneration Committee*

The role of the remuneration committee is to assist pSivida's board in ensuring that appropriate and effective remuneration packages and policies for the Managing Director and executive directors are implemented within pSivida's and its subsidiaries. The remuneration committee's role also extends to the review of non-executive directors' fees.

The duties and responsibilities of the remuneration committee are to:

- review and recommend to the board remuneration policies and packages for the Managing Director and executive directors;
- recommend to the board any changes in remuneration policy relating to superannuation, other benefits and remuneration structure for the Managing Director and executive directors and that are likely to have a material impact on pSivida's and its subsidiaries;
- review and recommend to pSivida's board proposals employee and non-executive director equity plans;
- review and recommend to pSivida's board proposals for short and long term incentive programs for the Managing Director and executive directors;
- review and recommend to pSivida's board any changes to non-executive directors' fees;
- ensure there is a proper performance management process in place throughout the organization and that it is operating effectively; and
- be informed of: current trends in executive remuneration and associated incentive initiatives; and legislative issues associated with executive remuneration programs.

## Table of Contents

The decisions of the committee, as contained in its minutes, shall constitute recommendations to pSivida's board. pSivida's board has adopted procedures whereby any action taken based on a recommendation of the remuneration committee must be ratified by a majority of the independent directors. In addition, the compensation of pSivida's Chief Executive Officer will be determined, or recommended to the board for determination, either by a majority of the independent directors or a compensation committee comprised solely of independent directors. Further, pSivida's Chief Executive Officer may not be present during voting or deliberations. Compensation of all other executive officers will also be determined, or recommended to pSivida's board for determination, either by a majority of the independent directors, or a compensation committee comprised solely of independent directors.

The remuneration committee is comprised of at least two members of the board. From August 2, 2004 until November 15, 2005, the members of the remuneration committee were Dr. Brimblecombe (Chairperson), Mr. Lake and Dr. Aston. Since November 15, 2005, the members of the remuneration committee have been Dr. Brimblecombe (Chairperson) and Mr. Lake.

The terms of appointment to the remuneration committee are at the discretion of the board and vacancies may be filled as they arise.

### *Audit and Compliance Committee*

pSivida's board established the audit and compliance committee to facilitate:

- the effective operation of systems and controls which minimize financial and operational risk;
- reliable financial and management reporting policies and procedures;
- compliance with laws and regulations;
- maintenance of an effective and efficient internal and external audit process; and
- oversight of the accounting and financial reporting processes of pSivida and the audits of pSivida's financial statements.

The audit and compliance committee is particularly concerned with audit compliance amongst pSivida's company and its subsidiaries.

The audit and compliance committee is directly responsible as a committee of the board for the following:

- ensuring appropriate accounting policies and procedures are defined, adopted and maintained;
- ensuring that operating and management reporting procedures, and the system of internal control, are of a sufficiently high standard to provide timely, accurate and relevant information;
- reviewing the financial statements prior to their approval by pSivida's board;
- reviewing the scope of work including approval of strategic and annual audit plans and effectiveness of both the external and internal audit functions;
- monitoring the proper operation of and issues raised through pSivida's subsidiary's audit and compliance committees;
- ensuring that appropriate processes are in place to ensure compliance with all legal requirements;
- ensuring that all internal and industry codes of conduct and standards of corporate behavior are being complied with;
- appointment of, on recommendation by the Managing Director, a person(s) responsible for internal audit functions as specified from time to time by, and in accordance with, the audit and compliance committee's terms of reference;

## Table of Contents

- establishing procedures for the receipt, retention, and treatment of complaints regarding accounting, internal accounting controls, or auditing matters; and the confidential, anonymous submission by pSivida's employees of concerns regarding questionable accounting or auditing matters;
- taking action with respect to any other business processes or functions that may be referred to it by pSivida's board; and
- ensuring its receipt from the outside auditors of a formal written statement delineating all relationships between the auditor and pSivida, consistent with appropriate standards, and actively engaging in a dialogue with the auditor with respect to any disclosed relationships or services that may impact the objectivity and independence of the auditor and for taking, or recommending that the full board take, appropriate action to oversee the independence of the outside auditor.

The decisions of the audit and compliance committee, as contained in its minutes, shall constitute recommendations to pSivida's board.

pSivida's audit and compliance committee is directly responsible for the appointment, reappointment or replacement (subject, if applicable, to shareholder ratification), remuneration, monitoring of effectiveness, and independence of the external auditors, including resolution of disagreements between management and the auditor regarding financial reporting.

pSivida's audit and compliance committee approves all audit and non-audit services provided by the external auditors and must not engage the external auditors to perform any non-audit/assurance services that may impair or appear to impair the external auditor's judgment or independence. pSivida's audit and compliance committee may delegate pre-approval authority to a member of the audit and compliance committee. The decisions of any audit and compliance committee member to whom approval authority is delegated must be presented to the full audit and compliance committee at its next scheduled meeting. pSivida's audit and compliance committee is empowered to determine its own procedures, and the charter for the committee and its adequacy must be reviewed annually by the committee and pSivida's board.

When reviewing the independence of the external auditor, pSivida's audit and compliance committee will encourage the rotation of the audit partner at least once every five years.

pSivida's audit and compliance committee is comprised of at least three members of the board. The shareholders of pSivida's audit and compliance committee shall meet the independence and experience requirements of the SEC and NASDAQ. At least one of the members of pSivida's audit and compliance committee appointed by pSivida's board shall be determined by the board to be a financial expert as defined by the SEC and NASDAQ, and all such members shall be able to read and understand fundamental financial statements. Since July 28, 2005, the committee's financial expert has been Mr. Rogers. The members of pSivida's audit and compliance committee as of July 31, 2005, were Mr. Rogers (Chair), Ms. Ledger and Dr. Mazzo.

The terms of appointment to pSivida's audit and compliance committee are at the discretion of the board and vacancies may be filled as they arise.

### ***Conduct and Ethics***

pSivida's code of conduct was adopted on June 30, 2003 and was made available from the corporate governance sections of pSivida's website on July 1, 2003. The code of conduct applies to all employees of pSivida including the Managing Director and Chief Financial Officer and covers a broad range of issues and practices necessary to maintain confidence in pSivida's integrity, including procedures in relation to:

- compliance with the law;
- financial records;
- contributions to political parties, candidates and campaigns;
- occupational health and safety;

## Table of Contents

- confidential information;
- conflict of interest;
- efficiency;
- equal opportunity;
- corporate bribery; and
- membership to industry and professional associations.

The code of conduct directs individuals to report any contraventions of the code to their immediate superior or the Managing Director.

In addition, pSivida has adopted separate corporate governance policies relating to insider trading, continuous disclosure, communications strategy and risk management. Summaries of these policies are available on pSivida's corporate website, and pSivida makes the full policies available to the public upon request. pSivida believes that its continuous disclosure policy and its communications strategy policy satisfy the requirements of the SEC's rules requiring companies to adopt written standards relating to the full, fair, accurate, timely, and understandable disclosure in reports and documents that a registrant files with, or submits to, the SEC and in other public communications made by the registrant. These policies mandate continuous disclosure of material information to the public by means of an ASX release and pSivida's corporate website. In addition, pSivida files with the SEC on Form 6-K a copy of each release which it files with the ASX and posts on pSivida's corporate website.

### ***Compensation***

Compensation of directors and officers is recommended by the remuneration committee of pSivida's board and approved by pSivida's full board including a majority of the independent directors.

Remuneration for the services of pSivida's executive directors are formalized in a service agreement. Details of the nature and amount of each element of the emoluments of each of pSivida's directors for the financial year are shown in the following table. The following table presents all compensation pSivida paid to all of its directors and to all of its directors and executive management for the year ended June 30, 2005.

### ***Remuneration Policy***

The remuneration committee of pSivida's board of directors is responsible for reviewing and recommending compensation arrangements for the directors, the managing director and the executive team. The remuneration committee assesses the appropriateness of the nature and amount of the emoluments of such officers on a periodic basis by reference to relevant employment market conditions with the overall objective of ensuring maximum stakeholder benefit from the retention of a high quality board and executive team.

*Remuneration of Specified Directors and Specified Executives*

	Primary		Post Employment Superannuation	Other Benefits	Equity Options	Total
	Salary and Fees	Bonus				
	\$	\$	\$	\$	\$	\$
<i>Specified directors</i>						
Dr R Brimblecombe	224,459	25,000	—	—	229,296	478,755
Mr G Rezos	348,062	75,000	10,905	—	1,361,127	1,795,094
Dr R Aston	315,683	25,000	8,438	1,189	558,592	908,902
Mr S Lake	22,917	—	—	—	91,718	114,635
Ms A Ledger	27,500	—	2,475	—	91,718	121,693
Mrs N Donovan	2,083	—	188	—	—	2,271
Total	940,704	125,000	22,006	1,189	2,332,451	3,421,350
<i>Specified executives(1)</i>						
Prof L Canham	193,780	—	22,553	6,056	353,524	575,913
Mr A Finlay	144,572	32,500	13,135	—	370,396	560,603
Dr A Kluczevska	208,333	10,000	—	—	299,808	518,141
Mr S Connor	181,146	—	21,738	10,612	143,751	357,247
Dr J Ogden	169,816	—	20,378	6,060	143,751	340,005
Total	897,647	42,500	77,804	22,728	1,311,230	2,351,909

(1) Specified executives are the five highest paid executives of pSivida other than members of the board of directors.

Options were granted to specified directors and executives on August 5, 2004 and have a value at the date of grant of A\$0.459 per option using a Black-Scholes model, taking into account time value and the volatility of the stock price. The options are exercisable at A\$1.18, being a 10% premium to the share price at the time of grant and may be exercised between August 5, 2004 and August 5, 2009.

Options were granted to specified directors (after receiving shareholder approval at pSivida's annual general meeting held on November 15, 2005) and executives on April 22, 2005 and have values ranging between A\$0.296 and A\$0.335 per option at the date of grant using a Black-Scholes model, taking into account time value and the volatility of the stock price. The options are exercisable at A\$0.80, being a 7% premium to the share price at the time of grant and may be exercised between April 22, 2005 and March 31, 2010 subject to vesting periods of up to 2 years.

pSivida has entered into consulting contracts with certain directors or their related entities for an indefinite period which may be terminated by either party on three months written notice or summary notice in the event of a breach in the terms of the agreement, the consultant is found guilty of any criminal act, misconduct or negligence or becomes insolvent. There are no termination benefits other than what applicable statute dictates.

*Pension, Retirement or Similar Benefits*

Under Australian government regulations, pSivida is legally required to contribute 9% of employees' gross income to an approved superannuation fund. Employees are entitled to contribute additional amounts to the fund at their own discretion. pSivida makes the required contribution to each employee's nominated Superannuation Fund. Contributions by pSivida of up to 9% of employees' wages and salaries are legally enforceable in Australia.

## [Table of Contents](#)

pSiMedica operates a defined contribution pension scheme. The pension cost charges for the years ended June 30, 2005, 2004 and 2003 under the defined contribution scheme were £79,411 (approximately A\$195,863), £30,660 (approximately A\$75,149) and £28,672 (approximately A\$77,740) respectively.

### **Share Ownership**

#### *Beneficial Ownership of Executive Officers and Directors*

The following table sets forth certain information as of September 30, 2005 regarding the beneficial ownership by each of pSivida's directors and executive officers:

	Ordinary Shares		Total Share Ownership	Options		Options in Subsidiary(14)	
	Held Directly	Held Indirectly		Held Directly	Held Indirectly	Held Directly	Held Indirectly
R Brimblecombe(7)	445,067	—	*	949,111	—	—	—
G J Rezos(3),(5)	2,018,630	9,300,652	5.01%	2,771,030	1,200,000	—	250,000
R Aston(4),(6)	5,618,586	1,475,000	3.14%	1,049,111	500,000	—	—
S Lake	—	—	*	242,061	—	—	—
A Ledger	—	1,900,000	0.84%	—	200,000	—	—
D Mazzo	—	—	*	—	—	—	—
M Rogers	—	—	*	—	—	—	—
A Finlay(8)	—	—	*	—	900,000	—	108,760
L Canham(9)	—	3,909,579	1.73%	739,289	—	—	110,840
A Kluczevska(10)	—	—	*	1,425,000	—	495,040	—
M Parry-Billings(11)	—	—	*	1,200,000	—	—	—
J Ogden(12)	—	—	*	554,708	—	—	—
S Connor(13)	—	189,000	*	444,645	—	—	—

- (1) Beneficial ownership is determined in accordance with the rules of the SEC, and generally include voting or investment power with respect to securities. Ordinary shares relating to options currently exercisable or exercisable within 60 days of the date of this information statement are deemed outstanding for computing the percentage of the person holding such securities but are not deemed outstanding for computing the percentage of any other person. Except as indicated, and subject to community property laws where applicable, the persons named in the table above have sole voting and investment power with respect to all shares shown as beneficially owned by them.
- (2) The percentages are based on 225,962,166 ordinary shares issued and outstanding as at September 30, 2005.
- (3) Of such shares, 2,018,630 are directly held by Mr. Rezos, 3,325,717 are held by Joanne Rezos, Mr. Rezos' wife, 3,059,333 are held by Mr. and Mrs. Rezos as trustees for the Rezos family superannuation Fund, 2,510,607 are held by Aymon Pacific Pty Ltd as trustee for the Jerezos Discretionary Trust and 376,995 are held by Viaticus Capital Pty Ltd, a Australian corporation owned by Mr. Rezos. Mr. Rezos may be deemed to be the beneficial owner of the ordinary shares held directly by Aymon Pacific Pty Ltd as trustee for the Jerezos Discretionary Trust, Mr. and Mrs. Rezos as trustees for the Rezos Family Superannuation Fund, Mrs. Rezos and Viaticus Capital Pty Ltd.
- (4) Of such shares, 5,618,586 are held directly by Dr Aston, 1,475,000 are held by Equity Insinger (Trust) (Jersey) Ltd, a Jersey corporation owned by Dr Aston. Dr Aston may be deemed to be the beneficial owner of the ordinary shares held directly by Insinger Equity (Trust) (Jersey) Ltd.
- (5) Of such options, 2,771,030 are held directly by Mr. Rezos available to be exercised into an equal number of ordinary shares with an exercise price of A\$1.18 per share expiring in August 2009 and 1,200,000 are held by Aymon Pacific Pty Ltd as trustee for the Jerezos Discretionary Trust available



## Table of Contents

to be exercised into an equal number of ordinary shares with an exercise price of A\$0.61 per share expiring on December 31, 2007.

- (6) Of such options, 500,000 are held directly by Dr Aston available to be exercised into an equal number of ordinary shares with an exercise price of A\$0.61 per share expiring on December 31, 2007; 49,111 are held directly by Dr Aston available to be exercised into an equal number of ordinary shares with an exercise price of A\$1.18 per share expiring in August 2009 and 1,000,000 are held by Newtonmore Biosciences Pty Ltd, an Australian corporation owned by Dr Aston, available to be exercised into an equal number of ordinary shares with an exercise price of A\$1.18 per share expiring in August 2009. Dr Aston may be deemed to be the beneficial owner of the options held directly by Insinger (Trust) Jersey Ltd and Newtonmore Biosciences Pty Ltd.
- (7) Of such options, 400,000 are held directly by Dr Brimblecombe available to be exercised into an equal number of ordinary shares with an exercise price of A\$0.61 per share expiring on December 31, 2007; and 549,111 are held directly by Dr Brimblecombe available to be exercised into an equal number of ordinary shares with an exercise price of A\$1.18 per share expiring in August 2009.
- (8) Of such options 700,000 are held by Mrs. Sophie Finlay as trustee for the Aylesford Trust available to be exercised into an equal number of ordinary shares with an exercise price of A\$1.18 per share expiring on August 5, 2009 and 200,000 are held by Mrs. Sophie Finlay as trustee for the Aylesford Trust available to be exercised into an equal number of ordinary shares with an exercise price of A\$0.80 per share expiring on March 31, 2010.
- (9) Of such options, 739,289 are held directly by Prof Canham available to be exercised into an equal number of ordinary shares with an exercise price of A\$1.18 per share expiring in August 2009.
- (10) Of such options, 1,200,000 are held directly by Dr Kluczevska with one third vesting annually from October 21, 2003 available to be exercised into an equal number of ordinary shares with an exercise price of A\$0.61 per share expiring in December 2007; 100,000 are held directly by Dr Kluczevska available to be exercised into an equal number of ordinary shares with an exercise price of A\$1.18 per share expiring in August 2009 and 125,000 are held directly by Dr Kluczevska available to be exercised into an equal number of ordinary shares with an exercise price of A\$0.80 per share expiring in 31 March 2010.
- (11) Of such options, 1,200,000 are held directly by Dr Mark Parry-Billings with one third vesting annually from April 22, 2005 available to be exercised into an equal number of ordinary shares with an exercise price of A\$0.80 per share expiring in March 2010.
- (12) Of such options, 429,708 are held directly by Dr Ogden available to be exercised into an equal number of ordinary shares with an exercise price of A\$1.18 per share expiring in August 2009 and 125,000 are held directly by Dr Ogden available to be exercised into an equal number of ordinary shares with an exercise price of A\$0.80 per share expiring in 31 March 2010.
- (13) Of such options, 319,645 held directly by Mr. Connor available to be exercised into an equal number of ordinary shares with an exercise price of A\$1.18 per share expiring in August 2009 and 125,000 are held directly by Mr. Connor available to be exercised into an equal number of ordinary shares with an exercise price of A\$0.80 per share expiring in 31 March 2010.
- (14) Options in a subsidiary represent options to acquire shares in the wholly-owned subsidiary AION Diagnostics Limited at an exercise price of nil, expiring 3 February 2008 and subject to various vesting conditions.

### *Stock Option Plan*

At pSivida's annual general meeting on November 1, 2001, shareholders approved the Employee Share Option Plan, or ESOP, whereby directors and executives of the consolidated entity are issued options over the ordinary shares of pSivida. Shareholders re-approved the ESOP at the Company's annual general meeting held on November 17, 2004. The options are issued without consideration in accordance

## [Table of Contents](#)

with performance guidelines established by the board of directors of pSivida. The following table presents option grant information as of September 30, 2005.

<u>Options Outstanding</u>	<u>Weighted Average Exercise Price</u>
19,561,713	A\$1.00

\* Note that 2,830,000 of these options were not issued under the ESOP.

### *Plan Administration*

The ESOP is administered by pSivida's board.

### *Exercise of Options Since June 30, 2005*

As of September 30, 2005 no options issued under the ESOP had been exercised since June 30, 2005.

## **PRINCIPAL SHAREHOLDERS AND RELATED PARTY TRANSACTIONS**

### ***Principal Shareholders***

The following table sets forth certain information as at September 30, 2005, regarding the beneficial ownership by all shareholders known to pSivida to own beneficially more than 5% of pSivida's ordinary shares. The voting rights of pSivida's major shareholders do not differ from the voting rights of other holders of its ordinary shares.

<u>Shareholder</u>	<u>Number of Ordinary Shares Beneficially Owned(1)</u>	<u>Percentage of Outstanding Ordinary Shares(2)</u>
QinetiQ Group Plc	35,699,629(3)	15.80%
Gavin Rezos	11,291,282(4)	5.00%
Directors and Executive Officers as a Group	24,856,514	11.00%

- (1) Beneficial ownership is determined in accordance with the rules of the SEC, and generally include voting or investment power with respect to securities. Ordinary shares relating to options currently exercisable or exercisable within 60 days of the date of this information statement are deemed outstanding for computing the percentage of the person holding such securities but are not deemed outstanding for computing the percentage of any other person. Except as indicated, and subject to community property laws where applicable, the persons named in the table above have sole voting and investment power with respect to all ordinary shares shown as beneficially owned by them.
- (2) The percentages are based on 225,962,166 ordinary shares issued and outstanding as at September 30, 2005.
- (3) Of such shares, 10,053,203 are held directly by QinetiQ Group Plc, and 25,646,426 are held indirectly by QinetiQ Group Plc. QinetiQ's address is Cody Technology Park, Ively Road, Hampshire GU14oLX, United Kingdom.
- (4) Of such shares, 2,018,630 are directly held by Mr. Rezos, 3,325,717 are held by Joanne Rezos, Mr. Rezos' wife, 3,059,333 are held by Mr. and Mrs. Rezos as trustees for the Rezos Family Superannuation Fund, 2,510,607 are held by Aymon Pacific Pty Ltd as trustee for the Jerezos Discretionary Trust and 376,995 are held by Viaticus Capital Pty Ltd, a Australian corporation owned by Mr. Rezos. Mr. Rezos may be deemed to be the beneficial owner of the ordinary shares held directly by Aymon Pacific Pty Ltd and Viaticus Capital Pty Ltd. Mr. Rezos' address is Level 12 BGC Centre, 28 The Esplanade, Perth WA 6000, Australia.

As of September 30, 2005, pSivida had 225,962,166 ordinary shares on issue, of which 155,143,201 were held by 3,538 Australian resident holders and 70,818,965 were held by 665 foreign holders. 525 of the

## Table of Contents

foreign holders, representing 8,487,230 ordinary shares, or less than 3.8%, are known by pSivida to have U.S. addresses at September 30, 2005.

As of September 30, 2005, pSivida had 19,561,713 options convertible into ordinary shares on issue, of which 9,715,141 were held by 15 Australian resident holders and 9,846,572 were held by 44 foreign holders. Twenty of the foreign holders, representing 3,145,000 options, are known by pSivida to have U.S. addresses as of September 30, 2005.

QinetiQ on behalf of itself and its affiliates has entered into a deed poll whereby it has pledged that, until October 26, 2009, as long as it holds 10% or more of pSivida's outstanding ordinary shares, it will exercise its voting rights in line with the majority of proxy votes exercisable by validly appointed proxies in relation to any resolution of pSivida's shareholders. The deed poll can be enforced by any of pSivida's shareholders. In addition, if at some time QinetiQ owns less than 10% of pSivida's outstanding ordinary shares and subsequently again owns 10% or more of pSivida's outstanding ordinary shares, QinetiQ's obligations under the deed poll would again be effective. The voluntary restriction on QinetiQ is irrevocable and applies for a period of five years until October 26, 2009.

pSivida is not aware of any direct or indirect ownership or control of pSivida by another corporation(s), by any foreign government or by any other natural or legal person(s) severally or jointly. pSivida does not know of any arrangements, the operation of which may at a subsequent date result in a change in control of pSivida.

### ***Related Party Transactions***

During the years ended June 30, 2005, 2004 and 2003, pSivida paid consultancy fees and other amounts totaling Nil, A\$341,362 and A\$173,333, respectively to Aymon Pacific Pty Ltd, a company controlled by Mr. Rezos. These fees and other amounts have been included in remuneration of directors and executive remuneration.

During the years ended June 30, 2005, 2004 and 2003, amounts of £220,689 (approximately A\$544,320), £186,682 (approximately A\$457,567) and £207,492 (approximately A\$564,033), respectively, were paid or payable to QinetiQ, then a shareholder of pSiMedica, for the use of laboratory facilities and for patent filing and administration. Following the transaction on August 4, 2004 to acquire the shares in pSiMedica that pSivida did not already own, QinetiQ and its related entities held approximately 17.5% of pSivida's issued share capital.

During the years ended June 30, 2005, 2004 and 2003 pSivida paid consultancy fees and other amounts totaling A\$319,941 and A\$44,000 and Nil, respectively, to Newtonmore Biosciences Pty Ltd, a company controlled by Dr. Aston. These fees and other amounts have been included in remuneration of directors and executive remuneration.

During the years ended June 30, 2005, 2004 and 2003, pSivida paid consultancy fees of A\$2,083, A\$71,858 and A\$45,000, respectively, to Blackwood Pty Ltd, a company controlled by Mrs. Donovan. These fees have been included in remuneration of directors and executive remuneration.

During the years ended June 30, 2005, 2004 and 2003, pSivida paid amounts of Nil, A\$12,367 and A\$52,187, respectively, to Viaticus Capital Ltd, a company controlled by Mr. Rezos, for sublease of BGC Centre office space.

During the years ended June 30, 2005, 2004 and 2003, pSivida paid Blake Dawson Waldron A\$114,832, A\$78,068 and A\$22,622, respectively, for various routine arms-length legal services. Blake Dawson Waldron is a national Australian law firm, and one of the partners thereof is a relative of a pSivida director.

During the years ended June 30, 2005, 2004 and 2003, amounts of A\$125,982, A\$149,489, and Nil respectively, were paid or payable to Albion Capital Partners, of which Mr. Rezos is a partner, for sublease of BGC Centre office space.

## [Table of Contents](#)

Amounts owing to directors, director-related parties and other related parties as of June 30, 2005, 2004 and 2003 were A\$50,102 A\$37,145 and A\$31,182, respectively.

From July 1, 2005 through to the date of this information statement, there have been no material related party transactions.

### **ENFORCEABILITY OF CIVIL LIABILITIES**

pSivida is a public company limited by shares incorporated under the laws of Western Australia. The majority of pSivida's directors and executive officers and all of its current employees named in this information statement reside outside the United States, and the assets of those non-resident directors and all of pSivida's 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.

### **INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The consolidated financial statements of pSivida Limited and subsidiaries as of June 30, 2005 and 2004 and for each of the three years in the period ended June 30, 2005 and for the period from December 1, 2000 (date of inception of development stage) to June 30, 2005, included in this information statement have been audited by Deloitte Touche Tohmatsu, an independent registered public accounting firm, as stated in their report appearing herein.

## CDS INFORMATION

## SELECTED CONSOLIDATED FINANCIAL DATA OF CDS

You should read the following selected consolidated financial information in conjunction with the consolidated financial statements and related notes of CDS as well as “Management’s Discussion and Analysis of Financial Condition and Results of Operations of CDS” included elsewhere in this information statement. The consolidated statement of operations data for the years ended December 31, 2002, 2003 and 2004 and the consolidated balance sheet data at December 31, 2003 and 2004 are derived from audited financial statements included elsewhere in the information statement. The statement of operations data for the years ended December 31, 2000 and 2001 and the balance sheet data at December 31, 2000, 2001 and 2002 have been derived from CDS’ audited financial statements that are not included in this information statement. The consolidated statement of operations data for the nine months ended September 30, 2004 and 2005 and the consolidated balance sheet data at September 30, 2005 have been taken from CDS’ unaudited condensed consolidated financial statements that are included elsewhere in this information statement and include, in the opinion of CDS management, all adjustments necessary for a fair statement of such data. Historical results are not necessarily indicative of results to be expected for any future period.

	Year Ended December 31,					Nine Months Ended September 30,	
	2000	2001	2002	2003	2004	2004	2005
	(In US\$ thousands)					(Unaudited)	
<b>Consolidated Statement of Operations Data:</b>							
Revenues:							
Collaborative research and development — related party	\$ 4,025	\$ 12,614	\$ 20,875	\$ 10,945	\$ 3,000	\$ —	\$ 3,500
Collaborative research and development — other	—	—	—	—	—	—	176
Royalties — related party	380	265	168	132	120	89	3,074
Government research grants	524	287	—	—	—	—	—
Total revenues	4,929	13,166	21,043	11,077	3,120	89	6,750
Operating expenses:							
Research and development	7,033	11,915	17,983	12,187	3,083	2,336	1,507
Royalties paid	356	131	82	66	60	44	37
General and administrative	1,955	9,690	11,022	7,571	5,646	4,539	3,741
Charge for asset impairment	—	—	—	6,575	—	—	—
Total operating expenses	9,344	21,736	29,087	26,399	8,789	6,919	5,285
Earnings (loss) from operations	(4,415)	(8,570)	(8,044)	(15,322)	(5,669)	(6,830)	1,465
Interest income and other, net	804	1,346	495	68	(207)	(151)	(38)
Earnings (loss) before income taxes	(3,611)	(7,224)	(7,549)	(15,254)	(5,876)	(6,981)	1,427
Net earnings (loss)	(3,803)	(7,224)	(7,549)	(15,254)	(5,876)	(6,981)	1,427
Accretion of redeemable convertible preferred stock	(197)	(472)	(472)	(942)	(2,124)	(1,501)	(1,926)
Net (loss) attributable to common stockholders	\$ (4,000)	\$ (7,696)	\$ (8,021)	\$ (16,196)	\$ (8,000)	\$ (8,482)	\$ (499)

[Table of Contents](#)

	<u>December 31,</u>					<u>September 30,</u>
	<u>2000</u>	<u>2001</u>	<u>2002</u>	<u>2003</u>	<u>2004</u>	<u>2005</u>
						<u>Unaudited</u>
	(In thousands)					
<b>Consolidated Balance Sheet Data:</b>						
Cash and cash equivalents	\$ 18,789	\$ 13,387	\$ 17,217	\$ 6,273	\$ 1,015	\$ 1,817
Working capital	23,726	15,431	7,229	2,136	(4,105)	(1,814)
Total assets	34,304	40,604	31,920	12,007	5,434	2,625
Redeemable convertible preferred stock	31,376	31,848	32,320	27,767	28,027	29,677
Total stockholders' deficit	(6,194)	(8,592)	(16,197)	(26,494)	(31,126)	(30,932)

**MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION  
AND RESULTS OF OPERATIONS OF CDS**

*You should read the following discussion and analysis of financial condition and results of operations of CDS in conjunction with "Selected Consolidated Financial Data of CDS" and the consolidated financial statements of CDS and related notes appearing elsewhere in this information statement. The merger, if completed, may have material effects on the business of CDS in the future and on the forward-looking statements contained in this information statement.*

**Overview**

CDS designs and develops innovative sustained-release drug delivery products. Since it was founded in 1991, CDS has primarily engaged in the research and development of products and product candidates using its proprietary technologies. To date, CDS has developed two commercial products, Vitrasert and Retisert. Vitrasert, a product for the treatment of cytomegalovirus retinitis, or CMV retinitis, a blinding eye disease that affects late-stage AIDS patients, has been marketed since 1996, and Retisert, a product for the treatment of posterior uveitis, was approved by the FDA in April 2005 and received Medicare reimbursement coverage in October 2005. CDS has an additional product, Medidur for the treatment of diabetic macular edema, or DME, in Phase III trials and additional product candidates in various stages of clinical and pre-clinical development.

Commercialized in 1996, Vitrasert is licensed to and sold by Bausch & Lomb Incorporated under a 1992 licensing and development agreement. Improvements in the treatment of AIDS/HIV have significantly decreased the incidence of CMV retinitis in the more developed nations that have the resources to provide advanced medical care, and sales of Vitrasert have declined each year since 2000. As a result, CDS' royalty revenues from sales of Vitrasert have also declined, together with the royalties paid by CDS on those sales pursuant to patent licenses.

CDS' revenues during the three years ended December 31, 2004 and during the nine months ended September 30, 2005 were primarily from payments for research and development, achievement of milestones and license fees, which CDS recorded as collaborative research and development revenue.

Under a 1999 licensing and development agreement with Bausch & Lomb, CDS licensed Bausch & Lomb its technologies for treatment of eye disease, and Bausch & Lomb committed to fund budgeted research and development performed by them and by CDS with respect to product candidates for the treatment of three eye diseases, including posterior uveitis and DME, and to make license fee and milestone payments to CDS. Research and development revenue under that agreement aggregated \$20.9 million in 2002 and \$10.9 million in 2003, comprising substantially all of CDS' revenues in those periods. In June 2003, Bausch & Lomb informed CDS that all future research and development under the 1999 licensing and development agreement would be undertaken by Bausch & Lomb and that Bausch & Lomb would no longer fund research and development by CDS. As a result of this loss of revenue, CDS terminated the employment of approximately 74 employees, or 70% of its workforce, in June 2003, most of whose costs were funded directly or indirectly by Bausch & Lomb, transferred clinical trials to Bausch & Lomb and significantly cut back its research and development program. CDS recorded a \$6.6 million impairment charge with respect to its assets that would no longer be used as had been contemplated under the 1999 licensing agreement. CDS undertook a second reduction in its workforce in August 2004 as a result of decreasing cash resources.

In December 2003, CDS and Bausch & Lomb amended their 1992 and 1999 licensing and development agreements into one licensing and development agreement. Retisert for posterior uveitis and DME are licensed to Bausch & Lomb under the amended agreement. As a result of the amended Bausch & Lomb agreement, CDS reacquired significant rights to its technologies.

In February 2005, CDS entered into a license and development agreement with Alimera Sciences Inc. to co-develop Medidur for DME. In the nine months ended September 30, 2005, Alimera Sciences paid

CDS the license fee and milestone payments provided under that agreement. The Medidur product for DME entered phase III trials in 2005.

### ***Critical Accounting Policy***

The following is a description of CDS' revenue recognition policy, which it believes is important to the portrayal of its financial condition and results and requires its most difficult, subjective or complex judgments as a result of the need to make estimates about the effect of matters that are inherently uncertain. CDS' significant accounting policies are more fully described in Note 2 to its Consolidated Financial Statements.

In accounting for revenue, a key component of CDS' results of operations, CDS follows the provisions of the Securities and Exchange Commission's Staff Accounting Bulletin (SAB) No. 104 (SAB No. 104), *Revenue Recognition*, Emerging Issues Task Force (EITF) Issue No. 00-21 (EITF 00-21), *Accounting for Revenue Arrangements with Multiple Deliverables*, EITF Issue No. 99-19 (EITF 99-19), *Reporting Revenue Gross as a Principal Versus Net as an Agent*, and EITF Issue No. 01-9 (EITF 01-9), *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*.

Non-refundable license fees are recognized as revenue when CDS has a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured, and CDS has no further performance obligations under the license agreement. Multiple element arrangements, such as license and development arrangements, are analyzed to determine whether the elements, the license and the performance obligations can be separated or whether they must be accounted for as a single unit of accounting in accordance with EITF 00-21. CDS recognizes up-front license payments as revenue upon delivery of the license only if the license has stand-alone value and the fair value of the undelivered performance obligations can be determined. If the fair value of the undelivered performance obligations can be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not to have stand-alone value or (ii) to have stand-alone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted for as a single unit of accounting and the license payments and payments for performance obligations are recognized as revenue over the estimated period of when the performance obligations are performed.

Whenever CDS determines that an arrangement should be accounted for as a single unit of accounting, CDS must determine the period over which the performance obligations will be performed and revenue will be recognized. Revenue will be recognized using either a relative performance or straight-line method. CDS recognizes revenue using the relative performance method provided that it can reasonably estimate the level of effort required to complete its performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Direct labor hours, full-time equivalents or costs may be used as the measure of performance. Revenue recognized under the relative performance method is determined by multiplying the total payments under the arrangement excluding royalties and unearned milestones, by the ratio of level of effort incurred to date to estimated total level of effort required to complete CDS' performance obligations under the arrangement. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the relative performance method, as of each reporting period.

If CDS cannot reasonably estimate the level of effort required to complete its performance obligations under an arrangement and the performance obligations are provided on a best-efforts basis, the total payments under the arrangement, excluding royalties and payments contingent upon achievement of substantive milestones, are recognized as revenue on a straight-line basis over the period CDS expects to complete its performance obligations. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the straight-line basis, as of the period ending date.

Significant management judgment is required in determining the level of effort required under an arrangement and the period over which CDS is expected to complete its performance obligations under an



## Table of Contents

arrangement. For its 1999 contract with Bausch & Lomb, CDS used total project costs as a measure of the level of effort completed and the total level of effort required to complete its performance obligations under the arrangement. The amount of revenue recognized was dependent upon CDS estimates of the total costs, and such estimates are highly judgmental given the uncertainties involved in clinical development of products. In June 2003 Bausch & Lomb took over the development efforts under the 1999 agreement and thus CDS' performance obligation under the arrangement ended.

Reimbursement of costs is recognized as revenue provided the provisions of EITF 99-19 are met, the amounts are determinable, and collection of the related receivable is reasonably assured.

Royalty revenue is recognized upon the sale of the related products, provided that the royalty amounts are fixed or determinable, collection of the related receivable is reasonably assured and CDS has no remaining performance obligations under the arrangement.

For revenue generating arrangements where CDS, as a vendor, provides consideration to a licensor or collaborator, as a customer, CDS applies the provisions of EITF 01-9. EITF 01-9 addresses the accounting for revenue arrangements where the vendor gives consideration to the customer. Cash consideration paid to a customer is presumed to be a reduction of the selling price unless CDS receives an identifiable benefit for the payment and CDS can reasonably estimate the fair value of the benefit received. Payments to a customer that are deemed a reduction of selling price are recorded first as a reduction of revenue, to the extent of both cumulative revenue recorded to date and of probable future revenues, which include any unamortized deferred revenue balances, under all arrangements with such customer and then as an expense. Payments that are not deemed to be a reduction of selling price would be recorded as an expense.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets.

### **Results of Operations**

#### *Nine months ended September 30, 2005 and 2004*

*Revenues.* Total revenues increased \$6.7 million to \$6.8 million for the nine months ended September 30, 2005, from \$89,000 for the nine months ended September 30, 2004 as the result of a \$3.5 million milestone payment earned in the 2005 period under CDS' agreement with Bausch & Lomb, \$3.0 million of royalties from Bausch & Lomb recognized as a result of a royalty advance and \$176,000 of license fee and milestone payment earned under CDS' agreement with Alimera Sciences.

*Research and Development.* Research and development expenses decreased \$.8 million, or 35%, to \$1.5 million for the nine months ended September 30, 2005, from \$2.3 million for the nine months ended September 30, 2004. The decrease was primarily due to a significant reduction in the size of CDS' workforce, which occurred in August 2004. Salary and benefits decreased by \$425,000 and third party research and development costs decreased by \$214,000.

*General and Administrative.* General and administrative expenses decreased \$.8 million or 19%, to \$3.7 million for the nine months ended September 30, 2005, from \$4.5 million for the nine months ended September 30, 2004. The decrease was due primarily to a significant reduction in the size of CDS' workforce in August 2004 resulting in a decrease of \$146,000 of salaries and benefits and a decrease of \$1.0 million of non-cash stock compensation charges, partially offset by an increase of \$563,000 of investment banking expenses related to potential financing transactions .

*Interest Expense.* Interest expense decreased \$120,000 or 67% to \$59,000 for the nine months ended September 30, 2005, from \$179,000 for the nine months ended September 30, 2004. The decrease was due to CDS' repayment of its mortgage financing in April 2005 upon the sale of its real estate.

#### *Years ended December 31, 2004 and 2003*

*Revenues.* Total revenues decreased \$8.0 million, or 72%, to \$3.1 million for the year ended December 31, 2004, from \$11.1 million for the year ended December 31, 2003.

## Table of Contents

Collaborative research and development revenue-related party decreased \$7.9 million, or 73%, to \$3.0 million for the year ended December 31, 2004, from \$10.9 million for the year ended December 31, 2003. The decrease was due to the decision by Bausch & Lomb in mid-2003 to cease funding CDS' research under CDS' agreement with Bausch & Lomb and to undertake the research directly. This reduction in collaborative research and development revenue-related party was partially offset by a \$3.0 million milestone payment earned in 2004 under that agreement.

Royalty revenue decreased \$12,000, or 9%, to \$120,000 for the year ended December 31, 2004, from \$132,000 for the year ended December 31, 2003. The decrease was due to a decrease in Vitrasert royalties paid to CDS as the result of lower Vitrasert sales.

*Research and Development.* Research and development expenses decreased \$9.1 million, or 75%, to \$3.1 million for the year ended December 31, 2004, from \$12.2 million for the year ended December 31, 2003. The decrease was primarily due to cessation in mid-2003 of research and development activities by CDS under its agreement with Bausch & Lomb as a result of Bausch & Lomb's decision to undertake the research directly. This resulted in a decrease of \$3.3 million of salaries and benefits and a decrease of \$4.4 million of third party research and development costs. Depreciation expense decreased by \$602,000 from 2003 to 2004, primarily resulting from the asset impairment charge incurred in June 2003.

*Royalties Paid.* Royalties expense decreased \$6,000, or 9%, to \$60,000 for the year ended December 31, 2004, from \$66,000 for the year ended December 31, 2003. The decrease was attributable to lower Vitrasert sales.

*General and Administrative.* General and administrative expenses decreased \$2.0 million, or 25%, to \$5.6 million for the year ended December 31, 2004, from \$7.6 million for the year ended December 31, 2003. The decrease was due primarily to significant reductions in CDS' workforce in June 2003 and August 2004. This resulted in a decrease of \$1.2 million of salaries and benefits costs, \$712,000 of legal and accounting costs, \$475,000 of facility occupancy and \$363,000 of consulting and recruitment costs. Non-cash stock compensation charges increased by \$876,000 from 2003 to 2004.

*Interest Income.* Interest income, decreased \$205,000, or 84%, to \$38,000 for the year ended December 31, 2004 from \$243,000 for the year ended December 31, 2003 primarily as the result of lower average investments and marketable securities in 2004.

### *Years ended December 31, 2003 and 2002*

*Revenues.* Total revenues decreased \$9.9 million, or 47%, to \$11.1 million for the year ended December 31, 2003, from \$21.0 million for the year ended December 31, 2002.

Collaborative research and development revenue-related party decreased \$10.0 million, or 48%, to \$10.9 million for the year ended December 31, 2003, from \$20.9 million for the year ended December 31, 2002, due to the decision by Bausch & Lomb in mid-2003 to cease funding CDS' research under the agreement with Bausch & Lomb.

Royalties — related party revenue decreased \$36,000, or 21%, to \$132,000 for the year ended December 31, 2003, from \$168,000 for the year ended December 31, 2002. This decrease was due to a decrease in Vitrasert royalties paid to CDS as the result of lower Vitrasert sales.

*Research and Development.* Research and development expenses decreased \$5.8 million, or 32%, to \$12.2 million for the year ended December 31, 2003, from \$18.0 million for the year ended December 31, 2002. The decrease was due to reduced research and development activities in 2003 under CDS' agreement with Bausch & Lomb. This resulted in a decrease of \$1.2 million of salaries and benefits and a decrease of \$4.6 million in third party research and development costs.

*Royalties Paid.* Royalties expense decreased \$16,000 or 20%, to \$66,000 for the year ended December 31, 2003, from \$82,000 for the year ended December 31, 2002. The decrease was attributable to decreased royalty payments as the result of lower Vitrasert sales.

## Table of Contents

*General and Administrative.* General and administrative expenses decreased \$3.5 million, or 31%, to \$7.6 million for the year ended December 31, 2003, from \$11.0 million for the year ended December 31, 2002. The decrease was due to the significant reduction in the size of CDS' workforce in June 2003. This resulted in a decrease of \$538,000 of salaries and benefits, \$450,000 of non-cash stock compensation charges, \$436,000 of consulting and recruitment costs. In addition costs of \$2.1 million related to a potential initial public offering were recorded in 2002.

*Interest Income.* Interest income decreased \$272,000, or 53%, to \$243,000 for the year ended December 31, 2003, from \$515,000 for the year ended December 31, 2002. The decrease was due to decreased interest earned from the lower average outstanding balances of cash and cash equivalents in 2004. The decrease was also due to higher interest expense in 2004 attributable to a mortgage financing in August 2002.

### ***Liquidity and Capital Resources***

During the three years ended December 31, 2004, CDS incurred net losses. For the period from January 1, 2002 through September 30, 2005, CDS' primary source of revenues and cash flows were payments under its agreements with Bausch & Lomb. Because Bausch & Lomb ceased funding research and development by CDS under the 1999 licensing and development agreement in mid-2003, CDS' revenues have decreased significantly, and CDS has significantly reduced operations and sold its real estate to reduce its expenditures and conserve cash. Although CDS expects to receive royalties from Retisert sales, it is unable to predict the amount or timing of receipt of such royalties. Accordingly, CDS believes that it will require additional financing. If the merger with pSivida is not completed, there can be no assurance that CDS will be able to obtain additional financing, or, if available, that CDS will be able to obtain such additional financing on acceptable terms. CDS' future capital requirements will depend on many factors, including:

- the number, rate, progress and results of research programs and pre-clinical and clinical trials of CDS and those to whom it has licensed and may license its technologies,
- the terms of licensing agreements and collaborations entered into by CDS with respect to its technologies, including CDS' decisions with respect to funding under the Alimera Sciences agreement,
- the decisions of CDS and its licensees with respect to commercialization of products and the timing and success of CDS and its licensees in commercializing products, and
- costs incurred in obtaining, enforcing and defending patent and other intellectual property rights.

Cash used in operating activities was \$10.2 million for the year ended December 31, 2002, \$9.3 million for the year ended December 31, 2003, \$5.0 million for the year ended December 31, 2004, and \$4.9 million for the nine months ended September 30, 2004. Cash provided by operating activities was \$579,000 million for the nine months ended September 30, 2005. The decrease in cash used in operating activities from the year ended December 31, 2002 to the year ended December 31, 2003 was primarily due to significant reductions during 2003 of accounts payable, accrued expenses and deferred revenue offset by a \$5.8 million advance from Bausch and Lomb. The decrease in cash used in operating activities from the year ended December 31, 2003 to the year ended December 31, 2004 was due primarily to a significant reduction in CDS' loss before taxes, partially offset by the repayment of \$3.0 million of advances from Bausch and Lomb. The increase in cash provided by operating activities from the nine months ended September 30, 2004 to the nine months ended September 30, 2005 was primarily due to improved operating results in the 2005 period as a result of increased collaborative research and development and royalty revenues.

Cash provided by investing activities was \$868,000 for the year ended December 31, 2002, \$6.0 million for the year ended December 31, 2003, \$1.5 million for the year ended December 31, 2004; \$1.5 million for the nine months ended September 30, 2004 and \$3.8 million for the nine months ended September 30, 2005. The increase in cash provided by investing activities from the year ended

## [Table of Contents](#)

December 31, 2002 to the year ended December 31, 2003 was primarily due to \$4.8 million lower purchases of property and equipment in 2003 than 2002, which included the purchase of real estate. The decrease in cash provided by investing activities from the year ended December 31, 2003 to the year ended December 31, 2004 was primarily due to the net effects of CDS' short-term investing activities which resulted in the net sales of \$7.4 million of short-term investments during 2003 compared to \$1.5 million of net sales in 2004, partially offset by equipment purchases which were \$1.4 million lower in 2004. The increase in cash provided by investing activities from the nine months ended September 30, 2004 to the nine months ended September 30, 2005 was primarily due to proceeds received from the sale of real estate in the 2005 period offset by no sales of investments in 2005.

Cash provided by financing activities was \$4.1 million for the year ended December 31, 2002, cash used in financing activities was, \$205,000 for the year ended December 31, 2003; \$200,000 for the year ended December 31, 2004, \$150,000 for the nine months ended September 30, 2004 and \$3.5 million for the nine months ended September 30, 2005. The decrease in cash provided by financing activities from the year ended December 31, 2002 to the year ended December 31, 2003 was primarily due to \$4.0 million provided in 2002 by the proceeds from the issuance of long-term debt. The increase of approximately \$3.4 million in cash used in financing activities from the nine months ended September 30, 2004 to the nine months ended September 30, 2005 was due to \$3.5 million of payments of long term debt related to the sale of CDS' facility in 2005.

CDS had working capital of \$7.2 million at December 31, 2002 and \$2.1 million at December 31, 2003, a working capital deficit of \$4.1 million at December 31, 2004 and a working capital deficit of \$1.8 million at September 30, 2005. The decrease in working capital from December 31, 2002 to December 31, 2003 was primarily due to a net loss in 2003 and \$1.4 million of property and equipment purchases, partially offset by the reclassification during 2003 of \$3.0 million of liabilities to Bausch & Lomb to long-term liabilities. The decrease in working capital from December 31, 2003 to December 31, 2004 was primarily due to a net loss in 2004. The working capital deficit decreased from December 31, 2004 to September 30, 2005 as a result of net losses.

CDS had cash and cash equivalents of \$8.1 million at December 31, 2002, \$4.7 million at December 31, 2003, \$1.0 million at December 31, 2004 and \$1.8 million at September 30, 2005. The decrease of approximately \$3.4 million in cash and cash equivalents from December 31, 2002 to December 31, 2003 was primarily due to cash used by operations of \$9.2 million, partly offset by sales of short-term investments of \$7.5 million net of \$1.5 million of property and equipment purchases. The decrease of approximately \$3.7 million in cash and cash equivalents from December 31, 2003 to December 31, 2004 was primarily due CDS' operating loss during 2004, partially offset by net sales of \$1.5 million of short-term investments. The increase of \$0.8 million in cash and cash equivalents from December 31, 2004 to September 30, 2005 was primarily due to cash provided by operating activities. Although CDS expects to receive royalties from Retisert sales, it is unable to predict the amount or timing of receipt of such royalties. Accordingly, CDS believes that it will require additional financing. If the merger with pSivida is not completed, there can be no assurance that CDS will be able to obtain additional financing, or, if available, that CDS will be able to obtain such additional financing on acceptable terms.

The following table outlines CDS' contractual obligations as of September 30, 2005 for payments under its indebtedness (including capital leases), purchase obligations, operating leases and other obligations:

	Payments due by period (in thousands of U.S. Dollars)				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating Lease Obligations	702	226	476	—	—
<b>Total</b>	<b>702</b>	<b>226</b>	<b>476</b>		

## [Table of Contents](#)

The lease commitments in the above table do not include costs for insurance, real estate taxes and common area maintenance costs that CDS is obligated to pay.

### **Recent accounting pronouncements**

In December 2004, the FASB issued SFAS No. 153, “*Exchange of Nonmonetary Assets*” (“SFAS 153”), which is an amendment to APB Opinion No. 29, “*Accounting for Nonmonetary Transactions*” (“APB 29”). The guidance of APB 29, is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The guidance in that opinion, however, included certain exceptions to that principle. SFAS 153 amends APB 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. The adoption of SFAS 153 is not expected to change significantly as a result of the exchange. the adoption of SFAS 153 is not expected to have a material impact on CDS’ financial position or results of operations.

In July 2005, the FASB issued a staff position, or FSP, No. 150-5, “*Issuer’s Accounting Under FAS 150 for Freestanding Warrants and Other Similar Instruments or Shares that are Redeemable.*” This FSP addresses whether freestanding warrants and other similar instruments that are redeemable would be subject to the requirements of FASB Statement No. 150, “*Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity,*” regardless of the timing of the redemption feature or the redemption price. FSP FAS 150-1 “*Issuers Accounting for Freestanding Instruments Composed of More Than One Option or Forward Contract Embodying Obligations Under FASB Statement No. 150,*” or FSP 150-1, explains that both warrants for shares that are puttable and warrants for mandatorily redeemable shares are classified as liabilities under FAS 150 because they embody obligations to transfer assets. FSP 150-5 clarifies that this treatment as a liability applies whether the shares are redeemable immediately after the warrant exercise or at some date in the future and whether the obligation of the issuer to redeem is conditional or unconditional. The adoption of FSP FAS 150-1 is not expected to have a material impact on CDS’ financial position or results of operations.

### **Stock-Based Compensation**

In December 2004, the FASB issued Statement of Financial Accounting Standards, or SFAS, No. 123 (revised 2004), “*Share-Based Payments*” or SFAS 123R. This statement eliminates the option to apply the intrinsic value measurement provisions of Accounting Principles Board, or APB, Opinion No. 25, “*Accounting for Stock Issued to Employees*” to stock compensation awards issued to employees. Rather, SFAS 123R requires companies to measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost will be recognized over the period during which an employee is required to provide services in exchange for the award — the requisite service period (usually the vesting period). SFAS 123R applies to all awards granted after the required effective date and to awards modified, repurchased, or cancelled after that date.

CDS applied APB No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, in accounting for its stock-based compensation plans for the year ended December 31, 2002. CDS had adopted the disclosure only provisions of SFAS No. 148, *Accounting for Stock-Based Compensation — Transition and Disclosure, an amendment of FASB Statement No. 123*; therefore, no compensation expense was included in the statement of operations for fiscal year 2002 related to employee options, for which the exercise price was equal to or greater than the fair market value of CDS’ common stock on the date of grant.

Effective January 1, 2003, CDS adopted SFAS 148, on a prospective-basis. Accordingly, for the years ended December 31, 2003 and 2004 and for the nine months ended September 30, 2005, compensation expense related to all stock options granted during the period is included in the statement of operations, as calculated under the fair value method.

[Table of Contents](#)**Market Price of and Dividends on the Registrant's Common Equity and Related Stockholder Matters****Market information**

There is currently no public market for the common stock or preferred stock of CDS.

**Security holders**

As of October 31, 2005, there were 77 stockholders of record of the CDS' common stock and 50 stockholders of record of CDS' preferred stock.

**Dividends**

CDS has never declared or paid dividends on its capital stock.

**Equity compensation plan information**

The following table shows information about the securities, shares of common stock, authorized for issuance under CDS' equity compensation plans as of October 31, 2005:

<u>Plan Category</u>	<u>(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</u>	<u>(b) Weighted-average Exercise Price of Outstanding Options, Warrants and Rights</u>	<u>(c) Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a))</u>
Equity compensation plans approved by security holders	49,500	\$ 23.77	46,167
Equity compensation plans not approved by security holders	—	—	—
<b>Total</b>	<b>49,500</b>	<b>\$ 23.77</b>	<b>46,167</b>

**CDS' BUSINESS****Overview**

CDS designs and develops innovative sustained-release drug delivery products. CDS' 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 CDS' target diseases: adverse side effects characteristic of high dosing levels and reduced treatment benefits due to variations in drug levels at the target site.

CDS has two commercial products utilizing the AEON system approved by the FDA 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 and sold since 1996, Vitrasert is one of the most effective treatments for CMV retinitis, a disease that afflicts late-stage AIDS patients. Approved by the FDA in April 2005 and also marketed by Bausch & Lomb, Retisert treats chronic noninfectious uveitis affecting the posterior segment of the eye, or posterior uveitis, a leading cause of vision loss. Bausch & Lomb is also conducting two long-term multi-center clinical trials of Retisert for the treatment of diabetic macular edema, or DME, another leading cause of vision loss. Medidur, 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. CDS also has two AEON product candidates in pre-clinical studies for other back of the eye diseases.

To date, CDS has focused its efforts primarily on research and development of products based on its AEON system. In Phase I Studies, CDS has explored the use of its CODRUG system for the treatment of post-surgical pain and two skin diseases.

## [Table of Contents](#)

CDS' products and product candidates are currently at the following stages of development for the listed diseases:

<u>Disease</u>	<u>Stage of Development</u>
<i>AEON System</i>	
CMV retinitis	FDA approved and commercialized
Posterior uveitis	FDA approved and commercialized
Diabetic macular edema	Phase III trials (fast-track)
Dry age-related macular degeneration	Pre-clinical development
Retinitis pigmentosa	Pre-clinical development
<i>CODRUG System</i>	
Post-surgical pain	Phase I
Psoriasis/ Actinic keratosis	Phase I

### **Market Overview**

#### *Drug Delivery Generally*

The therapeutic value of a drug depends on its distribution throughout the body, reaction with the targeted site, reaction with other tissues and organs in the body, and clearance from the body. In an ideal treatment, the appropriate amount of drug is delivered to the intended site in the body and maintained there for an adequate period of time without adversely affecting other tissues and organs. Accordingly, the manner in which a drug is delivered can be as important to the ultimate therapeutic value of the treatment as the intrinsic properties of the drug itself.

Drugs are typically administered systemically by oral dosing or by injection and are subsequently dispersed throughout the body via the circulatory system. In many cases, systemic administration does not deliver drugs to the intended site at an adequate concentration for a sufficient period of time or fails to achieve the maximum potential therapeutic benefit.

Because systemically delivered drugs disperse throughout the body, they often must be administered at high dosage levels in order to achieve sufficient concentrations at the intended site. Some areas of the body, such as the eyes, joints, brain, and nervous system, have natural barriers that impede the movement of drugs to those areas, requiring the administration of even higher systemic doses. These high dosage levels can cause harmful side effects when the drug interacts with other tissues and organs.

Timely and repeated administration of drugs by the patient is often necessary to maintain therapeutic drug levels over an extended period of time. Patients, however, often fail to take drugs as prescribed and, as a result, do not receive the potential therapeutic benefit. The risk of patient noncompliance increases if multiple drugs are required, if the dosing regimen is complicated, or if the patient is elderly or cognitively impaired.

Due to the drawbacks of traditional systemic drug delivery, the development of novel methods to deliver drugs to patients in a more precise, controlled fashion over sustained periods of time has become a multi-billion dollar industry. More recently developed drug delivery methods include oral and injectable controlled-release products and skin patches. These methods seek to improve the consistency of the dosage over time and extend the duration of delivery. However, most of these methods still cannot provide constant, controlled dosage or deliver drugs for a sufficiently long duration. This reduces their effectiveness for diseases that are chronic or require precise dosing. In addition, most of these methods still deliver drugs systemically and, as a result, can still cause adverse systemic side effects.

#### *Ophthalmic Drug Delivery*

Treatment for diseases in the back of the eye is a significant issue in ophthalmology. Due to the efficiency of the blood/eye barrier, it is difficult for systemically administered drugs to reach the eye in sufficient quantities to have a beneficial effect. There is a need for delivering drugs inside the eye in a

manner that is safe, effective, and practical for long-term use. While there are currently many approaches to delivering medications to the eye, most do not achieve sufficient concentrations within the eye for the appropriate period of time.

Injecting solutions of drugs directly into the back of the eye can achieve effective but often transient drug levels in the eye, requiring repeated injections. Examples include Macugen™ (pegaptanib sodium) and Lucentis™ (ranibizumab, formerly RhuFab V2), both of which must be injected into the eye approximately every month. Apart from inconvenience and cost, repeated intravitreal injections carry the risk of cataract formation, perforated schlera, vitreous hemorrhage and serious intraocular infection.

#### *The CDS Technology Systems*

CDS' two proprietary technology systems, the AEON system and the CODRUG system, are designed to offer three principal advantages:

- *Localized Delivery.* The AEON and CODRUG systems permit implantation, injection or other application directly at the target site. CDS' delivery systems use the natural barriers of the body to isolate and maintain appropriate concentrations of the drug at the target site in an effort to achieve the maximum therapeutic effect of a drug while minimizing unwanted systemic effects.
- *Controlled Release Rate.* The AEON and CODRUG systems release drugs at a constant or controlled rate. CDS believes that this allows its products and product candidates to maintain the optimal drug concentration at a target site and eliminate variability in dosing over time.
- *Extended Delivery.* CDS' AEON and CODRUG systems deliver drugs for predetermined periods of time ranging from days to years. CDS believes that uninterrupted, sustained delivery offers the opportunity to develop products that reduce the need for repeat applications, eliminates the risk of patient noncompliance and provides more effective treatment.

#### *AEON System*

The AEON system uses a drug core with one or more surrounding polymer layers. The drug permeates through the polymers into the body at a controlled rate for a predetermined period of time ranging from days to years. By changing the design of the AEON system, CDS can control both the rate and duration of release to meet different therapeutic needs. CDS believes that its AEON system might be used to deliver a wide variety of different drugs. CDS is currently using AEON technology for all of its ophthalmic products and product candidates. As of the date of this information statement, CDS either has, or has exclusive licenses to, 34 issued patents and 133 patent applications covering different aspects of its AEON technology.

The following diagram demonstrates CDS' AEON system:

Vitrasert, Retisert and Medidur represent the evolution of the AEON system. Vitrasert is a device surgically implanted through a 5-6 mm incision that releases drug from its core for approximately 6-8 months. Retisert is a device implanted through a 3-4 mm incision that releases drug from its core for 30 months. Medidur is a device injected through a needle to the back of the eye in an in-office procedure designed to release drug from its core for up to three years. CDS is working to develop a bioerodible Medidur system.



The following picture shows, from left to right, Medidur, Retisert and Vitrasert.

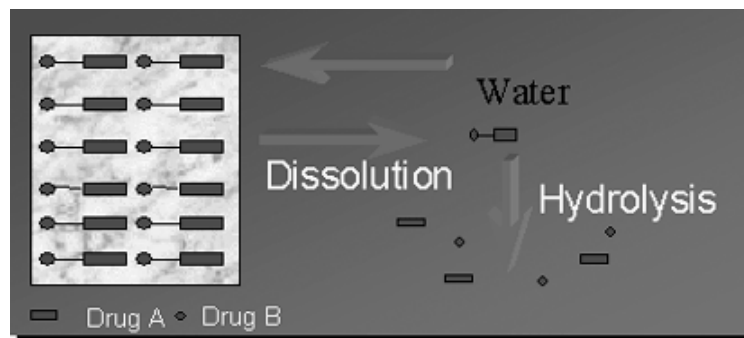
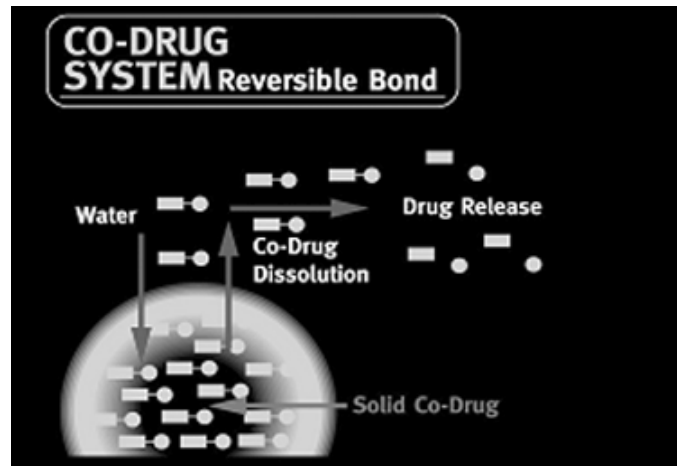


*CODRUG Technology*

CDS' proprietary CODRUG system allows for the simultaneous release of two or more drugs from the same product at the same controlled rate over a predetermined period of time. Using this technology, CDS chemically links together two or more identical or different drugs. CODRUGs can be administered by virtually any delivery method. Regardless of delivery method, CODRUGs dissolve into the body at a predetermined rate and then separate into the original active drug(s) when the chemical bond breaks apart. CDS believes that many drugs can be chemically linked with its CODRUG technology and has synthesized a library of approximately 298 CODRUG compounds. CDS has performed Phase I clinical trials involving CODRUGs for the treatment of post-surgical pain and two skin diseases. As of the date of this information statement, CDS either has, or has exclusive licenses to, three issued patents and 69 patent applications covering its CODRUG technology.

## [Table of Contents](#)

The following diagrams demonstrate CDS' CODRUG system:



### PRODUCTS AND PRODUCT CANDIDATES OF CDS

CDS' products, Vitrasert and Retisert, are the only two sustained-release products approved by the FDA for back of the eye diseases. The Vitrasert AEON implant is approved for the treatment of CMV retinitis and the Retisert AEON implant is approved for the treatment of posterior uveitis, both leading causes of vision loss. CDS also has AEON product candidates for DME, dry age-related macular degeneration, or AMD, and retinitis pigmentosa, or RP, three other leading causes of vision loss.

CDS is also developing two products, currently in Phase I clinical trials, that rely on its CODRUG system to treat post-surgical pain and the skin disorders psoriasis and actinic keratosis, or AK.

#### *Sight-Threatening Eye Diseases*

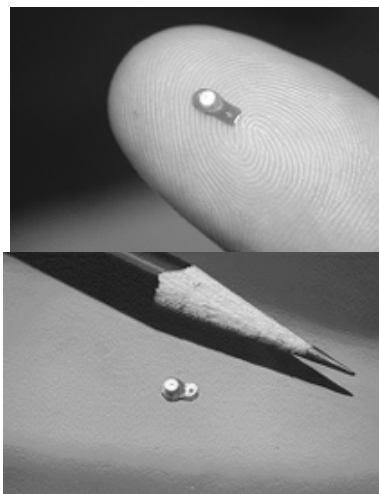
**CMV Retinitis.** CDS' Vitrasert implant treats CMV retinitis, a blinding eye disease that frequently occurs in individuals with advanced AIDS. Vitrasert provides sustained treatment of the disease through the intravitreal delivery of the anti-viral drug ganciclovir for six to eight months. Vitrasert has been marketed and sold since 1996, first by Chiron Corporation and subsequently by Bausch & Lomb. Although CMV retinitis was common in the early 1990s, improvements in the treatment of AIDS/ HIV have since significantly decreased the incidence of the disease in more developed countries. CDS' implant has been used in over 12,000 eyes since 1996. Studies show that Vitrasert is one of the most effective approved treatments for CMV retinitis.

**Posterior Uveitis.** CDS' Retisert implant for treatment of posterior uveitis was approved by the FDA in April 2005, the first drug approved by the FDA to treat this disease. Posterior uveitis is an autoimmune condition characterized by inflammation of the inside of the eye that can cause sudden or gradual vision loss. Retisert was approved as an orphan drug and has 7-year exclusive marketing rights that the FDA provides for orphan drugs first approved for a particular indication. Retisert is marketed and sold by Bausch & Lomb.

## Table of Contents

Like Vitrasert, Retisert is implanted into the back of the eye in a simple, outpatient procedure. It delivers sustained levels of the anti-inflammatory corticosteroid, fluocinolone acetonide or FA, for 30 months. The most common adverse events — which are anticipated given the nature of the disease and the type of drug used — include cataract progression, which is managed by standard cataract surgery, increased intraocular pressure, which is managed with the use of interocular pressure, or IOP-, lowering eye drops or filtering surgery; and procedural complications and eye pain. Although no other drugs are approved for posterior uveitis, off-label treatments include steroidal eye drops, ocular injections of steroids, orally administered steroids, immunosuppressants, and chemotherapy. These treatments, if successful, generally only slow the progression of the disease and can have serious side effects such as severe osteoporosis, muscle wastage, psychosis, cancer and stunted growth. Bausch & Lomb estimates that posterior uveitis affects 175,000 people in the United States and 800,000 people worldwide.

In two clinical trials involving patients with posterior uveitis, patients were implanted with either a 2.1 mg or a 0.59 mg Retisert device. In patients with the 0.59 mg device, the rates of recurrence in the 34 weeks after implantation ranged from approximately 7% to 14% compared to approximately 40% and 54% for the 34 week pre-implantation period. In the first study involving over 250 patients, 10% of those receiving an implant (either dose) experienced a three line improvement on the eye chart in vision at 34 weeks, while in the second study of 234 patients, 21% experienced an improvement of three lines at 34 weeks. The main side effects were elevated intraocular pressure and cataracts. After two years, approximately 30% of patients with posterior uveitis with a Retisert implant required a second operation to reduce pressure, and substantially all patients with a Retisert implant developed cataracts.



*Diabetic Macular Edema.* CDS' injectable Medidur product is currently in Phase III trials for treatment of diabetic macular edema, a disease causing swelling in the macula, the most sensitive part of the retina, and a major cause of vision loss in diabetics. CDS is not aware of any approved drug treatment for this disease. It is currently treated by laser therapy, which burns the retina either in specific sites or in a grid, and vitrectomy, eye surgery that involves the removal of the vitreous gel from the cavity of the eye. Both have serious limitations, which include repeat treatments or invasive surgical procedures. Both treatments generally only temporarily reverse vision loss and slow the progression of the disease.

Medidur is an implant small enough to be injected through a needle to the back of the eye and is expected to release drug for up to three years. Alimera Sciences is currently conducting two Phase III clinical trials for Medidur to treat DME which will follow 900 patients in the U.S. and Europe for 36 months. If approved, CDS has licensed Alimera Sciences to market and sell Medidur for DME.

Bausch & Lomb is also conducting two randomized, multi-center trials using the Retisert implant to treat DME, which follow 277 patients for 36 months. The FDA has stated that in order to approve a product for DME, there must be a statistically significant difference in vision of three lines at three years. At two years, both Bausch & Lomb studies showed a statistical difference in vision of three lines in patients with Retisert implants. Specifically, in the smaller study at two years, 37% of patients with Retisert implants experienced an improvement in vision of three lines compared with 14% of the patients randomized to standard of care. In addition, more Retisert patients had a complete resolution of their edema, and fewer patients had a worsening of their diabetic retinopathy (both also statistically significant). In the larger study, 28% of patients with Retisert experienced a three line improvement compared to 9% of patients receiving standard of care. More patients with Retisert had complete resolution of their edema at

## Table of Contents

two years, and fewer patients with Retisert had a worsening of their diabetic retinopathy (both statistically significant). As with Retisert for uveitis, the primary side effects were elevated intraocular pressure and cataracts. Two years after receiving the Retisert implant, approximately 20% of patients with DME needed a second surgery to reduce intraocular pressure while essentially all Retisert patients developed cataracts. CDS is unable to predict the outcome of these trials at three years. CDS has licensed the rights with respect to Retisert for DME to Bausch & Lomb.

*Dry Age-Related Macular Degeneration.* CDS is in pre-clinical development of a Medidur product to treat dry age-related macular degeneration. AMD is a leading cause of visual impairment in Americans over 60 and affects over 10 million people in the United States. With dry AMD, the cells in the central retina die slowly resulting in gradual central vision loss. There are currently no approved treatments for dry AMD though some studies show that treatment with high doses of antioxidants and zinc may help delay its development in individuals with less severe forms of dry AMD.

*Retinitis Pigmentosa.* CDS is in pre-clinical development of a Medidur product to treat retinitis pigmentosa. RP comprises a group of inherited eye diseases that affect the retina, causing the degeneration of photoreceptor cells and resulting in progressive vision loss. Approximately 100,000 adults in the U.S. have RP. RP is currently treated by antioxidants such as vitamin A palmitate, which have been shown to slightly slow the progression of the disease.

### *Non-Ophthalmic Disorders*

*Post-Surgical Pain Management.* CDS is conducting Phase I clinical trials for an injectable, biodegradable product for post-surgical pain based on its CODRUG system. Post-surgical pain is caused by the trauma inflicted on the body by surgical intervention. Doctors treat post-surgical pain with a variety of drugs, including narcotics and local anesthetics. Narcotics are typically delivered systemically, either orally or intravenously, and are often used to treat pain that affects large areas of the body. Narcotics are associated with a variety of side effects including dizziness, decreased mental and physical capability, excessive sleepiness and sedation, nausea, and potential dependency. Local anesthetics work for a short period of time directly at the incision or surgical site to dull feeling without causing sleepiness or loss of sensation in other body parts. Local anesthetics are commonly delivered by injection and have fewer side effects than narcotics. Local anesthetics also may be delivered following surgery through an external pump that delivers the drug to the surgical site through a catheter. Other than through use of the external pump, which is expensive and poses a risk of serious infection, local anesthetics cannot be delivered locally by patients at home, leading patients to rely on systemic narcotics.

*Psoriasis and Actinic Keratosis.* CDS is studying another CODRUG product candidate for the treatment of two chronic skin disorders, psoriasis and actinic keratosis, and successfully completed a Phase I trial of this product candidate in the UK involving 20 patients in 2004. Psoriasis is an autoimmune skin disorder in which the growth cycle of skin cells speeds up from approximately one month to three or four days, causing inflamed lesions. In more cases, lesions can cover a significant portion of the body, including the face, hands, and feet. Psoriasis has no cure. The National Psoriasis Foundation estimates that more than 4.5 million adults in the United States have psoriasis. Treatments include topical treatment of the skin with corticosteroids, phototherapy, or light (including sunlight) and oral or intravenous medications designed to suppress the immune system.

AK is a common skin condition characterized by scaly or crusty bumps on the skin surface that are horn-like, dry and rough and range in size from one-quarter to one-inch in diameter. AK lesions are pre-cancerous, with up to 10% of active lesions progressing to squamous cell carcinomas. AK affects approximately 10 million people in the United States and AK lesions are the most common premalignant lesions in the United States. AK can be treated through surgical removal, electrical cautery, cryosurgery, chemical peels and topical medications if caught in an early stage but, if neglected, may metastasize and spread to internal organs.

## [Table of Contents](#)

A problem in the treatment of both psoriasis and AK has been effecting the penetration of drugs through the outer skin layers. The impermeability of many drugs used to treat these conditions can necessitate systemic delivery, despite the drawbacks of the associated side effects.

### STRATEGIC COLLABORATIONS

CDS has entered into three collaboration agreements to develop and commercialize its initial products and product candidates, Vitrasert, Retisert and Medidur. In all of these agreements, CDS retains its rights to the underlying technologies.

#### *Chiron Vision Corporation*

CDS' first collaboration was with Chiron Vision Corporation, a subsidiary of Chiron Corporation. Under a 1992 licensing and development agreement, Chiron Vision financed the development of Vitrasert, and CDS granted Chiron Vision a worldwide, exclusive license to make and sell products based on the AEON technology used in Vitrasert for the treatment of conditions of the eye. Chiron Vision commenced commercial sales of Vitrasert following FDA approval in 1996. Bausch & Lomb acquired Chiron Vision in 1997, assumed this agreement and currently markets and sells Vitrasert. Bausch & Lomb pays CDS royalties on net sales of Vitrasert under its current agreement, described further below.

#### *Bausch & Lomb Incorporated*

In 1999, CDS entered into a licensing and development agreement with Bausch & Lomb for additional products for the treatment of eye diseases. CDS granted Bausch & Lomb a worldwide, exclusive license for the life of the relevant patents to use its technologies for the treatment, prevention or diagnosis of any disease, disorder or condition of the eye in humans or in animals.

In December 2003, the two companies entered into an amended and restated license agreement that significantly revised the 1992 and 1999 agreements. Under this new agreement, CDS granted Bausch & Lomb a worldwide, exclusive license to certain of CDS technologies to make and sell Vitrasert and CDS' first generation products, as defined in the agreement, including the Retisert device, for the treatment, prevention and diagnosis of any disease, disorder or condition of the human eye. Bausch & Lomb agreed to pay CDS royalties based on net sales for any products that meet the definition of first generation products.

CDS also granted Bausch & Lomb a non-exclusive license to these technologies to make and sell certain other products for the delivery of specified active ingredients, using specified delivery systems, methods of delivery and anchoring methods, to be used in specified locations for specified indications. If Bausch & Lomb does not commence an Investigational New Drug, or IND, a status granted by the FDA to investigational drugs approved for administration to humans, for any such product by December 9, 2005, CDS may terminate the non-exclusive license for such product (unless this breach is cured within 90 days of receipt of notice). To CDS' knowledge, Bausch & Lomb has not to date commenced an IND for any such product. If Bausch & Lomb does market such products, it will pay CDS a royalty based on net sales of the products.

Bausch & Lomb is responsible for funding and managing the development and commercialization of all products under the agreement. Bausch & Lomb also agreed to pay CDS specified amounts if it achieved certain milestones related to certain licensed products.

CDS agreed not to develop, commercialize or license to a third party rights to develop or commercialize any product to treat posterior uveitis so long as (1) Bausch & Lomb is actively pursuing the commercialization of a product to treat uveitis for which Bausch & Lomb would be required to pay CDS a specified level of royalty, and (2) Bausch & Lomb is not selling any other uveitis product for which it would not be required to pay CDS a specified level of royalty. CDS also may not develop, commercialize or license any product that meets the definition of first generation product as long as Bausch & Lomb has an exclusive license to such products using CDS technologies.

## Table of Contents

Bausch & Lomb may terminate this agreement, in its entirety or with respect to Vitrasert or any non-exclusively licensed product, at any time on 90 days' written notice. In the event Bausch & Lomb terminates the agreement in its entirety, Bausch & Lomb's license to the CDS technologies will terminate. In the event Bausch & Lomb terminates the agreement with respect to Vitrasert or a non-exclusively licensed product, Bausch & Lomb will lose the right to rely upon CDS' intellectual property to make and sell the relevant product.

### *Alimera Sciences Inc.*

In February 2005, CDS granted Alimera Sciences a world-wide exclusive right to use certain CDS technologies to make and sell, for the treatment and prevention of eye diseases (except uveitis) in humans products that have a drug core within a polymer layer and are approved or designed to be approved to deliver only specified compounds by a direct delivery method to the posterior portion of the eye. In addition, CDS granted to Alimera Sciences a world-wide exclusive right to use certain CDS technologies to treat DME by delivering a compound or formulation by a direct delivery method other than through specified incisions, and which are not exclusively licensed to Bausch & Lomb.

A joint development team of both parties is responsible for monitoring the execution of activities under the development plan for licensed products. CDS and Alimera Sciences each pays codevelopment costs that are incurred included in the development budget. The agreement provided for Alimera Sciences to pay a licensing fee and milestone payment to CDS. Alimera Sciences has sole responsibility for making commercially reasonable efforts to commercialize products licensed under the agreement and for paying all costs and expenses incurred in connection with such commercialization. After a product becomes profitable in a country, Alimera Sciences and CDS share the net profits for that product in that country, subject to Alimera Sciences' pre-profitability net losses for that product. If either party fails to pay the other party its share of development costs, the unpaid amount plus a delay charge is recouped from net profits and in the case of CDS milestone payments.

Improvements and other inventions developed during the term in whole or in part by Alimera Sciences that are covered by or derived from the practice of the licensed CDS technologies are jointly owned by Alimera Sciences and CDS, except for improvements specifically related to active ingredients provided by Alimera Sciences, which are owned by Alimera Sciences. Each party is free to use and sublicense such improvements, except that Alimera Sciences shall not have the right to use such improvements in connection with ophthalmic drug delivery devices (or related methods or processes) that include a drug core.

Either party may terminate the agreement for the other party's failure to make a development payment. Either party may terminate the agreement with respect to a particular product if the other party gives written notice of its intent to abandon the product. The agreement provides for specific, exclusive remedies in the event of termination resulting from the occurrence of one of the above events.

### **SALES AND MARKETING**

Bausch & Lomb currently markets and sells both Vitrasert and Retisert and has rights to market and sell any other products licensed to Bausch & Lomb. Alimera Sciences has the rights to market and sell Medidur for DME if approved and any other products developed under its license agreement with CDS. In the future, CDS may independently commercialize and sell some of its other products. In appropriate cases, CDS may also enter into joint marketing or license arrangements for other products.

### **REIMBURSEMENT**

The successful commercialization of CDS' products will depend in significant part on the extent to which reimbursement of the cost of the products and the related implantation or injection procedures will be available from government health administration authorities, private health insurers, and other organizations. Medicaid and Medicare, most major health maintenance organizations, and most health insurance carriers reimburse \$4,240 for the cost of the Vitrasert implant, with additional reimbursement for

## [Table of Contents](#)

associated surgical fees. The Centers for Medicare and Medicaid Services recently designated Retisert as eligible for Medicare reimbursement at the rate of \$19,345, with associated surgical fees to be reimbursed separately.

### **PATENTS, LICENSES AND INTELLECTUAL PROPERTY**

#### *Intellectual Property Strategy*

CDS' commercial success will depend, in part, on its ability to obtain patent protection in the United States and elsewhere for its products or its processes. CDS therefore seeks, whenever possible, to obtain protection for these products and processes. CDS also seeks to expand our product and process portfolio through collaborations, funded research and licensing technology from others.

#### *Patents and Patent Applications*

CDS has filed and continues to file patent applications with respect to multiple aspects of its technologies, products, and processes. As of the date of this information statement CDS has, or has exclusive rights to, 12 United States patents and 26 foreign patents. In addition, as of the date of this information statement, CDS has, or has exclusive rights to, 40 patent applications pending in the United States and 163 patent applications pending in foreign countries. CDS' patents expire at various dates starting in 2012.

Of the above-referenced issued patents, the University of Kentucky Research Foundation holds 6 United States patents and 12 related foreign patents on aspects of CDS' technologies. CDS has exclusive licenses for these patents and related know-how and is obligated to pay the University of Kentucky Research Foundation royalties based on sublicensing of these patents and sales of products utilizing these patents.

#### *Other Proprietary Rights*

Some elements of CDS' products, processes, and methods of manufacturing involve unpatented proprietary technology, processes, know-how, or data. With respect to proprietary technology, know-how, and data that are not patentable or potentially patentable or processes other than production processes for which patents are difficult to enforce, CDS has chosen or may choose to protect its interests by relying on trade secret protection and confidentiality agreements with its employees, consultants and contractors. To maintain the confidentiality of trade secrets and proprietary information, CDS maintains a policy of requiring employees, scientific advisors, consultants and collaborators to execute confidentiality and invention assignment agreements upon commencement of a relationship. These agreements are designed both to enable CDS to protect its proprietary information by controlling the disclosure and use of technology to which CDS has rights, and to provide for its ownership of proprietary technology that CDS develops.

### **COMPETITION**

The pharmaceutical and drug delivery industries are highly competitive. Vitrasert primarily competes with treatments involving the systemic delivery of ganciclovir, a Roche Holdings AG product, and other drugs. Retisert is the only FDA approved treatment for posterior uveitis, though steroids and other existing drugs approved for other uses are commonly administered systemically or by local injection to treat this condition in off-label use. In addition, CDS expects that its proposed products, if approved, will compete with existing therapies for CDS' targeted diseases as well as new drugs, therapies, drug delivery systems or technological approaches that may be developed to treat these diseases or their underlying causes.

CDS expects that its products and product candidates, if approved, will compete with existing therapies for its targeted diseases, as well as new drugs, therapies, drug delivery systems, or technological approaches that may be developed and approved to treat these diseases or their underlying causes as well as off-label use of products approved to treat other diseases. CDS believes that pharmaceutical, drug

delivery, and biotechnology companies, research organizations, governmental entities, universities, hospitals, other nonprofit organizations, and individual scientists are seeking to develop therapies for CDS' targeted diseases. For many of its targeted diseases, competitors have alternate therapies that are already commercialized or are in various stages of development ranging from discovery to advanced clinical trials. Most of the entities with whom CDS will or may compete are much larger, have much greater financial resources and have much more experience in drug development and sale than CDS.

Many companies are pursuing products to treat back of the eye diseases. These include the following:

- Eli Lilly and Company is in advanced clinical trials for its protein kinase C beta inhibitor for the treatment of diabetic retinopathy.
- Genentech, Inc. has developed an FDA approved cancer drug, Avastin, which may be used as an off-label treatment for DME.
- Novartis Ophthalmics AG markets cyclosporine, which is used for the systemic treatment of uveitis.
- Allergan, Inc. is in Phase III clinical trials of its product, Posurdex® for the treatment of persistent macular edema. If approved by the FDA, this product may be used off-label for the treatment of DME or edema associated with diabetes. In addition, Allergan and EntreMed, Inc. are collaborating on a program to develop a treatment for AMD that is at the pre-clinical development stage.
- Eyetech Pharmaceuticals, Inc., which recently entered into an agreement to be acquired by OSI Pharmaceuticals, Inc., has an intraocular injectable product, Macugen, approved to treat wet AMD and had commenced pivotal clinical trial for the use of Macugen in the treatment of DME. In addition, Eyetech entered into a collaboration with Pfizer, Inc. to co-promote Macugen.
- SurModics Inc. has initiated a Phase I clinical trial of a helical coil coated with drug releasing polymer which is implanted in the back of the eye to treat DME.
- Neurotech SA has completed Phase I clinical trials of its NT-501, a cell-based implant that releases ciliary neurotrophic factor for the treatment of RP.

If CDS successfully develops a product for post-surgical pain, it will compete against numerous options available for the management of post-surgical pain, including narcotic and non-narcotic anesthetics delivered orally, by catheter, or by pump. Products in development in the United States include Pfizer's injectable cyclooxygenase-2 inhibitor parecoxib, SkyePharma's sustained-release injectable DepoBupivacaine anesthetic, AP Pharma, Inc.'s APF112, a long acting anesthetic in Phase I trials, and Omeros Medical Systems, Inc.'s OMS-103HP, a product in Phase II clinical trials for the management of pain following orthopedic surgery, Durect Corporation's product in Phase III clinical trials designed to treat post-surgical pain through the sustained release of a local anesthetic, and a number of products in clinical trials designed to evaluate the sustained release of bupivacaine, a local anesthetic.

If CDS successfully develops a product for psoriasis, it is likely to compete against various products that are currently marketed or in the final stages of evaluation for the treatment of psoriasis. Topical agents include Allergan's Tazorac® cream and gel and Bristol-Myers Squibb Co.'s Dovonex® cream and ointment. Allergan also is developing an oral formulation of its Tazorac product, which is in Phase III trials. Oral agents also include Roche's Soriatane® product. The first of a class of biologic agents for more severe forms of the disease has recently been approved for U.S. marketing by Biogen, Inc. Others are currently in late-stage clinical trials, including the Enbrel® (Amgen, Inc.) and Raptiva™ (Genentech, Inc. and Xoma, Inc.) injectable products. If CDS successfully develops a product for AK, it will compete against a variety of AK treatment options currently available, including 5-fluorouracil cream, surgical removal, electrical cauterization, cryosurgery and chemical peels.



## Legal Proceedings

A potential lender to CDS has claimed a break-up fee as a result of the royalty advance agreement between CDS and Bausch & Lomb. An investment banker has claimed an advisory fee in connection with that agreement as well as the merger. CDS intends to defend against these claims.

## GOVERNMENT REGULATION

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our drug delivery products. The process required by the FDA under the new drug provisions of the Federal Food, Drug, and Cosmetic Act before our products may be marketed in the United States generally involves the following:

- pre-clinical laboratory and animal tests,
- submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical trials may begin in the United States,
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed pharmaceutical in CDS' intended use,
- submission to the FDA of a new drug application, and
- FDA review and approval of the new drug application.

The testing and approval process requires substantial time, effort, and financial resources, and CDS cannot be certain that any approval will be granted on a timely basis, if at all.

Pre-clinical tests include laboratory evaluation of the product, its chemistry, formulation and stability, as well as animal studies to assess the potential safety and efficacy of the product. The results of the pre-clinical tests, together with manufacturing information, analytical data and protocols for proposed human clinical trials, are submitted to the FDA as part of an IND, which must become effective before CDS may begin human clinical trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the proposed clinical trials as outlined in the IND and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. There is no certainty that pre-clinical trials will result in the submission of an IND or that submission of an IND will result in FDA authorization to commence clinical trials.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of a qualified principal investigator. Clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor safety and any efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Further, each clinical study must be conducted under the auspices of an independent institutional review board at the institution where the study will be conducted. The institutional review board will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution. Some clinical trials, called "investigator-sponsored" clinical trials, are conducted by third-party investigators. The results of these trials may be used as supporting data by a company in its application for FDA approval, provided that the company has contractual rights to use the results.

Human clinical trials are typically conducted in three sequential phases which may overlap:

- PHASE I: The drug is initially introduced into healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.

## Table of Contents

- PHASE II: Studies are conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- PHASE III: Phase III trials are undertaken to further evaluate clinical efficacy and to further test for safety in an expanded patient population, often at geographically dispersed clinical study sites.

In the case of products for life-threatening diseases such as cancer, or severe conditions such as blinding eye disease, the initial human testing is often conducted in patients with the disease rather than in healthy volunteers. Since these patients already have the targeted disease or condition, these studies may provide initial evidence of efficacy traditionally obtained in Phase II trials and so these trials are frequently referred to as Phase I/II trials. If a product uses a combination of drugs, the FDA requires that clinical trials demonstrate that the combination is safe and effective and that each drug contributes to efficacy. CDS cannot be certain that it will successfully complete Phase I, Phase II or Phase III testing of CDS' product candidates within any specific time period, if at all. Furthermore, CDS, the FDA, the institutional review board or the sponsor, if any, may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The results of product development, pre-clinical studies and clinical studies are submitted to the FDA as part of a new drug application, or NDA, for approval of the marketing and commercial shipment of the product. The FDA may deny an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data. Even if the additional data are submitted, the FDA may ultimately decide that the new drug application does not satisfy the criteria for approval. As a condition of approval, the FDA may require post-marketing "Phase IV" clinical trials to confirm that the drug is safe and effective for its intended uses. Once issued, the FDA may withdraw product approval if compliance with regulatory standards for production and distribution is not maintained or if safety problems occur after the product reaches the market. The FDA requires surveillance programs to monitor approved products which have been commercialized, and the agency has the power to require changes in labeling or to prevent further marketing of a product based on the results of these post-marketing programs.

If a drug is intended for the treatment of a serious or life-threatening condition and has the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA "fast track" designation. The fast track designation applies only for the specific indications for which the product satisfies these two requirements. Under fast track provisions, the FDA is committed to working with the sponsor for the purpose of expediting the clinical development and evaluation of the drug's safety and efficacy for the fast track indication.

Marketing applications filed by sponsors of products in fast track development often will qualify for expedited review under policies or procedures offered by the FDA, but fast track designation does not assure this qualification.

If a drug treats a disease or condition that affects fewer than 200,000 people in the United States, the drug sponsor may apply to the FDA for "orphan drug" designation under the Orphan Drug Act. More than one drug may be given an orphan drug designation by the FDA for a given disease or condition, but the first drug with an orphan drug designation to receive marketing approval for the treatment of that disease or condition is granted a period of marketing exclusivity. Sponsors are granted seven years of exclusive rights to market the first approved orphan drug for treatment of that disease or condition, independent of any additional patent protection that may apply to the product. This marketing exclusivity does not prevent a competitor from obtaining approval to market a different drug that treats the same disease or condition or the same drug to treat a different disease or condition. Sponsors also are granted tax incentives for clinical research undertaken to support an application for an orphan drug, and grants to defray some of these clinical costs may also be available. In addition, the FDA will typically coordinate with the sponsor on research study design for an orphan drug and may exercise its discretion to grant marketing approval on the basis of more limited product safety and efficacy data than would ordinarily be required. If the FDA withdraws a product's orphan drug designation, however, these various benefits no longer apply.

## Table of Contents

Satisfaction of FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years, and the actual time required may vary substantially based upon factors including the type, complexity and novelty of the pharmaceutical product. Such government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon CDS' activities. Success in pre-clinical or early stage clinical trials does not assure success in later stage clinical trials. Data from pre-clinical and clinical activities is not always conclusive and may be susceptible to varying interpretations which could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be subject to significant limitations. Further, even after the FDA approves a product, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

Any products CDS manufactures or distributes under FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the products. Drug manufacturers and their subcontractors are required to register with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and state agencies for compliance with good manufacturing practices, which impose procedural and documentation requirements upon CDS and CDS' third-party manufacturers.

CDS is also subject to numerous other federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. CDS may incur significant costs to comply with such laws and regulations now or in the future. In addition, CDS cannot predict what adverse governmental regulations may arise from future United States or foreign governmental action.

CDS also is subject to foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products which CDS sells outside the U.S. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. Whether or not CDS obtains FDA approval, it must obtain approval of a product by the comparable regulatory authorities of foreign countries before manufacturing or marketing the product in those countries. The approval process varies from country to country, and the time required for these approvals may differ substantially from that required for FDA approval. There is no assurance that clinical trials conducted in one country will be accepted by other countries or that approval in one country will result in approval in any other country. For clinical trials conducted outside the United States, the clinical stages generally are comparable to the phases of clinical development established by the FDA.

### **EMPLOYEES**

As of November 30, 2005, CDS had 12 full-time employees. Of these employees, 8 hold Ph.D. or other advanced degrees. None of CDS' employees is represented by a collective bargaining unit, and CDS has never experienced a work stoppage. CDS considers its relations with its employees to be good.

### **FACILITIES**

CDS' headquarters are in Watertown, Massachusetts, located approximately eight miles from downtown Boston. CDS leases 13,411 square feet of laboratory and office space pursuant to a lease that expires in October 2006. Annual rent under the lease is \$304,000. CDS has the right to extend, and the landlord has a separate right to require CDS to extend, this lease for an additional 18 months at the rate of \$25,704 per month.

## [Table of Contents](#)

### PRINCIPAL STOCKHOLDERS OF CDS

The following table sets forth information regarding the beneficial ownership of CDS' common stock and Series A preferred stock as of November 30, 2005 by the following persons:

- each stockholder known by CDS to be the beneficial owner of more than 5% of CDS' common stock or CDS' Series A preferred stock,
- each director of CDS,
- each executive officer of CDS, and
- all directors and executive officers of CDS as a group.

The percentage of common stock beneficially owned by each person is based on 3,189,691 shares of CDS' common stock outstanding as of November 30, 2005 on an as-converted basis, which includes 795,844 shares of common stock issuable upon conversion of Series A preferred stock outstanding on that date. The percentage of Series A preferred stock beneficially owned by each person is based on 641,642 shares of CDS' Series A preferred stock outstanding as of November 30, 2005.

CDS has determined beneficial ownership in the table in accordance with the rules of the Securities and Exchange Commission. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, CDS has deemed shares of common stock subject to options held by that person that are currently exercisable or will become exercisable within 60 days of November 30, 2005 to be outstanding, but CDS has not deemed these shares to be outstanding for computing the percentage ownership of any other person. To CDS' knowledge, except as set forth in the footnotes below, each stockholder identified in the table possesses sole voting and investment power with respect to all shares of common stock shown as beneficially owned by that stockholder.

Unless otherwise noted, the address for each person listed in the chart below is c/o Control Delivery Systems, Inc., 400 Pleasant Street, Watertown, MA 02472.

	Common Stock		Series A Preferred Stock	
	Number of Shares Beneficially Owned	Percentage of Class	Number of Shares Beneficially Owned	Percentage of Class
Bausch & Lomb Incorporated(1)	600,000	18.8%	—	—
Paul Ashton(2)(3)	547,280	17.0%	—	—
Thomas J. Smith(4)	515,600	16.2%	—	—
Essex Woodlands Health Ventures(5)	230,801	7.2%	186,081	29.0%
James L. Currie(6)	230,801	7.2%	186,081	29.0%
T. Rowe Price(7)	138,480	4.3%	111,648	17.4%
Morgan Stanley Dean Witter(8)	115,401	3.6%	93,040	14.5%
Brookside Capital Partners Fund L.P.(9)	92,320	2.9%	74,432	11.6%
Essex Private Placement Funds(10)	69,242	2.2%	55,825	8.7%
SMALLCAP World Fund Inc.(11)	69,240	2.2%	55,824	8.7%
Anvil Investment Associates L.P.(12)	57,700	1.8%	46,520	7.2%
Michael J. Soja	80,040	2.5%	—	—
Lori H. Freedman	71,700	2.3%	—	—
Stephen C. McCluski(13)	600,000	18.8%	—	—
Alan L. Crane(2)(14)	24,700	*	—	—
William S. Karol(2)(15)	9,200	*	—	—

[Table of Contents](#)

	Common Stock		Series A Preferred Stock	
	Number of Shares Beneficially Owned	Percentage of Class	Number of Shares Beneficially Owned	Percentage of Class
Douglas R. Potter(2)(16)	8,100	*	—	—
Joyce Erony (17)	5,000	*	—	—
All directors and officers as a group (9 persons)(18)	1,576,821	48.8%	186,081	29.0%

\* Less than 1% of the outstanding shares of common stock.

- (1) The address for Bausch & Lomb Incorporated is One Bausch & Lomb Place, Rochester, NY 14604.
- (2) Number of shares of common stock includes shares issuable upon the exercise of options that are exercisable or will become exercisable within 60 days of October 31, 2005 for the following individuals: Dr. Ashton (25,000 shares), Mr. Crane (12,200 shares), Mr. Karol (4,200 shares) and Mr. Potter (3,100 shares).
- (3) Number of shares of common stock includes 19,055 shares held by the Paul Ashton Children's Irrevocable Trust as to which Dr. Ashton disclaims beneficial ownership.
- (4) Number of shares of common stock includes 93,555 shares held by the Thomas J. and Ellen Doble-Smith Family Irrevocable Trust, 4,200 shares held by the Thomas J. and Ellen Doble-Smith Trusts for Minors and 417,845 shares held by St. James Associates LLC, of which Dr. Smith serves as managing member. The address for Dr. Smith is Auritec Pharmaceuticals, 2275 E Foothill Blvd, Pasadena CA 91107.
- (5) Number of shares of Series A preferred stock includes 148,865 shares held by Essex Woodlands Health Ventures Fund V, LP and 37,216 shares held by Essex Woodlands Health Ventures Fund IV, LP. The address for Essex Woodlands Health Ventures is 190 South LaSalle Street, Suite 2800, Chicago, IL 60603.
- (6) Number of shares of Series A preferred stock includes 186,081 shares held by entities affiliated with Essex Woodlands Health Ventures, with which Mr. Currie is affiliated. Mr. Currie disclaims beneficial ownership of those shares except to the extent of his pecuniary interest therein. The address for Mr. Currie is Essex Woodlands Health Ventures, 190 South LaSalle Street, Suite 2800, Chicago, IL 60603.
- (7) The address for T. Rowe Price is 100 East Pratt Street, 9th Floor, Baltimore, MD 21202.
- (8) Number of shares of Series A preferred stock includes 44,659 shares held by Morgan Stanley Dean Witter Equity Funding, Inc., 4,626 shares held by Morgan Stanley Dean Witter Venture Investors IV,-L.P., 1,555 shares held by Morgan Stanley Dean Witter Venture Offshore Investors IV, L.P., 39,874 shares held by Morgan Stanley Dean Witter Venture Partners IV, L.P. and 2,326 shares held by Originators Investment Plan, L.P. The address for Morgan Stanley Dean Witter is 1585 Broadway, New York, NY 10036.
- (9) The address for Brookside Capital Partners Fund L.P. is 1111 Huntington Avenue, Boston, MA 02199.
- (10) Number of shares of Series A preferred stock includes 11,882 shares held by Essex Private Placement Fund III-A, L.P. and 43,943 shares held by Essex Private Placement Fund III-B, L.P. The address for Essex Private Placement Fund is 125 High Street, Boston, MA 02108.
- (11) The address for SMALLCAP World Fund, Inc. is c/o Capital Research and Management Company, 1 Market Street, Stuart Tower, Suite 1800, San Francisco, CA 94105.
- (12) The address for Anvil Investment Associates L.P. is c/o Ashford Capital Management, Inc., 3801 Kennett Pike, Suite B107, Wilmington, DE 19807.
- (13) Number of shares of common stock includes 600,000 shares held by Bausch & Lomb Incorporated, of which Mr. McCluski is an executive officer. Mr. McCluski disclaims beneficial ownership of these

## Table of Contents

shares. The address for Mr. McCluski is Bausch & Lomb Incorporated, One Bausch & Lomb Place, Rochester, NY 14604.

- (14) Number of shares of common stock includes 2,400 shares held by three family members of Mr. Crane. The address for Mr. Crane is Momenta Pharmaceuticals, Inc., 675 West Kendall St., Cambridge, MA 02142.
- (15) The address for Mr. Karol is KODA Enterprises Group, LLC, 800 South Street, Suite 355, Waltham, MA 02453.
- (16) The address for Mr. Potter is P.O. Box 511, North Woodstock, NH 03262.
- (17) The address for Ms. Erony is 99 Oliphant Avenue, Dobbs Ferry, NY 10522.
- (18) Number of shares of common stock includes 44,500 shares in the aggregate issuable upon the exercise of options that are exercisable or will become exercisable within 60 days of October 31, 2005.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

	<u>Page</u>
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Statements of Financial Position	F-3
Consolidated Statements of Financial Performance	F-4
Consolidated Statements of Cash Flows	F-5
Consolidated Statements of Changes in Stockholders' Equity	F-6
Notes to Consolidated Financial Statements	F-7

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

**To The Board of Directors and Shareholders of pSivida Limited**

We have audited the accompanying consolidated statements of financial position of pSivida Limited and subsidiaries (a development stage company) (the "Company") as at June 30, 2005 and 2004 and the related consolidated statements of financial performance, cash flows and changes in stockholders' equity for each of the three years in the period ended June 30, 2005, and for the period from December 1, 2000 (date of inception of development stage) to June 30, 2005. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of pSivida Limited and subsidiaries as at June 30, 2005 and 2004, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2005, and for the period from December 1, 2000 (date of inception of development stage) to June 30, 2005, in conformity with accounting principles generally accepted in Australia.

Accounting principles generally accepted in Australia vary in certain significant respects from accounting principles generally accepted in the United States of America ("US GAAP"). Information relating to the nature and effect of such differences is presented in Note 27 to the consolidated financial statements. As discussed in Note 27, the Company has restated its reconciliation of total equity to US GAAP as of June 30, 2004, its opening total equity under US GAAP as of July 1, 2003 and its reconciliation of net loss to US GAAP for the years ended June 30, 2004 and 2003 for certain errors related to deferred income taxes.

DELOITTE TOUCHE TOHMATSU  
Chartered Accountants

Perth, Australia  
December 14, 2005



**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**  
**CONSOLIDATED STATEMENTS OF FINANCIAL POSITION**  
**(In Australian Dollars)**

		As at 30 June	
	Notes	2005 \$	2004 \$
<b>Current Assets</b>			
Cash assets	17(a)	12,892,061	31,350,656
Receivables	6	709,418	340,482
Other	7	322,933	38,958
<b>Total Current Assets</b>		<b>13,924,412</b>	<b>31,730,096</b>
<b>Non-Current Assets</b>			
Property, plant and equipment, net	8	3,273,663	669,699
Intangible assets	9	55,927,494	7,934,622
Goodwill, net	9	8,909,744	—
Other, net	7	—	32,641
<b>Total Non-Current Assets</b>		<b>68,110,901</b>	<b>8,636,962</b>
<b>Total Assets</b>		<b>82,035,313</b>	<b>40,367,058</b>
<b>Current Liabilities</b>			
Payables	10	1,967,718	1,844,960
Payables, related party	10, 21(f)	50,102	37,144
Provisions	11	29,879	56,011
<b>Total Current Liabilities</b>		<b>2,047,699</b>	<b>1,938,115</b>
<b>Total Liabilities</b>		<b>2,047,699</b>	<b>1,938,115</b>
<b>Net Assets</b>		<b>79,987,614</b>	<b>38,428,943</b>
<b>Equity</b>			
Parent entity interest			
Contributed equity	12(a)	107,883,835	49,957,982
Reserves	13	20,761	78,220
Deficit accumulated prior to development stage	14	(3,813,181)	(3,813,181)
Deficit accumulated during development stage	14	(24,103,801)	(9,377,278)
Total parent entity interest		79,987,614	36,845,743
Total outside equity interest	15	—	1,583,200
<b>Total Equity</b>		<b>79,987,614</b>	<b>38,428,943</b>

The consolidated statements of financial position should be read in conjunction with the accompanying notes.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**  
**CONSOLIDATED STATEMENTS OF FINANCIAL PERFORMANCE**  
**(In Australian Dollars)**

	Notes	Years Ended 30 June			Period from Inception of Development Stage (1 Dec 2000) to 30 June 2005
		2005 \$	2004 \$	2003 \$	2005 \$
Revenues from ordinary activities	3	828,976	381,679	110,675	2,351,075
Depreciation and amortization expense		(1,029,382)	(39,360)	(37,835)	(1,156,849)
Research and development expense	4	(8,287,930)	(7,011,666)	(4,586,182)	(23,243,409)
Interest expense		—	(5,635)	—	(5,635)
Employee benefits expense		(1,040,007)	(1,238,381)	(522,977)	(3,281,475)
Foreign currency (loss)/ gain, net		(1,623,484)	1,461,368	(1,203)	(163,111)
Corporate office expenses		(3,973,892)	(1,066,981)	(318,806)	(7,350,373)
<b>Loss from ordinary activities before income tax</b>		(15,125,719)	(7,518,976)	(5,356,328)	(32,849,777)
Income tax expense relating to ordinary activities	5	—	—	—	—
<b>Net loss before outside equity interest</b>		(15,125,719)	(7,518,976)	(5,356,328)	(32,849,777)
Net loss attributable to outside equity interest	15	399,196	3,835,771	2,591,175	8,745,976
<b>Net loss attributable to members of the parent entity</b>		(14,726,523)	(3,683,205)	(2,765,153)	(24,103,801)
(Decrease)/increase in foreign currency translation reserve arising on translation of self-sustaining foreign operations		(350,287)	77,985	(31,765)	(301,367)
Total revenue, expense and valuation adjustments attributable to members of the parent entity recognized directly in equity		(350,287)	77,985	(31,765)	(301,367)
Total changes in equity other than those resulting from transactions with owners as owners		(15,076,810)	(3,605,220)	(2,796,918)	(24,405,168)
Loss per share (basic and diluted)	20	(0.07)	(0.03)	(0.03)	(N/A)

The consolidated statements of financial performance should be read in conjunction with the accompanying notes.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(In Australian Dollars)**

	Notes	Years Ended 30 June			Period from Inception of Development Stage (1 Dec 2000) to 30 June 2005
		2005 \$	2004 \$	2003 \$	
<b>Cash flows from operating activities</b>					
Payments to suppliers and employees		(4,815,520)	(2,044,430)	(787,216)	(8,002,194)
Interest received		667,310	326,576	110,675	1,357,745
Interest paid		—	(6,782)	—	(6,782)
Research and development expenditure		(8,318,054)	(6,124,304)	(3,878,326)	(21,126,373)
Income tax paid		—	—	—	—
Other receipts		161,666	27,474	—	191,269
Net cash used in operating activities	17(b)	<u>(12,304,598)</u>	<u>(7,821,466)</u>	<u>(4,554,867)</u>	<u>(27,586,335)</u>
<b>Cash flows from investing activities</b>					
Purchase of property, plant and equipment		(3,410,218)	(527,168)	(52,956)	(4,837,357)
Proceeds from sale of property, plant and equipment		—	—	—	702,554
Cash paid for equity increase in controlled entities		(4,644,964)	—	(622,656)	(7,068,020)
Net cash held by subsidiaries on acquisition		—	—	623,664	3,152,962
Net cash used in investing activities		<u>(8,055,182)</u>	<u>(527,168)</u>	<u>(51,948)</u>	<u>(8,049,861)</u>
<b>Cash flows from financing activities</b>					
Proceeds from issue of ordinary shares		3,666,500	36,506,617	900,000	46,542,787
Payment of share issue costs		(27,422)	(2,150,819)	(47,433)	(2,381,469)
Equity contributions from outside equity interest		—	2,597,649	—	5,508,030
Net cash provided by financing activities		<u>3,639,078</u>	<u>36,953,447</u>	<u>852,567</u>	<u>49,669,348</u>
<b>Net (decrease)/ increase in cash held</b>		<u>(16,720,702)</u>	<u>28,604,813</u>	<u>(3,754,248)</u>	<u>14,033,152</u>
<b>Cash at the beginning of the financial period</b>					
		31,350,656	1,180,134	5,051,509	597,000
Effect of exchange rate changes on the balance of cash held in foreign currencies		<u>(1,737,893)</u>	<u>1,565,709</u>	<u>(117,127)</u>	<u>(1,738,091)</u>
<b>Cash at the end of the financial period</b>	17(a)	<u><u>12,892,061</u></u>	<u><u>31,350,656</u></u>	<u><u>1,180,134</u></u>	<u><u>12,892,061</u></u>

The consolidated statements of cash flows should be read in conjunction with the accompanying notes.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**  
**(In Australian Dollars except number of shares)**

	Number of Shares	Contributed Equity \$	Deficit Accumulated Prior to Development Stage \$	Deficit Accumulated During Development Stage \$	Reserves \$	Total \$
Balance at inception of development stage (1 December 2000)	62,329,947	6,060,181	(3,813,181)	—	—	2,247,000
Shares issued, net of issue costs	20,218,535	6,047,668	—	—	—	6,047,668
Net loss	—	—	—	(738,501)	—	(738,501)
Foreign currency translation adjustment	—	—	—	—	29,300	29,300
Balance, 30 June 2001	82,548,482	12,107,849	(3,813,181)	(738,501)	29,300	7,585,467
Shares issued, net of issue costs	13,298,500	2,541,767	—	—	—	2,541,767
Net loss	—	—	—	(2,190,419)	—	(2,190,419)
Foreign currency translation adjustment	—	—	—	—	2,700	2,700
Balance, 30 June 2002	95,846,982	14,649,616	(3,813,181)	(2,928,920)	32,000	7,939,515
Shares issued, net of issue costs	8,069,231	952,568	—	—	—	952,568
Net loss	—	—	—	(2,765,153)	—	(2,765,153)
Foreign currency translation adjustment	—	—	—	—	(31,765)	(31,765)
Balance, 30 June 2003	103,916,213	15,602,184	(3,813,181)	(5,694,073)	235	6,095,165
Shares issued, net of issue costs	50,021,572	34,355,798	—	—	—	34,355,798
Net loss	—	—	—	(3,683,205)	—	(3,683,205)
Foreign currency translation adjustment	—	—	—	—	77,985	77,985
Balance, 30 June 2004	153,937,785	49,957,982	(3,813,181)	(9,377,278)	78,220	36,845,743
Shares issued for cash, net of issue costs	15,570,000	3,666,500	—	—	—	3,666,500
Shares issued as consideration for acquisition, net of issue costs	49,804,381	54,259,353	—	—	—	54,259,353
Net loss	—	—	—	(14,726,523)	—	(14,726,523)
Foreign currency translation adjustment	—	—	—	—	(350,287)	(350,287)
Option premium reserve adjustment	—	—	—	—	292,828	292,828
Balance, 30 June 2005	219,312,166	107,883,835	(3,813,181)	(24,103,801)	20,761	79,987,614

The consolidated statements of changes in stockholders equity should be read in conjunction with the accompanying notes.

**PSIVIDA LIMITED AND SUBSIDIARIES  
(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
In Australian Dollars (except as otherwise stated)**

**1. Background and Summary of Significant Accounting Policies**

**Background**

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

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

**Financial Reporting Framework**

The accompanying financial statements have been prepared in accordance with Australian Accounting Standards and other mandatory professional reporting requirements. These standards and reporting requirements form part of generally accepted accounting principles in Australia (A-GAAP).

A reconciliation of the major differences between these principles and those applicable in the United States of America (US GAAP) is included in Note 27.

These financial statements have been prepared on the basis of historical cost and except where stated, do not take into account changing money values or current valuations of non-current assets. Cost is based on the fair values of the consideration given in exchange for assets.

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts that are reporting in the consolidated financial statements and accompanying disclosures. Although these estimates are based on management’s best knowledge of current events and actions that the company may undertake in the future, actual results may be different from the estimates.

The consolidated financial statements are presented in Australian dollars (\$) unless otherwise stated.

**Development Stage — Risks and Uncertainties**

As a development stage enterprise, the Company’s prospects are subject to the risks and uncertainties frequently encountered by companies, which have not yet commercialized any applications of their technology, particularly in new and evolving markets. pSivida’s operating results may fluctuate significantly in the future as a result of a variety of factors, including capital expenditure and other costs relating to establishing, maintaining and expanding the operations, the number and mix of potential customers, potential pricing of future products by the Company and its competitors, new technology introduced by the Company and its competitors, delays or expense in obtaining necessary equipment, economic and social conditions in the biotechnology industry and general economic conditions.

pSivida will continue to review the need to seek additional funding through public and private financing and/or through collaboration or other arrangements with corporate partners. The Company cannot be certain that they will be able to raise any required funding or capital, on favourable terms or at

**PSIVIDA LIMITED AND SUBSIDIARIES  
(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)  
In Australian Dollars (except as otherwise stated)**

all, or that they will be able to establish corporate collaborations on acceptable terms, if at all. If the Company is unable to obtain such additional funding or capital, they may be required to reduce the scope of their development plans.

pSivida's experience in exploiting their technology is limited. The Company cannot be certain that their operations will be profitable in the short-term, or at all. If pSivida fails in any of their efforts to establish or expand their business, the results of operations, financial condition and liquidity of the Company could be materially adversely affected. The Company cannot be certain that they will be able to obtain or retain any permits required by the Company to market, sell and deliver its technology. Any of these factors could result in cessation of pSivida's operations.

The date of inception of the development stage was 1 December 2000, being the date that pSivida (formerly Sumich Group Limited) was re-listed on the Australian Stock Exchange following a recapitalization and restructure. It was after this recapitalization and restructure that the Company acquired an interest in pSiMedica Limited, or pSiMedica, and commenced its research and development activities. Balances at inception of the development stage represent the Company's statement of financial position balances post-recapitalization and restructure.

**Significant Accounting Policies**

Accounting policies are selected and applied in a manner which ensures that the resulting financial information satisfies the concepts of relevance and reliability, thereby ensuring that the substance of the underlying transactions or other events is reported.

The following significant accounting policies have been adopted in the preparation of the financial report:

**(a) Principles of consolidation**

The consolidated financial statements are those of the consolidated entity, comprising pSivida (the parent entity) and all entities that pSivida controlled from time to time during the year and at the balance sheet date.

Information from the financial statements of subsidiaries is included from the date the parent company obtains control until such time as control ceases. Where there is loss of control of a subsidiary, the consolidated financial statements include the results for the part of the reporting period during which the parent company has control.

The financial statements of subsidiaries are prepared for the same reporting period as the parent entity, using consistent accounting policies. Adjustments are made to bring into line any dissimilar accounting policies which may exist.

On 24 August 2004, the Company incorporated AION Diagnostics Limited, or AION Diagnostics, an Australian resident wholly owned subsidiary of pSivida, to focus on developing the diagnostic applications of BioSilicon. pSivida funded AION Diagnostics through an investment of \$1,200,000 and intends to license diagnostic and sensor applications of the BioSilicon platform technology to AION Diagnostics.

During the year ended 30 June 2005 the Company also incorporated pSivida UK Limited in the United Kingdom ("UK") and pSivida Inc in the United States ("US"). These companies were set up in order to gain patent protection in the UK and US.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

All intercompany balances and transactions, including unrealized profits arising from intra-group transactions, have been eliminated in full.

**(b) Foreign currencies**

*Translation of Foreign Currency Transactions*

Transactions in foreign currencies of entities within the consolidated entity are converted to local currency at the rate of exchange ruling at the date of the transaction.

Amounts payable to and by the entities within the consolidated entity that are outstanding at the balance sheet date and are denominated in foreign currencies have been converted to local currency using rates of exchange ruling at the end of the financial year.

All resulting exchange differences arising on settlement or restatement are brought to account in determining the profit or loss for the financial year, and transaction costs, premiums and discounts on forward currency contracts are deferred and amortized over the life of the contract.

*Translation of Accounts of Overseas Operations*

All overseas operations are deemed to be self-sustaining as each is financially and operationally independent of pSivida. The financial reports of overseas operations are translated using the current rate method and any exchange differences are taken directly to the foreign currency translation reserve (Note 13a).

**(c) Cash assets**

Cash on hand and in banks and short-term deposits are stated at nominal value.

For the purposes of the Statement of Cash Flows, cash assets include cash on hand, in banks and money market investments readily convertible to cash within two working days.

**(d) Receivables**

Receivables are recognized and carried at original amount less a provision for any uncollectible debts.

**(f) Recoverable amount**

Non-current assets, including intangible assets, are carried at the lower of cost and recoverable amount. Non-current assets are not written up if the recoverable amount exceeds the carrying value. In determining recoverable amount, expected net cash flows have not been discounted to their present value.

**(g) Property, plant and equipment**

*Cost*

All classes of property, plant and equipment are measured at cost.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

*Depreciation*

Depreciation is provided on a straight-line basis on all property, plant and equipment, over the following estimated useful lives:

<u>Leasehold improvements</u>	<u>Lesser of the lease term and the useful economic life</u>
Plant and equipment	3 years

Assets in the course of construction are not depreciated until such assets are available for use.

**(h) Operating leases**

The minimum lease payments of operating leases, where the lessor effectively retains substantially all of the risks and benefits of ownership of the leased item, are recognized as an expense on a straight line basis.

The cost of improvements to or on leasehold property is capitalized, disclosed as leasehold improvements, and amortized over the unexpired period of the lease or the estimated useful lives of the improvements, whichever is the shorter.

**(i) Intangibles**

*Intellectual Property*

Intellectual property represents acquired biotechnology intellectual property owned by pSiMedica Limited, a subsidiary of pSivida. pSiMedica owns the world-wide BioSilicon™ intellectual property rights royalty free. pSiMedica also owns the patented rights to BioSilicon™, a porous form of silicon and an enabling platform nanotechnology in the biomedical industry.

Intellectual property is recorded at the cost of acquisition and is carried forward as an asset on the expectation that it will lead to commercialization. The carrying amount of intangibles is reviewed by the Directors at each reporting date.

The directors gave due consideration to the technical and commercial life of the intellectual property (being patents and licences) concluding that a 12 year estimated useful economic life, commencing on the date of acquisition, was appropriate. Amortization will be calculated on a straight-line basis so as to write off the cost of the asset over its remaining estimated useful economic life, commencing with commercial production of products.

Costs associated with new patent applications have been expensed as research and development.

**Goodwill**

Goodwill, representing the excess of the cost of acquisition over the fair value of the identifiable net assets acquired, is amortized on a straight line basis over a period of nine years.

**(j) Research and development costs**

Research and development costs are expensed as incurred, except where future benefits are expected, beyond any reasonable doubt, to exceed those costs. Where research and development costs are deferred such costs are amortized over future periods on a basis related to expected future benefits. To date, no research and development costs have been capitalized.



**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

**(k) Trade and other payables**

Liabilities for trade creditors and other amounts are carried at cost which is the fair value of the consideration to be paid in the future for goods and services received, whether or not billed to the consolidated entity.

Payables to related parties are carried at the principal amount.

**(l) Provisions**

Provisions are recognized when the economic entity has a legal, equitable or constructive obligation to make a future sacrifice of economic benefits to other entities as a result of past transactions or other past events, it is probable that a future sacrifice of economic benefits will be required and a reliable estimate can be made of the amount of the obligation.

A provision for dividends is not recognized as a liability unless the dividends are declared, determined or publicly recommended on or before the reporting date.

**(m) Contributed equity**

Ordinary share capital is recognized at the fair value of the consideration received by the Company.

Any directly attributable transaction costs arising on the issue of ordinary shares are recognized in equity as a reduction of the share proceeds received.

**(n) Revenue recognition**

Revenue is recognized to the extent that it is probable that the economic benefits will flow to the entity and the revenue can be reliably measured.

Interest income is recognized as earned where collectibility is reasonably assured.

**(o) Taxes**

***Income Tax***

Tax-effect accounting is applied using the liability method whereby income tax is regarded as an expense and is calculated on the accounting profit after allowing for permanent differences. To the extent timing differences occur between the time items are recognized in the financial statements and when items are taken into account in determining taxable income or loss, the net related taxation benefit or liability, calculated at current rates, is disclosed as a future income tax benefit or a provision for deferred income tax. The net future income tax benefit relating to tax losses and timing differences is not carried forward as an asset unless the benefit is virtually certain of being realized

***Goods and Services Tax (GST)***

Revenues, expenses and assets are recognized net of the amount of GST except:

- where the GST incurred on a purchase of goods and services is not recoverable from the taxation authority, in which case the GST is recognized as part of the cost of acquisition of the asset or as part of the expense item as applicable; and
- receivables and payables are stated with the amount of GST included.

**PSIVIDA LIMITED AND SUBSIDIARIES  
(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)  
In Australian Dollars (except as otherwise stated)**

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

**(p) Employee entitlements**

Provision is made for employee entitlement benefits accumulated as a result of employees rendering services up to the reporting date. These benefits include wages and salaries, annual leave, sick leave and long service leave.

Liabilities arising in respect of wages and salaries, annual leave, sick leave and any other employee entitlements expected to be settled within twelve months of the reporting date are measured at their nominal amounts based on remuneration rates which are expected to be paid when the liability is settled. All other employee entitlement liabilities are measured at the present value of the estimated future cash outflow to be made in respect of services provided by employees up to the reporting date. In determining the present value of future cash outflows, the interest rates attaching to government guaranteed securities which have terms to maturity approximating the terms of the related liability are used.

Employee entitlements expenses arising in respect of the following categories:

- wages and salaries, non-monetary benefits, annual leave, long service leave, sick leave and other leave entitlements; and
- other types of employee entitlements;

are charged against profits in their respective categories.

The value of the employee share option plan described in Note 21 is not being charged as an employee entitlement expense.

Any contributions made to the superannuation fund by entities within the consolidated entity are charged against operations when due.

**(q) Loss per share**

Basic loss per share is calculated as net loss, adjusted to exclude costs of servicing equity (other than dividends) and preference share dividends, divided by the weighted average number of ordinary shares.

Diluted loss per share is calculated as net loss divided by the weighted average number of ordinary shares and dilutive potential ordinary shares.

**(r) Acquisitions**

Acquisitions are accounted for using the purchase method of accounting. The consolidated financial statements include the operating results of acquirees from the date of acquisition.

For acquisitions, including step acquisitions, completed from 1 July 2004, the cost of acquisition includes all direct acquisition costs.

**2. Purchase price allocation**

On 4 August 2004, the Company acquired the remaining 55.28% interest in pSiMedica Limited that it did not already own. pSivida acquired the remaining interest in pSiMedica in order to obtain 100% ownership of pSiMedica and therefore own 100% of the BioSilicon technology. The consideration paid was \$59,224,568 which comprised of \$4,323,622 in cash, a total of 49,804,381 ordinary shares of pSivida issued

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

at a value of \$1.09 for A-GAAP purposes, 638,537 pSivida options with an estimated fair value of \$292,828, (issued to employees of pSiMedica in exchange for their rights being waived in relation to options previously issued by pSiMedica) and direct acquisition costs totalling \$321,342.

The total acquisition price recognized for A-GAAP is an amount equal to:

Cash	\$	4,323,622
Fair value of shares issued		54,286,776
Fair value of options issued		292,828
Direct acquisition costs		321,342
<b>Total cost of acquisition</b>		<b>59,224,568</b>

The results of the operations of pSiMedica were included for the entire financial year as pSivida held more than 50% of the voting rights of pSiMedica for the whole of this period.

The balance sheet showing the purchase price allocation of net assets acquired is listed as follows:

<b>Item</b>	<b>Total Fair Value</b>	<b>Acquired Interest 55.28%</b>
Cash assets	\$ 520,173	\$ 287,552
Receivables	\$ 198,239	\$ 109,587
Property, plant and equipment	\$ 600,640	\$ 332,034
Creditors	\$ (1,462,721)	\$ (808,592)
<b>Intangible assets</b>		
License	\$ 64,400,000	\$ 35,600,320
Patents	\$ 25,000,000	\$ 13,820,000
<b>Total</b>		<b>\$ 49,340,901</b>
Consideration		<b>\$ 59,224,568</b>
Initial goodwill arising under A-GAAP		<b>\$ 9,883,667</b>

**3. Revenue from ordinary activities**

	<b>Years Ended 30 June</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>Revenues from ordinary activities</b>			
Interest income on bank deposits	667,310	325,479	110,675
Other revenue	161,666	56,200	—
<b>Total revenue from ordinary activities</b>	<b>828,976</b>	<b>381,679</b>	<b>110,675</b>

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

**4. Expenses and (Losses)/ Gains****(a) Expenses**

	<b>Years Ended 30 June</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>
<i>Depreciation and amortisation of non-current assets</i>			
Borrowing costs	11,520	11,520	9,600
Goodwill on acquisition	973,923	—	—
Plant and equipment	36,839	23,683	18,502
Leasehold improvements	7,100	4,157	9,733
	<u>1,029,384</u>	<u>39,360</u>	<u>37,835</u>
Included in research and development costs:			
Plant and equipment	569,071	287,702	258,432
Leasehold improvements	18,717	—	—
Other non-current assets	18,130	19,666	19,433
<b>Total depreciation and amortisation of non-current assets</b>	<b><u>1,635,300</u></b>	<b><u>346,728</u></b>	<b><u>315,700</u></b>
Write off of borrowing costs	1,919	—	—
Operating lease charges(i)	97,738	95,772	36,569
Research and development costs	8,287,930	7,011,666	4,586,182

(i) Excludes operating lease charges classified as “research and development.”

**(b) (Losses)/ Gains**

Net loss on disposal of property, plant and equipment	(6,910)	—	—
Foreign currency (loss)/ gain, net	(1,623,484)	1,461,368	(1,203)

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

**5. Income tax**

The prima facie tax, using the tax rate applicable in Australia, on operating loss differs from the income tax provided in the accounts as follows:

	Years Ended 30 June		
	2005 \$	2004 \$	2003 \$
Prima facie income tax benefit calculated at 30% on the loss from ordinary activities before income tax	(4,537,716)	(2,255,693)	(1,606,899)
Tax effect of permanent differences			
Goodwill amortization	292,177	—	—
Other items (net)	3,866	10,637	52,782
Income tax benefit attributable to ordinary activities	(4,241,673)	(2,245,056)	(1,554,117)
Future income tax benefit not brought to account	4,241,673	2,245,056	1,554,117
Income tax expense	—	—	—
Future income tax benefit from tax losses not brought to account at balance date as realization of the benefit is not virtually certain (at 30%)	9,291,377	5,049,704	2,892,095

This Company has future income tax benefits relating to tax losses not recognized as assets because recovery is not virtually certain. Such benefits will only be obtained if:

- (a) future assessable income is derived of a nature and of an amount sufficient to enable the benefit to be realized;
- (b) the conditions for deductibility imposed by tax legislation continue to be complied with; and
- (c) no changes in tax legislation adversely affect the consolidated entity in realising the benefit.

The Company has elected not to consolidate under the tax regime.

The Company has no franking credits available at year end.

**6. Receivables**

	As at 30 June	
	2005 \$	2004 \$
<b>Current</b>		
Indirect tax	709,418	340,482

Indirect tax receivables relate to goods and services tax (GST) and value added tax (VAT). These amounts are non-interest bearing and have repayment terms applicable under the relevant government authorities.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

**7. Other assets**

	<u>As at 30 June</u>	
	<u>2005</u>	<u>2004</u>
	<u>\$</u>	<u>\$</u>
<b><i>Current</i></b>		
Prepayments	322,933	38,958
<b><i>Non-current</i></b>		
Loan facility arrangement costs(i)	34,559	34,559
Accumulated amortization	(34,559)	(21,120)
	—	13,439
Other non-current assets(ii)	53,061	58,301
Accumulated amortization	(53,061)	(39,099)
	—	19,202
	—	32,641

- (i) Loan facility arrangement costs were incurred in connection with the September 2002 agreement with Global Emerging Markets (“GEM”), a New York based private equity group, for a fully underwritten US\$7.5 million equity line of credit facility. Such costs were being amortized on a straight-line basis over the three-year term of the facility. As part of the commitment fee, pSivida issued to GEM 2,000,000 options to acquire shares in pSivida at 20 cents each, expiring on 31 December 2004. Additionally, a commitment fee equivalent to 1.67% of the total value of the facility was payable by the Company to GEM on the proceeds of any drawdowns. The facility was terminated during the year ended 30 June 2005 with no drawdowns having been made.
- (ii) Other non-current assets comprises the fair value of non-cash consideration in pSiOncology made by minority shareholders. This amount has been amortized over three years on a straight line basis.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

**8. Property, plant and equipment, net**

	<b>As at 30 June</b>	
	<b>2005</b>	<b>2004</b>
	<b>\$</b>	<b>\$</b>
<b>Plant and equipment</b>		
At cost	2,439,455	1,360,533
Accumulated depreciation	<u>(1,119,916)</u>	<u>(699,938)</u>
	<u>1,319,539</u>	<u>660,595</u>
<b>Leasehold improvements</b>		
At cost	155,799	14,214
Accumulated depreciation	<u>(30,188)</u>	<u>(5,110)</u>
	<u>125,611</u>	<u>9,104</u>
<b>Construction in progress(i)</b>		
At cost	<u>1,828,513</u>	<u>—</u>
<b>Total property, plant and equipment</b>		
At cost	4,423,767	1,374,747
Accumulated depreciation	<u>(1,150,104)</u>	<u>(705,048)</u>
	<u>3,273,663</u>	<u>669,699</u>

- (i) Construction in progress for 30 June 2005 relates to the construction of a new production facility in Germany, which was completed subsequent to year end.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
(A Development Stage Enterprise)

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
In Australian Dollars (except as otherwise stated)

**(a) Reconciliations**

Reconciliations of the carrying amounts for each class of property, plant and equipment are set out below:

	As at 30 June	
	2005 \$	2004 \$
<b>Plant and equipment</b>		
Carrying amount at beginning of year	660,595	400,549
Additions	1,358,690	549,880
Disposals	(6,910)	—
Depreciation	(605,910)	(311,385)
Net foreign currency movements	(86,926)	21,551
Carrying amount at end of year	<u>1,319,539</u>	<u>660,595</u>
<b>Leasehold improvements</b>		
Carrying amount at beginning of year	9,104	3,736
Additions	146,977	9,525
Depreciation	(25,817)	(4,157)
Net foreign currency movements	(4,653)	—
Carrying amount at end of year	<u>125,611</u>	<u>9,104</u>
<b>Construction in progress</b>		
Carrying amount at beginning of year	—	—
Additions	1,904,551	—
Net foreign currency movements	(76,038)	—
Carrying amount at end of year	<u>1,828,513</u>	<u>—</u>
<b>9. Intangibles</b>		
Intellectual property — at cost(i)	55,927,494	7,934,622
Goodwill on acquisition(ii)	9,883,667	—
Accumulated amortization — goodwill	(973,923)	—
	<u>64,837,238</u>	<u>7,934,622</u>

- (i) The intellectual property comprises the licence to develop applications for BioSilicon™ and the related patents. As described in Note 1(i), amortization of this asset will commence on commercial production of related products, which had not commenced at 30 June 2005.
- (ii) Goodwill on acquisition relates to the acquisition of the remaining outside equity interest in pSiMedica in August 2004. Refer to Note 2.



**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

**10. Payables**

	As at 30 June	
	2005 \$	2004 \$
<b>Current</b>		
Trade creditors	806,047	1,162,281
Accruals	994,444	565,456
Payroll taxes payable	167,227	117,223
Amounts payable to directors and director-related entities	38,253	29,910
Amounts payable to other related parties	11,849	7,234
	2,017,820	1,882,104

**11. Provisions**

	<i>Current</i>	Consolidated	
		2005 Number	2004 Number
Provision for employee entitlements	29,879	36	20
Number of employees at end of financial year		36	20

**Superannuation**

Under government regulations the Company is legally required to contribute 9% of employees' gross income to an approved superannuation fund. Employees are entitled to contribute additional amounts to the fund at their own discretion. The Company makes the required contribution to each employee's nominated Superannuation fund.

The Company does not provide employee benefits under defined benefit arrangements.

The United Kingdom subsidiary, pSiMedica Limited, operates a defined contribution pension scheme. The pension cost charge for the year under the defined contribution scheme was £79,411 (\$195,863) (2004: £30,660 (\$75,149), 2003: £28,672 (\$77,740)). An increase in employee numbers for pSiMedica has caused the increase in the charge in the 2005 year.

*Employee share option plan (ESOP)*

An employee share option plan has been established where directors and employees of the consolidated entity Company are issued with options over the ordinary shares of pSivida Limited. Shareholders reapproved the plan at the annual general meeting ("AGM") held on 17 November 2004. The options, issued for nil consideration, are issued in accordance with performance guidelines established by the directors of pSivida Limited.

Employee share options carry no rights to dividends and no voting rights.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

**12. Contributed equity**

**(a) Contributed equity**

	As at 30 June	
	2005 \$	2004 \$
Ordinary shares, fully paid	107,883,835	49,957,982

**(b) Movements in share capital**

	Years ended 30 June			
	2005 Number	2004 Number	2005 \$	2004 \$
Balance at beginning of year	153,937,785	103,916,213	49,957,982	15,602,183
Issued during the year				
Consideration for acquisition	49,804,381	—	54,286,776	—
Share placements	—	38,000,000	—	33,946,640
Share purchase plan	—	3,891,572	—	933,977
Options exercised	15,570,000	8,130,000	3,666,500	1,626,000
Share issue costs	—	—	(27,423)	(2,150,818)
Balance at end of year	219,312,166	153,937,785	107,883,835	49,957,982

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

Details of share issuances are as follows:

<u>Date</u>	<u>Details</u>	<u>Number</u>	<u>Issue price</u> <u>\$</u>	<u>Total</u> <u>\$</u>
4 Aug 2003	Share purchase plan, net of \$1,679 issue costs	3,891,572	\$ 0.24	932,298
20 Aug 2003	Exercise of options	650,000	\$ 0.20	130,000
27 Aug 2003	Exercise of options	650,000	\$ 0.20	130,000
28 Aug 2003	Exercise of options	1,725,000	\$ 0.20	345,000
8 Sep 2003	Exercise of options	1,000,000	\$ 0.20	200,000
3 Oct 2003	Exercise of options	1,000,000	\$ 0.20	200,000
6 Oct 2003	Private placement, net of \$338,400 issue costs	13,000,000	\$ 0.50	6,161,600
24 Dec 2003	Exercise of options	30,000	\$ 0.20	6,000
6 Jan 2004	Exercise of options	475,000	\$ 0.20	95,000
4 Feb 2004	Exercise of options	2,000,000	\$ 0.20	400,000
20 Apr 2004	Private placement, net of \$1,523,865 issue costs	19,375,000	US\$ 0.80	19,413,109
23 Apr 2004	Private placement, net of \$286,875 issue costs	5,625,000	US\$ 0.85	6,222,791
3 May 2004	Exercise of options	300,000	\$ 0.20	60,000
19 May 2004	Exercise of options	300,000	\$ 0.20	60,000
Year ended 30 June 2004		<u>50,021,572</u>		<u>34,355,798</u>
14 Jul 2004	Exercise of options	50,000	\$ 0.20	10,000
5 Aug 2004	Shares issued as consideration for acquisition, net of \$27,422 issue costs	49,804,381	\$ 1.09	54,259,353
6 Aug 2004	Exercise of options	250,000	\$ 0.20	50,000
13 Aug 2004	Exercise of options	200,000	\$ 0.20	40,000
17 Aug 2004	Exercise of options	150,000	\$ 0.20	30,000
20 Aug 2004	Exercise of options	300,000	\$ 0.20	60,000
27 Aug 2004	Exercise of options	100,000	\$ 0.20	20,000
8 Oct 2004	Exercise of options	450,000	\$ 0.20	90,000
27 Oct 2004	Exercise of options	100,000	\$ 0.40	40,000
11 Nov 2004	Exercise of options	450,000	\$ 0.20	90,000
14 Dec 2004	Exercise of options	8,650,000	\$ 0.20	1,730,000
14 Dec 2004	Exercise of options	1,550,000	\$ 0.40	620,000
14 Dec 2004	Exercise of options	150,000	\$ 0.50	75,000
14 Dec 2004	Exercise of options	150,000	\$ 0.65	97,500
31 Dec 2004	Exercise of options	2,470,000	\$ 0.20	494,000
31 Dec 2004	Exercise of options	550,000	\$ 0.40	220,000
Year ended 30 June 2005		<u>65,374,381</u>		<u>57,925,853</u>

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

**(c) Share options**

	Exercise Price	Expiry Date	Balance at beginning of year Number	Issued during the year Number	Exercised during the year Number	Forfeited during the year Number	Balance at end of year Number
Unlisted options	\$ 0.20	31/12/04	12,570,000	—	(12,570,000)	—	—
Unlisted options	\$ 0.50	31/12/04	150,000	—	(150,000)	—	—
Unlisted options	\$ 0.65	31/12/04	150,000	—	(150,000)	—	—
Unlisted options *	\$ 0.40	31/12/04	2,200,000	—	(2,200,000)	—	—
Unlisted options *	\$ 0.20	31/12/04	500,000	—	(500,000)	—	—
Unlisted options *	\$ 0.61	31/12/07	4,395,000	—	—	(20,000)	4,375,000
Unlisted options **	\$ 1.09	5/8/08	—	2,050,000	—	—	2,050,000
Unlisted options *	\$ 1.18	5/8/09	—	9,114,537	—	(59,824)	9,054,713
Unlisted options *	\$ 1.02	31/12/08	—	200,000	—	—	200,000
Unlisted options *	\$ 0.80	31/12/08	—	115,000	—	—	115,000
Unlisted options *	\$ 0.80	31/3/10	—	3,202,000	—	(25,000)	3,177,000
			<u>19,965,000</u>	<u>14,681,537</u>	<u>(15,570,000)</u>	<u>(104,824)</u>	<u>18,971,713</u>

\* Options issued pursuant to the Company's Employee Share Option Plan (ESOP).

\*\* 2,050,000 options issued as payment of share issue costs to consultants not under the ESOP

The options on issue at 30 June 2005 have a weighted average exercise price of \$0.97 and a weighted average remaining contractual life of 45 months. The options on issue and currently exercisable at 30 June 2005 have a weighted average exercise price of \$1.01 and a weighted average remaining contractual life of 43 months.

The options on issue at 30 June 2005 have the following range of exercise prices:

Range of Exercise Price	Number of Options	Weighted Average Exercise Price
\$0.00 to \$0.10	—	—
\$0.10 to \$0.25	—	—
\$0.25 to \$0.50	—	—
\$0.50 to \$0.70	4,375,000	\$ 0.61
\$0.70 to \$0.90	3,292,000	\$ 0.80
\$0.90 to \$1.10	2,250,000	\$ 1.08
\$1.10 and above	9,054,713	\$ 1.18
	<u>18,971,713</u>	<u>\$ 0.97</u>

***Employee share option plan (ESOP)***

An employee share option plan has been established where directors and employees of the Company are issued with options over the ordinary shares of pSivida Limited. Shareholders reapproved the plan at the AGM held on 17 November 2004. The options, issued for nil consideration, are issued in accordance with performance guidelines established by the directors of pSivida Limited.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

Employee share options carry no rights to dividends and no voting rights.

The ESOP is designed to reward directors, executives and employees of the Company and consultants for their contributions to the Company. It is also proposed as a method of retaining personnel that are key to the growth of the Company's intellectual property rights.

		2005 Number	2004 Number	2003 Number
Balance at beginning of financial year	i	7,095,000	2,700,000	2,200,000
Granted during financial year	ii	12,631,537	4,395,000	520,000
Exercised during financial year	iii	(1,050,000)	—	—
Transferred and exercised during financial year	iv	(1,650,000)	—	—
Forfeited during financial year	v	(104,824)	—	(20,000)
Balance at end of financial year	vi	<u>16,921,713</u>	<u>7,095,000</u>	<u>2,700,000</u>

(i) *Balance at beginning of financial year*

Options — Series 2005	Number	Grant Date	Vesting Date	Expiry Date	Exercise Price \$
Issued 31 December 2001	2,200,000	31/12/01	13/10/03	31/12/04	\$ 0.40
Issued 1 November 2002	500,000	1/11/02	1/11/03	31/12/04	\$ 0.20
Issued 21 October 2003	250,000	21/10/03	21/10/03	31/12/07	\$ 0.61
Issued 21 October 2003	250,000	21/10/03	21/7/04	31/12/07	\$ 0.61
Issued 21 October 2003	2,345,000	21/10/03	21/4/04	31/12/07	\$ 0.61
Issued 21 October 2003	350,000	21/10/03	21/1/04	31/12/07	\$ 0.61
Issued 21 October 2003	400,000	21/10/03	21/10/03	31/12/07	\$ 0.61
Issued 21 October 2003	400,000	21/10/03	21/10/04	31/12/07	\$ 0.61
Issued 21 October 2003	400,000	21/10/03	21/10/05	31/12/07	\$ 0.61
	<u>7,095,000</u>				

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

(ii) *Granted during financial year*

<b>Options — Series 2005</b>	<b>Number</b>	<b>Grant Date</b>	<b>Vesting Date</b>	<b>Expiry Date</b>	<b>Exercise Price \$</b>
Issued 5 August 2004	175,000	5/8/04	5/8/04	5/8/09	\$ 1.18
Issued 5 August 2004	50,000	5/8/04	5/8/05	5/8/09	\$ 1.18
Issued 5 August 2004	8,889,537	5/8/04	5/8/04	5/8/09	\$ 1.18
Issued 22 April 2005	200,000	22/4/05	22/4/05	22/4/10	\$ 1.02
Issued 22 April 2005	115,000	22/4/05	22/4/05	31/12/08	\$ 0.80
Issued 22 April 2005	50,000	22/4/05	22/4/06	31/3/10	\$ 0.80
Issued 22 April 2005	450,000	22/4/05	22/4/05	31/3/10	\$ 0.80
Issued 22 April 2005	2,252,000	22/4/05	22/4/06	31/3/10	\$ 0.80
Issued 22 April 2005	450,000	22/4/05	22/4/07	31/3/10	\$ 0.80
	<u>12,631,537</u>				

<b>Options — Series 2004</b>	<b>Number</b>	<b>Grant Date</b>	<b>Vesting Date</b>	<b>Expiry Date</b>	<b>Exercise Price \$</b>
Issued 21 October 2003	250,000	21/10/03	21/10/03	31/12/07	\$ 0.61
Issued 21 October 2003	250,000	21/10/03	21/7/04	31/12/07	\$ 0.61
Issued 21 October 2003	2,345,000	21/10/03	21/4/04	31/12/07	\$ 0.61
Issued 21 October 2003	350,000	21/10/03	21/1/04	31/12/07	\$ 0.61
Issued 21 October 2003	400,000	21/10/03	21/10/03	31/12/07	\$ 0.61
Issued 21 October 2003	400,000	21/10/03	21/10/04	31/12/07	\$ 0.61
Issued 21 October 2003	400,000	21/10/03	21/10/05	31/12/07	\$ 0.61
	<u>4,395,000</u>				

<b>Options — Series 2003</b>	<b>Number</b>	<b>Grant Date</b>	<b>Vesting Date</b>	<b>Expiry Date</b>	<b>Exercise Price \$</b>
Issued 1 November 2002	520,000	1/11/02	1/11/03	31/12/04	\$ 0.20
	<u>520,000</u>				

(iii) *Exercised during financial year*

<b>Options — Series 2005</b>	<b>Number</b>	<b>Grant Date</b>	<b>Vesting Date</b>	<b>Expiry Date</b>	<b>Exercise Price \$</b>
Issued 31 December 2001	(550,000)	31/12/01	13/10/03	31/12/04	\$ 0.40
Issued 1 November 2002	(500,000)	1/11/02	1/11/03	31/12/04	\$ 0.20
	<u>(1,050,000)</u>				

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

(iv) *Transferred during financial year*

<u>Options — Series 2005</u>	<u>Number</u>	<u>Grant Date</u>	<u>Vesting Date</u>	<u>Expiry Date</u>	<u>Exercise Price</u> <u>\$</u>
Issued 31 December 2001	(1,650,000)	31/12/01	13/10/03	31/12/04	\$ 0.40
	<u>(1,650,000)</u>				

During the 2005 financial year these options were transferred by Directors to independent third parties for consideration of \$1.18 per option less applicable option exercise price, brokerage commission and fees. All transferred options were exercised prior to 31 December 2004.

(v) *Forfeited during financial year*

<u>Options — Series 2005</u>	<u>Number</u>	<u>Grant Date</u>	<u>Vesting Date</u>	<u>Expiry Date</u>	<u>Exercise Price</u> <u>\$</u>
Issued 21 October 2003	(20,000)	21/10/03	21/4/04	31/12/07	\$ 0.61
Issued 5 August 2004	(59,824)	5/8/04	5/8/04	5/8/09	\$ 1.18
Issued 22 April 2005	(25,000)	22/4/05	22/4/06	31/3/10	\$ 0.80
	<u>(104,824)</u>				

<u>Options — Series 2003</u>	<u>Number</u>	<u>Grant Date</u>	<u>Vesting Date</u>	<u>Expiry Date</u>	<u>Exercise Price</u> <u>\$</u>
Issued 1 November 2002	(20,000)	1/11/02	1/11/03	31/12/04	\$ 0.20
	<u>(20,000)</u>				

**PSIVIDA LIMITED AND SUBSIDIARIES**  
(A Development Stage Enterprise)

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
In Australian Dollars (except as otherwise stated)

(vi) Balance at end of financial year

<b>Options — Series 2005</b>	<b>Number</b>	<b>Grant Date</b>	<b>Vesting Date</b>	<b>Expiry Date</b>	<b>Exercise Price \$</b>
Issued 21 October 2003	250,000	21/10/03	21/10/03	31/12/07	\$ 0.61
Issued 21 October 2003	250,000	21/10/03	21/7/04	31/12/07	\$ 0.61
Issued 21 October 2003	2,325,000	21/10/03	21/4/04	31/12/07	\$ 0.61
Issued 21 October 2003	350,000	21/10/03	21/1/04	31/12/07	\$ 0.61
Issued 21 October 2003	400,000	21/10/03	21/10/03	31/12/07	\$ 0.61
Issued 21 October 2003	400,000	21/10/03	21/10/04	31/12/07	\$ 0.61
Issued 21 October 2003	400,000	21/10/03	21/10/05	31/12/07	\$ 0.61
Issued 5 August 2004	175,000	5/8/04	5/8/04	5/8/09	\$ 1.18
Issued 5 August 2004	50,000	5/8/04	5/8/05	5/8/09	\$ 1.18
Issued 5 August 2004	8,829,713	5/8/04	5/8/04	5/8/09	\$ 1.18
Issued 22 April 2005	200,000	22/4/05	22/4/05	22/4/10	\$ 1.02
Issued 22 April 2005	115,000	22/4/05	22/4/05	31/12/08	\$ 0.80
Issued 22 April 2005	50,000	22/4/05	22/4/06	31/3/10	\$ 0.80
Issued 22 April 2005	450,000	22/4/05	22/4/05	31/3/10	\$ 0.80
Issued 22 April 2005	2,227,000	22/4/05	22/4/06	31/3/10	\$ 0.80
Issued 22 April 2005	450,000	22/4/05	22/4/07	31/3/10	\$ 0.80
	<u>16,921,713</u>				

<b>Options — Series 2004</b>	<b>Number</b>	<b>Grant Date</b>	<b>Vesting Date</b>	<b>Expiry Date</b>	<b>Exercise Price \$</b>
Issued 31 December 2001	2,200,000	31/12/01	13/10/03	31/12/04	\$ 0.40
Issued 1 November 2002	500,000	1/11/02	1/11/03	31/12/04	\$ 0.20
Issued 21 October 2003	250,000	21/10/03	21/10/03	31/12/07	\$ 0.61
Issued 21 October 2003	250,000	21/10/03	21/7/04	31/12/07	\$ 0.61
Issued 21 October 2003	2,345,000	21/10/03	21/4/04	31/12/07	\$ 0.61
Issued 21 October 2003	350,000	21/10/03	21/1/04	31/12/07	\$ 0.61
Issued 21 October 2003	400,000	21/10/03	21/10/03	31/12/07	\$ 0.61
Issued 21 October 2003	400,000	21/10/03	21/10/04	31/12/07	\$ 0.61
Issued 21 October 2003	400,000	21/10/03	21/10/05	31/12/07	\$ 0.61
	<u>7,095,000</u>				

<b>Options — Series 2003</b>	<b>Number</b>	<b>Grant Date</b>	<b>Vesting Date</b>	<b>Expiry Date</b>	<b>Exercise Price \$</b>
Issued 31 December 2001	2,200,000	31/12/01	13/10/03	31/12/04	\$ 0.40
Issued 1 November 2002	500,000	1/11/02	1/11/03	31/12/04	\$ 0.20
	<u>2,700,000</u>				



**PSIVIDA LIMITED AND SUBSIDIARIES  
(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)  
In Australian Dollars (except as otherwise stated)**

*Year ended 30 June 2005*

The Company issued 8,251,000 unquoted options to directors, executives and employees and 225,000 unquoted options to consultants of the Company under the ESOP in lieu of cash bonuses and/ or increased fees and as a method of providing an incentive to maximize shareholder value. The options were issued for no consideration with an exercise price of \$1.18, which was representative of an 8% premium to the market price at the date of issue. The various tranches of the options granted have different vesting dates; however all the options expire on 5 August 2009.

The Company also issued 638,537 unquoted options to directors, executives and employees of the Company under the ESOP in consideration for the waiver of their rights under outstanding options previously issued by pSiMedica. The options were issued for no consideration with an exercise price of \$1.18, which was representative of an 8% premium to the market price at the date of issue. The options vest immediately, and expire on 5 August 2009. The options were accounted for as part of the consideration for the purchase of pSiMedica — see Note 2.

The Company also issued 3,152,000 unquoted options to directors, executives and employees and 365,000 unquoted options to consultants of the Company under the ESOP in lieu of cash bonuses and/ or increased fees and as a method of providing an incentive to maximize shareholder value. The options were issued for no consideration with an exercise price of \$0.80, which was representative of a 7% premium to the market price at the date of issue. The various tranches of the options granted have different vesting dates, however all the options expire on 31 March 2010.

*Year ended 30 June 2004*

The Company granted 3,895,000 unquoted options to directors, executives and employees and 500,000 unquoted options to consultants of the Company under the ESOP in lieu of cash bonuses and/ or increased fees and as a method of providing an incentive to maximize shareholder value. The options were issued for no consideration with an exercise price of \$0.61, which was representative of a 25% premium to the 60 day volume weighted average price up to the date of the meeting of shareholders approving the grant. The various tranches of the options granted have different vesting dates, however all the options expire on 31 December 2007.

*Year ended 30 June 2003*

The Company granted 520,000 unquoted options to employees under the ESOP in lieu of cash bonuses and as a method of providing an incentive to maximize shareholder value. The options were issued for no consideration with an exercise price of \$0.20, expiring on 31 December 2004.

**(d) Terms and conditions of contributed equity**

*Ordinary shares*

Ordinary shares have the right to receive dividends as declared and, in the event of winding up the Company, to participate in the proceeds from the sale of all surplus assets in proportion to the number of and amounts paid up on shares held.

Ordinary shares entitle their holder to one vote, either in person or by proxy, at a meeting of the Company. Option holders do not have the right to receive dividends and are not entitled to vote at a meeting of the Company.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

**(e) Shares and options issued after report date**

Details of share issuances are as follows:

The Company issued 6,650,000 ordinary shares (in the form of 665,000 American Depositary Receipts, or ADRs at a price of US\$6.50 per ADR (\$8.61) in August 2005, pursuant to a Private Investment in Public Equity, or PIPE.

Details of option issuances are as follows:

The Company issued 780,000 options expiring 5 August 2008 and exercisable at US\$1.25 each, pursuant to a PIPE.

**13. Reserves**

	2005 \$	2004 \$
Foreign currency translation	(272,067)	78,220
Option premium	292,828	—
	<u>20,761</u>	<u>78,220</u>

**(a) Foreign currency translation reserve**

The foreign currency translation reserve is used to record exchange differences arising from the translation of the financial statements of self-sustaining foreign operations.

	2005 \$	2004 \$
Balance at beginning of year	78,220	235
(Gain)/loss on translation of foreign controlled entities	(350,287)	77,985
Balance at end of year	<u>(272,067)</u>	<u>78,220</u>

**(b) Option premium reserve**

The option premium reserve is used to recognize the value of options issued of a capital nature. The reserve arose during the year ended 30 June 2005 as a result of the issue of options to replace pSiMedica options previously held by directors and employees of pSiMedica as part of the acquisition of the remaining interest in pSiMedica. The amount charged to the reserve is the value of the options issued using the Black Scholes Option Pricing Model.

Balance at beginning of year	—	—
Increase on issue of options	292,828	—
Balance at end of year	<u>292,828</u>	<u>—</u>

**14. Accumulated deficit**

**(a) Deficit accumulated prior to development stage**

Balance at end of year	<u>(3,813,181)</u>	<u>(3,813,181)</u>
------------------------	--------------------	--------------------

**PSIVIDA LIMITED AND SUBSIDIARIES**  
(A Development Stage Enterprise)

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
In Australian Dollars (except as otherwise stated)

**(b) Deficit accumulated during development stage**

	2005 \$	2004 \$
Balance at beginning of year	(9,377,278)	(5,694,073)
Net loss attributable to members of the Company	(14,726,523)	(3,683,205)
Balance at end of year	<u>(24,103,801)</u>	<u>(9,377,278)</u>

**15. Outside equity interest**

Reconciliation of outside equity interest in controlled entities

Balance at beginning of year	1,583,200	204,354
Share of subsidiary acquisition	—	3,622,319
Share of current period loss (through the acquisition date)	(399,196)	(3,835,771)
Share of foreign currency translation reserve	79,361	90,489
Effect of change in shareholding	(1,263,365)	1,501,809
Balance at end of year	<u>—</u>	<u>1,583,200</u>

**16. Investments in controlled entities**

	Country of incorporation	Ownership Interest	
		2005 %	2004 %
pSiMedica Limited(i)	UK	100	44.72
pSiOncology Pte Ltd (ii)	Singapore	100	44.72
AION Diagnostics Limited (iii)	Australia	100	—
pSivida UK Limited (iii)	UK	100	—
pSivida Inc (iii)	USA	100	—

(i) Consolidation occurs due to the Company controlling more than 50% of the voting rights in pSiMedica.

(ii) 100% owned subsidiary of pSiMedica Limited.

(iii) These companies were incorporated during the year ended 30 June 2005 as wholly owned subsidiaries of pSivida.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
(A Development Stage Enterprise)

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
In Australian Dollars (except as otherwise stated)

**17. Notes to the statement of cash flows**

**(a) Reconciliation of cash**

For the purposes of the statement of cash flows, cash includes cash on hand and in banks and investments in money market instruments. Cash at the end of the financial year comprises the following:

	2005 \$	2004 \$
Cash on hand	1,637,560	665,355
Deposits at call	11,254,501	30,685,301
	<u>12,892,061</u>	<u>31,350,656</u>

**(b) Reconciliation of loss from ordinary activities after related income tax to net cash flows used in operating activities**

	Years ended 30 June		
	2005 \$	2004 \$	2003 \$
Loss from ordinary activities after tax	(15,125,719)	(7,518,976)	(5,356,328)
Non-cash items:			
Depreciation and amortization	1,635,300	346,728	315,700
Write off of borrowing costs	1,919	—	—
Loss on disposal of property, plant and equipment	6,910	—	—
Shares issued in lieu of cash	—	—	100,000
Foreign exchange loss/ (gain)	1,623,484	(1,461,368)	1,203
Changes in net assets and liabilities			
(Increase)/decrease in assets:			
Trade and other receivables	(408,904)	(238,081)	23,511
Prepayments	(290,102)	(12,061)	(6,172)
Deferred assets	—	—	(34,559)
Increase/ (decrease) in liabilities:			
Trade and other creditors	222,635	1,062,292	401,778
Provisions	29,879	—	—
Net cash flows used in operating activities	<u>(12,304,598)</u>	<u>(7,821,466)</u>	<u>(4,554,867)</u>

**(c) Non-cash financing and investing activities**

Year ended 30 June 2005

In August 2004 pSivida issued 49,804,381 shares at a value of \$1.09 each to former pSiMedica Limited shareholders as part consideration for the acquisition of the remaining interest in pSiMedica Limited.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

*Year ended 30 June 2004*

On 24 May 2004, pSiMedica issued 56,954 ordinary shares to acquire the remaining minority interest in pSiOncology.

*Year ended 30 June 2003*

Acquisition of controlled entity:

In July 2002, pSiMedica subscribed for 90% of the issued share capital of pSiOncology Pte Ltd., or pSiOncology, for consideration of £235,000.

The net assets of pSiOncology as of 30 July 2002 were comprised as follows:

Cash	623,664
Other non-current assets	63,615
Net assets acquired	687,279
Less minority interests	(64,623)
Net assets acquired	622,656
Goodwill arising	—
Net cash effect: Cash consideration paid	(622,656)
Cash included in net assets acquired	623,664
Net cash received on purchase of subsidiary	1,008

During the years ended 30 June 2005, 2004, and 2003, the Company issued shares and options in consideration for services rendered. See note 12(b) and 12(c).

**18. Expenditure commitments**

Operating leases (non-cancellable)

Year ended 30 June

2006	\$ 325,509
2007	119,424
2008	2,946
Thereafter	—
	447,879

Operating leases relate primarily to the lease of office and laboratory premises in Australia, the UK and Singapore, as well as some office equipment. Rental payments for leased premises are subject to annual or biannual rental reviews. The Company has a three year renewal option on its Australian office premises.

**19. Subsequent events**

On 25 July 2005, the Company announced that it had appointed Dr David Mazzo as a non-executive director of the Company.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

On 27 July 2005, the Company announced that it had appointed Mr Michael Rogers as a non-executive director of the Company.

On 15 August 2005, the Company announced that it was in negotiations and undertaking due diligence to acquire a US based specialized drug delivery company through the issue of ADRs.

On 23 August 2005, the Company announced that it had raised US\$4.2 million (\$5.6 million) before costs via the private placement of 665,000 ADRs to predominantly US investors at US\$6.50 each (\$8.61) pursuant to a PIPE. Each ADR represents ten ordinary shares. The ADRs have an attached one for ten, three- year warrant (66,500 warrants) exercisable at US\$12.50 per ADR. The Company also issued a further 66,500 warrants as part payment of placing fees in relation to this transaction. The financial effects of this transaction are not reflected in the accounts as at 30 June 2005.

On 4 October 2005, the Company announced that it had entered into a definitive merger agreement to acquire Control Delivery Systems, Inc. (CDS), a private drug delivery company located in the Boston, Massachusetts area. The acquisition is subject to Australian regulatory and pSivida shareholder approvals, as well as other customary closing conditions.

The acquisition will be funded through the issue of approximately 16,000,000 pSivida American Depositary Shares (ADS) to CDS stockholders (representing 160,000,000 ordinary shares in the Company). Based on a price of US\$6.50 (\$8.66) per pSivida ADS, the transaction would represent a purchase price of approximately US\$250 million (\$333 million) for the combined company. The financial effects of this transaction are not reflected in the accounts as at 30 June 2005.

On 6 October 2005, the Company announced that it had signed an agreement with a New York based institutional accredited investor, pursuant to which the investor, subject to satisfaction of closing conditions, agreed to purchase US\$15 million of subordinated convertible debentures, convertible into PSDV ADRs at an initial conversion price of US\$7.10 (\$9.50). The proceeds of the issuance are expected to be used for the expanded development of BioSilicon™. The closing conditions were met and the convertible note was issued on 16 November 2005. The financial effects of this transaction are not reflected in the accounts as at 30 June 2005.

## 20. Loss per share

The following reflects the net loss and share information used in the calculation of basic and diluted loss per share:

	2005 \$	2004 \$	2003 \$
Net loss before outside equity interest	(15,125,719)	(7,518,976)	(5,356,328)
Adjustments:			
Net loss attributable to outside equity interest	399,196	3,835,771	2,591,175
Loss used in calculating basic and diluted loss per share	<u>(14,726,523)</u>	<u>(3,683,205)</u>	<u>(2,765,153)</u>

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

	<u>Number</u>	<u>Number</u>	<u>Number</u>
Weighted average number of ordinary shares used in calculating basic loss per share	207,802,540	126,990,066	101,281,292
Effect of dilutive securities:			
Share options	—	—	—
Adjusted weighted average number of ordinary shares used in calculating basic and diluted loss per share	<u>207,802,540</u>	<u>126,990,066</u>	<u>101,281,292</u>

The following potential ordinary shares are not dilutive and are therefore excluded from the weighted average number of ordinary shares and potential ordinary shares used in the calculation of diluted earnings per share:

Share options	<u>18,971,713</u>	<u>19,965,000</u>	<u>23,700,000</u>
---------------	-------------------	-------------------	-------------------

Since the end of the financial year the Company has issued 665,000 ADRs (representing 6,650,000 ordinary shares) at a price of US\$6.50 per ADR and 78,000 warrants over ADRs (representing 780,000 options over ordinary shares) expiring 5 August 2008, exercisable at US\$12.50 per warrant, pursuant to a PIPE.

There have been no other conversions to, calls of, or subscriptions for ordinary shares or issues of potential ordinary shares since the reporting date and before the completion of this annual report.

## **21. Director and executive disclosures**

### **(a) Details of specified directors and specified executives**

The specified directors of pSivida Limited during the year were:

- Dr Roger Brimblecombe — Non-Executive Chairman
- Mr Gavin Rezos — Managing Director
- Dr Roger Aston — Director, Strategy
- Mr Stephen Lake — Non-Executive Director (appointed 30 July 2004)
- Ms Alison Ledger — Non-Executive Director (appointed 30 July 2004)
- Mrs Nadine Donovan — Former Finance Director (resigned 30 July 2004)

The specified executives of the consolidated entity during the year were:

- Prof Leigh Canham — Chief Scientific Officer, pSiMedica Limited
- Mr Aaron Finlay — Company Secretary, Chief Financial Officer
- Dr Anna Kluczevska — Managing Director, AION Diagnostics Limited
- Mr Steve Connor — Operations Director, pSiMedica Limited
- Dr Jill Ogden — Commercialization Director, pSiMedica Limited

**PSIVIDA LIMITED AND SUBSIDIARIES**  
(A Development Stage Enterprise)

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
In Australian Dollars (except as otherwise stated)

**(b) Remuneration of specified directors and specified executives**

**(i) Remuneration policy**

The Remuneration Committee of the Board of Directors of pSivida Limited is responsible for determining and reviewing compensation arrangements for the directors, the managing director and the executive team. The Remuneration Committee assesses the appropriateness of the nature and amount of the emoluments of such officers on a periodic basis by reference to relevant employment market conditions with the overall objective of ensuring maximum stakeholder benefit from the retention of a high quality Board and executive team.

**(ii) Remuneration of specified directors and specified executives**

*Specified directors*

	Primary Salary and Fees \$	Bonus \$	Post Employment Super- annuation \$	Other Benefits \$	Equity Options* (ii) \$	Total \$	Total Cash-based Remuneration \$
<b>2005</b>							
Dr R Brimblecombe	224,459	25,000	—	—	229,296	478,755	249,459
Mr G Rezos	348,062	75,000	10,905	—	1,361,127	1,795,094	433,967
Dr R Aston	315,683	25,000	8,438	1,189	558,592	908,902	350,310
Mr S Lake	22,917	—	—	—	91,718	114,635	22,917
Ms A Ledger	27,500	—	2,475	—	91,718	121,693	29,975
Mrs N Donovan	2,083	—	188	—	—	2,271	2,271
<b>Total</b>	<b>940,704</b>	<b>125,000</b>	<b>22,006</b>	<b>1,189</b>	<b>2,332,451</b>	<b>3,421,350</b>	<b>1,088,899</b>
<b>2004</b>							
Dr R Brimblecombe	152,992	—	—	—	145,200	298,192	152,992
Mr G Rezos	363,881	250,000	27,320	—	435,600	1,076,801	641,201
Dr R Aston	302,822	40,000	40,711	—	181,500	565,033	383,533
Mrs N Donovan	90,325	—	2,250	—	127,050	219,625	92,575
<b>Total</b>	<b>910,020</b>	<b>290,000</b>	<b>70,281</b>	<b>—</b>	<b>889,350</b>	<b>2,159,651</b>	<b>1,270,301</b>

\* These options had no taxable value at the date of issue.



**PSIVIDA LIMITED AND SUBSIDIARIES**  
(A Development Stage Enterprise)

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
In Australian Dollars (except as otherwise stated)

*Specified executives*

	Primary Salary and Fees \$	Bonus \$	Post Employment Super- annuation \$	Other Benefits \$	Equity Options* (ii) \$	Total \$	Total Cash-based Remuneration \$
<b>2005</b>							
Prof L Canham	193,780	—	22,553	6,056	353,524	575,913	222,389
Mr A Finlay	144,572	32,500	13,135	—	370,396	560,603	190,207
Dr A Kluczevska	208,333	10,000	—	—	299,808	518,141	218,333
Mr S Connor	181,146	—	21,738	10,612	143,751	357,247	213,496
Dr J Ogden	169,816	—	20,378	6,060	143,751	340,005	196,254
<b>Total</b>	<b>897,647</b>	<b>42,500</b>	<b>77,804</b>	<b>22,728</b>	<b>1,311,230</b>	<b>2,351,909</b>	<b>1,040,679</b>
<b>2004</b>							
Dr A Kluczevska	143,600	25,000	—	—	295,572	464,172	168,600
Prof L Canham	180,537	—	35,410	3,832	—	219,779	219,779
Mr S Connor	176,773	—	23,683	6,941	—	207,397	207,397
Dr R Saffie	130,742	—	15,441	2,307	—	148,490	148,490
Dr J Ogden	102,873	—	11,581	3,072	—	117,526	117,526
<b>Total</b>	<b>734,525</b>	<b>25,000</b>	<b>86,115</b>	<b>16,152</b>	<b>295,572</b>	<b>1,157,364</b>	<b>861,792</b>

\* These options had no taxable value at the date of issue.

- (i) Bonuses were paid in cash on 17 March 2005 as part of an annual staff review. Bonuses were determined based on a review of staff performance conducted by the remuneration committee.
- (ii) During the year options were granted to directors and specified executives in August 2004 in respect of the pSiMedica acquisition and April 2005 in respect of annual performance reviews, pursuant to the Company's Employee Share Option Plan, which have been included as equity options remuneration above. These options have been valued using the Black Scholes Option Valuation Model, which takes into account time value and the volatility of the stock price.

A total of 8,251,000 options were issued to directors and employees in August 2004. The options are exercisable at \$1.18, being an 8% premium to the share price at the time of the grant, and may be exercised between the date of grant and expiry on 5 August 2009.

A total of 3,152,000 options were issued to employees in April 2005. The options are exercisable at \$0.80, being a 7% premium to the share price at the time of the grant. The options are subject to varying vesting and performance conditions and expire on 31 March 2010.

The following directors and executives were under contract at 30 June 2005:

Mr Gavin Rezos has a contract dated December 12, 2000, amended in April 2005, which provides for directors fees of \$126,000 plus superannuation at a rate of 9% and bonus payments and options to be awarded on a discretionary basis. The contract will continue until termination by either party on one months notice. Accrued entitlements are payable upon termination. In addition Mr Gavin Rezos has a consultancy agreement which provides for an annual fee of \$204,750 which will similarly continue until termination by either party.

**PSIVIDA LIMITED AND SUBSIDIARIES  
(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)  
In Australian Dollars (except as otherwise stated)**

Dr Roger Aston had a consultancy contract dated December 12, 2000, amended in April 2005, which provides for an annual fee of \$250,000 with bonus payments and options to be awarded on a discretionary basis. The contract will continue until termination by either party on one months notice. Accrued entitlements are payable upon termination.

Mr A Finlay has a contract dated May 17, 2004, amended in April 2005, which provides for a base annual salary of \$200,000 plus superannuation at a rate of 9% and bonus payments and options to be awarded on a discretionary basis. The employment contract will continue until termination by either party on one months notice. Accrued entitlements are payable upon termination.

Prof L Canham has a contract dated December 12, 2000, amended in January 2005, which provides for a base annual salary of £77,327 (A\$183,110) plus superannuation at a rate of 12% and bonus payments and options to be awarded on a discretionary basis. The employment contract will continue until termination by either party on six months notice. Accrued entitlements are payable upon termination.

Dr A Kluczevska has a consultancy contract dated April 7, 2004, amended in April 2005, which provides for an annual fee of \$250,000, 1.2 million options vesting over a three year period based on the achievement of performance milestones and bonus payments and any additional options to be awarded on a discretionary basis. The contract will continue until termination by either party on one months notice.

Mr S Connor has a contract dated November 1, 2001, amended in January 2005, which provides for a base annual salary of £74,884 (A\$177,325) plus superannuation at a rate of 12% and bonus payments and options to be awarded on a discretionary basis. The employment contract will continue until termination by either party on six months notice. Accrued entitlements are payable upon termination.

Dr J Ogden has a contract dated November 17, 2003, amended in January 2005, which provides for a base annual salary of £70,200 (A\$166,2334) plus superannuation at a rate of 12% and bonus payments and options to be awarded on a discretionary basis. The employment contract will continue until termination by either party on six months notice. Accrued entitlements are payable upon termination.

Dr M Parry-Billings has a contract dated January 6, 2005, which provides for a base annual salary of £125,000 (A\$296,000) plus superannuation at a rate of 12%, 1.2 million options vesting over a three year period based on the achievement of performance milestones and bonus payments and any additional options to be awarded on a discretionary basis. The employment contract will continue until termination by either party on six months notice. Accrued entitlements are payable upon termination.

**(c) Remuneration options granted and vested during the year**

During the financial year options were granted as equity compensation benefits to certain specified directors and specified executives as disclosed below. The options were issued free of charge. Each option entitles the holder to subscribe for one fully paid ordinary share in the entity at the exercise price stated below. The options may only be exercised after the vesting date stated below, and expire on the dates shown below. Vesting of the options is dependent on the achievement of certain key performance criteria where indicated. The key performance criteria to be met are in respect of certain employee performance targets.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
(A Development Stage Enterprise)

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
In Australian Dollars (except as otherwise stated)

*Share options issued by pSivida Limited*

	Vested Number	Granted Number	Grant Date	Terms and Conditions for Each Grant				
				Value Per Option at Grant Date** \$	Value of Underlying Share at Grant Date \$	Exercise Price Per Share \$	Vesting Date	Expiry Date
<b>Specified directors</b>								
Dr R Brimblecombe	500,000	500,000	5 Aug 04	\$ 0.46	\$ 1.09	\$ 1.18	5 Aug 04	5 Aug 09
Mr G Rezos	2,750,000	2,750,000	5 Aug 04	\$ 0.46	\$ 1.09	\$ 1.18	5 Aug 04	5 Aug 09
Dr R Aston	1,000,000	1,000,000	5 Aug 04	\$ 0.46	\$ 1.09	\$ 1.18	5 Aug 04	5 Aug 09
Mr S Lake	200,000	200,000	5 Aug 04	\$ 0.46	\$ 1.09	\$ 1.18	5 Aug 04	5 Aug 09
Ms A Ledger	200,000	200,000	5 Aug 04	\$ 0.46	\$ 1.09	\$ 1.18	5 Aug 04	5 Aug 09
<b>Total</b>	<b>4,650,000</b>	<b>4,650,000</b>						
<b>Specified executives</b>								
Prof L Canham	700,000	700,000	5 Aug 04	\$ 0.46	\$ 1.09	\$ 1.18	5 Aug 04	5 Aug 09
	—	125,000*	22 Apr 05	\$ 0.26	\$ 0.75	\$ 0.80	22 Apr 06	31 Mar 10
Mr A Finlay	700,000	700,000	5 Aug 04	\$ 0.46	\$ 1.09	\$ 1.18	5 Aug 04	5 Aug 09
	—	200,000	22 Apr 05	\$ 0.26	\$ 0.75	\$ 0.80	22 Apr 06	31 Mar 10
Dr A Kluczevska	100,000	100,000	5 Aug 04	\$ 0.46	\$ 1.09	\$ 1.18	5 Aug 04	5 Aug 09
	—	125,000	22 Apr 05	\$ 0.26	\$ 0.75	\$ 0.80	22 Apr 06	31 Mar 10
	400,000							
Mr S Connor	300,000	300,000	5 Aug 04	\$ 0.46	\$ 1.09	\$ 1.18	5 Aug 04	5 Aug 09
	—	125,000*	22 Apr 05	\$ 0.26	\$ 0.75	\$ 0.80	22 Apr 06	31 Mar 10
Dr J Ogden	300,000	300,000	5 Aug 04	\$ 0.46	\$ 1.09	\$ 1.18	5 Aug 04	5 Aug 09
	—	125,000*	22 Apr 05	\$ 0.26	\$ 0.75	\$ 0.80	22 Apr 06	31 Mar 10
<b>Total</b>	<b>2,500,000</b>	<b>2,800,000</b>						

*Share options issued by AION Diagnostics Limited*

	Vested Number	Granted Number	Grant Date	Terms and Conditions for Each Grant			
				Value Per Option at Grant Date** \$	Value of Underlying Share at Grant Date \$	Exercise Price Per Share \$	Expiry Date
<b>Specified directors</b>							
Mr G Rezos	—	250,000*	3 Feb 05	\$ 0.40	\$ 0.40	Nil	3 Feb 08
Dr R Aston	—	250,000*	3 Feb 05	\$ 0.40	\$ 0.40	Nil	3 Feb 08
<b>Total</b>	<b>—</b>	<b>500,000</b>					
<b>Specified executives</b>							
Prof L Canham	—	65,840*	3 Feb 05	\$ 0.40	\$ 0.40	Nil	3 Feb 08
Mr A Finlay	—	98,760*	3 Feb 05	\$ 0.40	\$ 0.40	Nil	3 Feb 08
Dr A Kluczevska	—	395,040*	3 Feb 05	\$ 0.40	\$ 0.40	Nil	3 Feb 08
<b>Total</b>	<b>—</b>	<b>559,640</b>					

**PSIVIDA LIMITED AND SUBSIDIARIES**  
(A Development Stage Enterprise)

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
In Australian Dollars (except as otherwise stated)

\* Vesting of these options is subject to performance conditions. Performance conditions for executive staff and directors include specific criteria relating to the employee's role within the Company. Performance conditions for other staff require the satisfactory performance of their role.

\*\* Options have been valued using the Black Scholes Option Valuation Model, which takes into account time value and the volatility of the stock price.

**(d) Shares issued on exercise of remuneration options**

	Shares Issued Number	Amount Paid Per Share \$	Amount Unpaid Per Share \$
<b>Specified directors</b>			
Mrs N Donovan	250,000	\$ 0.20	—
	150,000	\$ 0.40	—
<b>Total</b>	<b>400,000</b>		

**(e) Specified directors' and specified executives' equity holdings**

*Fully paid ordinary shares of pSivida Limited*

	Balance at 1 July 2004 Number	Granted as Remuneration Number	Net Other Change Number	Balance at 30 Jun 2005 Number
<b>Specified directors</b>				
Dr R Brimblecombe	320,833	—	124,234	445,067
Mr G Rezos	10,895,657	—	423,625	11,319,282
Dr R Aston	3,090,833	—	4,002,753	7,093,586
Mr S Lake*	—	—	—	—
Ms A Ledger*	2,000,000	—	(100,000)	1,900,000
Mrs N Donovan**	54,333	—	—	54,333
<b>Total</b>	<b>16,361,656</b>	<b>—</b>	<b>4,450,612</b>	<b>20,812,268</b>
<b>Specified executives</b>				
Prof L Canham	—	—	3,909,579	3,909,579
Mr A Finlay	—	—	—	—
Dr A Kluczevska	—	—	—	—
Mr S Connor	—	—	189,000	189,000
Dr J Ogden	—	—	—	—
<b>Total</b>	<b>—</b>	<b>—</b>	<b>4,098,579</b>	<b>4,098,579</b>

\* Opening balance at date of appointment

\*\* Closing balance at date of resignation

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

*Share options issued by pSivida Limited*

	<u>Balance at 1 July 2004 Number</u>	<u>Granted As Remuneration Number</u>	<u>Net Other Change Number</u>	<u>Balance at 30 Jun 2005 Number</u>
<b>Specified directors</b>				
Dr R Brimblecombe	1,000,000	500,000	(550,889)	949,111
Mr G Rezos	5,450,000	2,750,000	(4,228,970)	3,971,030
Dr R Aston	4,500,000	1,000,000	(3,950,889)	1,549,111
Mr S Lake*	—	200,000	42,061	242,061
Ms A Ledger*	—	200,000	—	200,000
Mrs N Donovan**	850,000	—	—	850,000
Total	<u>11,800,000</u>	<u>4,650,000</u>	<u>(8,688,687)</u>	<u>7,761,313</u>
<b>Specified executives</b>				
Prof L Canham	—	825,000	39,289	864,289
Mr A Finlay	—	900,000	—	900,000
Dr A Kluczevska	1,200,000	225,000	—	1,425,000
Mr S Connor	—	425,000	19,645	444,645
Dr J Ogden	—	425,000	129,708	554,708
Total	<u>1,200,000</u>	<u>2,800,000</u>	<u>188,642</u>	<u>4,188,642</u>

\* Opening balance at date of appointment

\*\* Closing balance at date of resignation

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

*Share options issued by AION Diagnostics Limited*

	<u>Balance at 1 July 2004 Number</u>	<u>Granted As Remuneration Number</u>	<u>Net Other Change Number</u>	<u>Balance at 30 Jun 2005 Number</u>
<b>Specified directors</b>				
Dr R Brimblecombe	—	—	—	—
Mr G Rezos	—	250,000	—	250,000
Dr R Aston	—	250,000	—	250,000
Mr S Lake*	—	—	—	—
Ms A Ledger*	—	—	—	—
Mrs N Donovan**	—	—	—	—
Total	—	500,000	—	500,000
<b>Specified executives</b>				
Prof L Canham	—	65,840	—	65,840
Mr A Finlay	—	98,760	—	98,760
Dr A Kluczewska	—	395,040	—	395,040
Mr S Connor	—	—	—	—
Dr J Ogden	—	—	—	—
Total	—	559,640	—	559,640

\* Opening balance at date of appointment

\*\* Closing balance at date of resignation

**(f) Other transactions with specified directors**

All transactions with related parties are made on normal commercial terms and conditions except where indicated.

Consultancy fees and other payments of Nil (2004: \$341,362; 2003: \$173,333) were paid to Aymon Pacific Pty Ltd, a company controlled by Mr G Rezos, and have been included in directors' remuneration above.

Consultancy fees and other payments of \$319,941 (2004: \$44,000; 2003: Nil) were paid to Newtonmore Biosciences Pty Ltd, a company controlled by Dr R Aston. The portion of this amount relating to services performed by Dr Aston has been included in directors' remuneration above.

Consultancy fees of \$2,083 (2004: \$71,858; 2003: \$45,000) were paid to Blackwood Pty Ltd, a company controlled by Mrs N Donovan, and have been included in directors' remuneration above.

An amount of £220,689 (\$544,320) (2004 £186,682 (\$457,567)) (2003: £207,492 (\$564,033)) was paid or payable to QinetiQ Limited, a shareholder of pSivida Limited and former shareholder of pSiMedica Limited, for the use of laboratory facilities and for patent filing and administration.

During the year \$114,732 (2004: \$78,068; 2003: \$22,622) was paid to Blake Dawson Waldron (BDW) for various routine arm's length legal services. BDW is a national Australian firm with over 180 partners. One of those partners is a relative of a pSivida director.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

An amount of Nil (2004: \$12,637; 2003: \$52,187) was paid to Viaticus Capital Ltd, a company controlled by Mr G Rezos, for sublease of BGC Centre office space. A further amount of \$332,085 (2004: Nil; 2003: Nil) was paid to Viaticus Capital Ltd for consultancy fees and other payments, and has been included in directors' remuneration above.

An amount of \$125,982 (2004: \$149,489; 2003: Nil) was paid to Albion Capital Partners, of which Mr G Rezos is a partner, for sublease of BGC Centre office space. A further amount of \$63,360 (2004: Nil; 2003: Nil) was paid to Albion Capital Partners for financial analyst services.

Amounts owing to directors, director-related parties and other related parties at 30 June 2005 were \$50,102 (2004: \$37,144; 2003: \$31,182).

**22. Auditor's remuneration**

	2005 \$	2004 \$	2003 \$
<i>Amounts received or receivable for:</i>			
An audit or review of the statutory financial report of the Company	24,240	16,500	16,000
Other services in relation to the Company	1,020	6,000	4,628
	<u>25,260</u>	<u>22,500</u>	<u>20,628</u>
<i>Amounts received or due and receivable by the auditors other than the statutory auditors of pSivida for:</i>			
An audit or review of the financial statements of subsidiary entities	42,423	30,393	38,600
Audit services in relation to US SEC and NASDAQ requirements on listing and annual lodgements	638,768	—	—
Other services in relation to the Company	14,432	—	—
	<u>695,623</u>	<u>30,393</u>	<u>38,600</u>

**PSIVIDA LIMITED AND SUBSIDIARIES**  
(A Development Stage Enterprise)

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
In Australian Dollars (except as otherwise stated)

**23. Segment information**

**(a) Business segment — primary segment**

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

**(b) Geographic segment — secondary segment**

Segment revenues are attributed to countries based on the location of where the revenue is earned.

	Australia \$	United Kingdom \$	Singapore \$	Unallocated \$	Eliminations \$	Consolidated \$
Segment revenues from external customers						
Year ended 30 June						
2005	—	161,666	—	667,310	—	828,976
2004	888	55,312	—	325,479	—	381,679
2003	25,065	72,729	12,881	—	—	110,675
Segment assets						
As at 30 June						
2005	11,429,117	68,660,341	1,934,243	—	(21,135)	82,002,566
2004	29,733,723	8,145,493	3,299,932	—	(812,090)	40,367,058
Acquisition of segment assets						
Year ended 30 June						
2005	56,920	61,176,255	20,836	—	—	61,254,011
2004	4,901,489	3,696,463	—	—	(5,501,723)	3,096,229
Goodwill, net						
As at 30 June						
2005	—	8,909,744	—	—	—	8,909,744
2004	—	—	—	—	—	—
Long lived assets						
As at 30 June						
2005	82,292	3,171,902	19,469	—	—	3,273,663
2004	69,313	600,386	—	—	—	669,699

**24. Financial instruments**

**(a) Significant accounting policies**

Details of the significant accounting policies and methods adopted, including criteria for recognition, the basis of measurement and the basis on which revenues and expenses are recognized, in respect of each class of financial asset, financial liability, and equity instrument are disclosed in Note 1.

**(b) Interest rate risk**

Deposits or withdrawals from term deposits may be made at any time without prior notice or penalty. Receivables and payables are non-interest bearing.



**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

The Company's exposure to interest rates and the effective weighted average interest rate for classes of financial assets and liabilities is set out below:

	Notes	Floating Interest Rate \$	Fixed Interest Rate \$	Non-Interest Bearing \$	Total \$	Weighted Average Interest Rate %
<b>2005</b>						
<i>Financial assets</i>						
Cash assets	17(a)	12,528,926	200,000	163,135	12,892,061	2.87
Receivables	6	—	—	709,418	709,418	n/a
		<u>12,528,926</u>	<u>200,000</u>	<u>872,553</u>	<u>13,601,479</u>	
<i>Financial liabilities</i>						
Payables	10	—	—	2,017,820	2,017,820	—
<b>2004</b>						
<i>Financial assets</i>						
Cash assets	17(a)	31,350,656	—	—	31,350,656	4.4
Receivables	6	—	—	340,482	340,482	n/a
		<u>31,350,656</u>	<u>—</u>	<u>340,482</u>	<u>31,691,138</u>	
<i>Financial liabilities</i>						
Payables	10	—	—	1,882,104	1,882,104	—

**(c) Fair values**

The fair values of the financial assets and liabilities at the balance sheet date approximate the carrying amounts in the financial statements, except where specifically stated and determined in accordance with the accounting policies disclosed in Note 1.

**(d) Credit risk exposure**

The Company's maximum exposure to credit risk to each class of recognized financial asset is the carrying amount, net of any provisions for doubtful debts, of those assets as indicated in the balance sheet. The directors believe the Company has no significant concentration of credit risk.

**25. Additional Company information**

pSivida Limited is a listed public company, incorporated and operating in Australia.

Level 12, BGC Centre  
28 The Esplanade  
Perth WA 6000  
Australia  
Tel: 61 8 9226 5099

**PSIVIDA LIMITED AND SUBSIDIARIES  
(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)  
In Australian Dollars (except as otherwise stated)**

**26. Impacts of adopting Australian equivalents to International Financial Reporting Standards (unaudited)**

**(a) Management of the transition to AIFRS**

pSivida Limited will be required to prepare financial statements that comply with the Australian equivalents of International Financial Reporting Standards (“AIFRS”) as adopted by the Australian Accounting Standards Board (“AASB”) for annual reporting periods beginning on or after 1 January 2005. Accordingly, pSivida’s first half-year report prepared under AIFRS will be for the half-year reporting period ending 31 December 2005, and its first annual financial report prepared under AIFRS will be for the year ending 30 June 2006.

The transitional rules for first time adoption of AIFRS require that the Company restate its comparative financial statements using AIFRS, except for AASB 132: “Financial Instruments: Disclosure and Presentation” (“AASB 132”) and AASB 139: “Financial Instruments: Recognition and Measurement” (“AASB 139”) where comparative information is not required to be restated. Currently, the Company provides two years of comparative financial information in its financial statements to comply with applicable US Securities and Exchange Commission (“SEC”) requirements. The SEC has granted a one-time relief from this requirement for foreign registered companies preparing their first set of financial statements in compliance with International Financial Reporting Standards. The Company has elected to apply this relief and will only provide one year of comparative information in the 30 June 2006 financial statements. For reporting in the 2006 fiscal year, comparatives will be remeasured and restated for the half-year ended 31 December 2004 and the financial year ended 30 June 2005. Most of the adjustments on transition are required to be made to opening retained profits at the beginning of the first comparative period (i.e. at 1 July 2004).

In 2004 the Company commenced a review of accounting policies in preparation for managing the transition to AIFRS. Priority has been given to considering the preparation of an opening balance sheet in accordance with AIFRS as at 1 July 2004, the Company’s transition date to AIFRS. This will form the basis of accounting for AIFRS in the future and is required when the Company prepares its first fully AIFRS compliant financial report for the year ended 30 June 2006.

**(b) The likely impacts of AIFRS on the results and financial position of the Company**

Set out below are the known key differences in accounting policy and our known estimable transitional differences identified as of 30 June 2005, where accounting policies are expected to change on adoption of AIFRS and the likely impacts on the current year operating results and financial position of the Company, had the financial statements been prepared using AIFRS, based on the directors’ accounting policy decisions current at the date of this financial report. The adjustments included are based on the AIFRS standards released as at June 30, 2005. These are subject to ongoing review and any amendments by the AASB, or by interpretative guidance from the International Accounting Standards Board or AASB, could change the adjustments included. The AIFRS standards and interpretations that will apply to the Company will be those released as at December 31, 2005 being the date of the first half year financial statements that the Company has to publish under AIFRS. The disclosures below represent the Company’s current best estimate of the quantitative impact of the AIFRS implementation at the date of this report and accordingly they remain subject to change.

There are certain items that still require resolution and additional differences in accounting policy that may be identified. The directors may, at any time until the completion of the Company’s first AIFRS

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

compliant financial report, elect to revisit, and where considered necessary, revise the accounting policies applied in preparing the disclosures below.

**(c) Adjustments to balance sheet items under AIFRS (net of tax)**

**(i) Intangibles**

Under AASB 3, “Business Combinations” (“AASB 3”) goodwill would not be permitted to be amortized but instead is subject to impairment testing on an annual basis or upon triggers which may indicate a potential impairment. As a result accumulated goodwill amortization of \$973,923 (all expensed during the year ended 30 June 2005) would be added back to the value of intangibles as at 30 June 2005.

**(ii) Share-based payments**

Under AASB 2: “Share-Based Payment” (“AASB 2”) equity-settled share-based payments in respect of equity instruments issued after 7 November 2002 that were unvested as at 1 January 2005 are measured at fair value at grant date. The fair value determined at grant date of equity-settled share-based payments is expensed on a straight-line basis over the vesting period, based on the estimated number of equity instruments that will vest. As a consequence, contributed equity will increase by \$591,900 as at 30 June 2005.

**(iii) Foreign currency translation reserve**

The directors have elected to set the translation reserve to zero as at AIFRS transition as permitted under AASB 1 “First-Time Adoption of Australian Equivalents to International Financial Reporting Standards” (“AASB 1”). This results in the transfer of \$78,220 from the foreign currency translation reserve to retained earnings as at AIFRS transition on 1 July 2004.

**(iv) Accumulated losses**

With limited exceptions, adjustments required on first-time adoption of AIFRS are recognized directly in accumulated losses at the date of transition to AIFRS. The cumulative effect of these adjustments for the Company will be a decrease in opening accumulated losses of \$78,220 as of 1 July 2004.

**(d) Adjustments to current year loss under AIFRS (net of tax)**

**(i) Intangibles**

Under AASB 3, goodwill would not be permitted to be amortized but instead is subject to impairment testing on an annual basis or upon triggers which may indicate a potential impairment. As a result goodwill amortization expense of \$973,923 recorded in the year ended 30 June 2005 would be added back to the net loss for the year. There is no goodwill amortization required to be added back to the net loss upon the transition date of 1 July 2004.

**(ii) Share-based payments**

Under AASB 2, equity-settled share-based payments in respect of equity instruments issued after 7 November 2002 that were unvested as at 1 January 2005 are measured at fair value at grant date. The fair value determined at grant date of equity-settled share-based payments is expensed on a straight-line basis over the vesting period, based on the estimated number of equity instruments that will vest. As a

**PSIVIDA LIMITED AND SUBSIDIARIES  
(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)  
In Australian Dollars (except as otherwise stated)**

consequence, an additional employee benefit expense of \$508,613 and consultancy fees expense of \$83,287 will be recognized in the profit and loss for the year ended 30 June 2005.

**(e) Other impacts**

(i) Management has decided to apply the exemption provided in AASB 1, which permits entities not to restate business combinations that occurred prior to the date of transition to AIFRS. Business combinations occurring after the date of transition (i.e., 1 July 2004) will be subject to the provisions of AASB 3.

(ii) Management has decided to apply the exemption provided in AASB 1 which permits entities not to apply the requirements of AASB 132 and AASB 139, for the year ended 30 June 2005. The standards will be applied from 1 July 2005. Management is in the process of determining the impact that adopting the standards would have on the financial statements of the Company.

(iii) Under AASB 136: "Impairment of Assets," the Company's assets, including goodwill would be tested for impairment as part of the cash generating unit to which they belong, and any impairment losses recognized in the statement of financial performance. At this stage in the Company's review process the Company is not aware of any impairment issues that would result in a material adjustment to the financial statements.

(iv) No material impacts are expected to the cash flows as presented under current A-GAAP on adoption of AIFRS.

**(f) Acquisition of minority interest**

During the year ended 30 June 2005, the Company purchased minority interests in controlled entity pSiMedica Limited. Under current A-GAAP this acquisition has been accounted for separately from other acquisitions (that is, as a step acquisition, which involved the separate determination and recognition of the fair values of the net assets of the subsidiary and any goodwill arising on the acquisition).

AASB 127: "Consolidated and Separate Financial Statements" requires minority interests to be classified as equity. Consequently, the acquisition by the Company of additional ownership interests in pSiMedica Limited represents an equity transaction. As such, accounting for the transaction as a step acquisition may not be appropriate. The financial effect of the adjustment required on the restatement of the 30 June 2005 accounts is yet to be determined.

**27. Reconciliation to US GAAP**

The financial statements have been prepared in accordance with A-GAAP, which differ in certain respects from US GAAP. The following is a summary of the adjustments to net loss and total equity required when reconciling such amounts recorded in the financial statements to the corresponding amounts in accordance with US GAAP, considering the differences between A-GAAP and US GAAP.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

**Restatement of US GAAP amounts**

Subsequent to the issuance of the June 30, 2004 consolidated financial statements, the Company changed the amounts previously reported in the US GAAP reconciliation for the accounting for deferred income taxes as follows:

- Deferred tax liability for acquired intangible assets — Previously, deferred taxes were not recorded on the intangible assets acquired in connection with the step acquisition of pSiMedica as the book to tax basis differences were deemed to be permanent as the amortization of the related intangibles is not deductible for income tax purposes. The Company has subsequently concluded that, although under tax law, it will not receive a tax deduction in the future for recovery of the intangible assets, recognition of a deferred tax liability on the acquired intangibles is nevertheless required under US GAAP because it is assumed for financial reporting purposes that the Company will generate future revenues at least equal to the recorded amount of the investment, and recovery will result in future taxable amounts.
- Valuation allowance for deferred income tax assets — Previously in establishing a valuation allowance, the Company fully reserved the total balance of the deferred income tax assets related to tax loss carryforwards as it was deemed more likely than not that the deferred tax assets would not be realized. As a result of the recognition of the US GAAP deferred tax liabilities in connection with the step acquisition of pSiMedica as per the above, the Company has reevaluated the recoverability of the deferred income tax assets, taking into consideration the reversal of taxable temporary differences under US GAAP.
- Amortization of intangible assets — Where the recognition of a deferred tax liability for acquired intangible assets as per the above resulted in additional basis of the related intangible, the additional basis is being amortized over the remaining estimated useful life of the intangible asset for US GAAP purposes.

The effect of the adjustments on previously reported US GAAP net loss and total equity is as follows:

	<b>Years Ended 30 June</b>	
	<b>2004</b>	<b>2003</b>
	<b>\$</b>	<b>\$</b>
US GAAP net loss, as previously reported	(6,059,011)	(3,288,418)
Correction to deferred income taxes, net	1,318,950	1,216,235
Correction to intangible amortization expense	(279,913)	(196,420)
US GAAP net loss, as restated	<u>(5,019,974)</u>	<u>(2,268,603)</u>
US GAAP basic and diluted loss per share, as previously reported	\$ (0.05)	\$ (0.03)
US GAAP basic and diluted loss per share, as restated	\$ (0.04)	\$ (0.02)
	<b>30 June</b>	<b>1 July</b>
	<b>2004</b>	<b>2004</b>
	<b>\$</b>	<b>\$</b>
US GAAP total equity, as previously reported	34,819,468	5,204,116
Correction to deferred income taxes, net	3,674,230	2,355,280
Correction to intangible amortization expense	(698,993)	(419,080)
US GAAP total equity, as restated	<u>37,794,705</u>	<u>7,140,316</u>

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

**Reconciliation of net loss**

The following is a reconciliation of net loss as reported in the consolidated statements of financial performance under A-GAAP to net loss as adjusted for the effects of the application of US GAAP for the years ended 30 June 2005, 2004 and 2003:

	Years Ended 30 June		
	2005 \$	2004 \$ (As restated)	2003 \$ (As restated)
Net loss in accordance with A-GAAP	(14,726,523)	(3,683,205)	(2,765,153)
<i>US GAAP adjustments:</i>			
Share-based compensation expense (a)			
Options issued to consultants	(156,204)	(250,933)	(54,951)
Options issued to directors, executives and employees	(125,018)	(448,920)	(10,000)
Intangible assets			
Fair value of shares issued as consideration — amortization expense (b)	(18,198)	(18,198)	(18,198)
Direct acquisition costs — amortization expense (c)	(9,357)	(9,357)	(9,357)
Amortization of intangible assets (d)	(5,749,870)	(650,140)	(451,606)
Sales of stock by subsidiaries — amortization expense (f)	(39,232)	15,840	20,847
In-process research and development (g)	—	(1,035,018)	—
Gross-up attributable to deferred tax liability — amortization expense (h)	(335,617)	(279,913)	(196,420)
Reversal of goodwill amortization (e)	973,923	—	—
Deferred income taxes (h)	3,645,504	1,318,950	1,216,235
Outside equity interest — US GAAP adjustments (i)	(20,920)	20,920	—
Net loss in accordance with US GAAP	<u>(16,561,512)</u>	<u>(5,019,974)</u>	<u>(2,268,603)</u>
Loss per share in accordance with US GAAP:			
Basic and diluted	\$(0.08)	\$(0.04)	\$(0.02)
Weighted average shares — basic and diluted	207,802,540	126,990,066	101,281,292

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

**Reconciliation of total equity**

The following is a reconciliation of total equity as reported in the consolidated statements of financial position under A-GAAP to total equity as adjusted for the effects of the application of US GAAP as of 30 June 2005 and 2004:

	30 June	
	2005 \$	2004 \$ (As restated)
Total equity in accordance with A-GAAP	79,987,614	38,428,943
<i>US GAAP adjustments:</i>		
<b>Intangible assets</b>		
Fair value of shares issued as consideration	(b) 142,546	160,744
Direct acquisition costs	(c) 73,292	82,648
Amortization of intangible assets	(d) (7,357,007)	(1,607,137)
Sales of stock by subsidiaries	(f) 312,335	351,568
In-process research and development	(g) (1,035,018)	(1,035,018)
Gross-up attributable to deferred tax liability	(h) (1,034,610)	(698,993)
<b>Goodwill</b>		
Fair value of shares issued as consideration	(b) 8,267,528	—
Reversal of amortization	(e) 973,923	
Deferred income taxes	(h) 7,319,734	3,674,230
<b>Outside equity interest</b>		
Consolidated statement of financial position classification	—	(1,583,200)
US GAAP adjustments	—	20,920
Total equity in accordance with US GAAP	<u>87,650,337</u>	<u>37,794,705</u>

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

**Roll forward analysis of total equity under US GAAP**

	<u>Years Ended 30 June</u>	
	<u>2005</u>	<u>2004</u>
	\$	\$ (As Restated)
Balance in accordance with US GAAP, beginning of year	37,794,705	7,140,316
Issuance of shares in connection with acquisition, net of issue costs	62,526,881	—
Issuance of shares in connection with private placements, net of issue costs	—	31,797,500
Issuance of shares in connection with share purchase plan, net of issue costs	—	932,298
Issuance of shares in connection with exercise of options	3,666,500	1,626,000
Issuance of options in connection with acquisition	292,828	—
Issuance of options to consultants for services rendered (a)	156,204	250,933
Issuance of options to directors, executives and employees (a)	125,018	448,920
Gain on sales of stock by subsidiaries (f)	—	540,727
Foreign currency translation adjustment	(350,287)	77,985
Net loss in accordance with US GAAP	<u>(16,561,512)</u>	<u>(5,019,974)</u>
Balance in accordance with US GAAP, end of year	<u>87,650,337</u>	<u>37,794,705</u>

Note: The above rollforward does not include the 2,050,000 options issued by pSivida in August 2004 as settlement of share issue costs through the issuance of options does not have an impact on net loss or total equity.

**(a) Share-based compensation*****Options issued to consultants***

Under A-GAAP, the Company did not recognize any compensation expense in connection with the issuance of share options to consultants disclosed in Note 12(c). Under US GAAP, such options are accounted for under Statement of Financial Accounting Standards (“SFAS”) No. 123, “Accounting for Stock-Based Compensation” (“SFAS 123”) and Emerging Issues Task Force Issue No. 96-18, “Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services” (“EITF 96-18”). Accordingly, the Company has calculated compensation cost based on the estimated fair value of the options measured on the date the services were completed by the respective consultants (the “measurement date”), using the Black-Scholes option pricing model. For those options issued prior to reaching a measurement date, interim measures of compensation cost are recorded based on the estimated fair value of the options as of each reporting date.

Following is a summary of the options issued to consultants accounted for under SFAS 123:

- The Company issued 2,640,000 share options to outside consultants during the year ended 30 June 2005, consisting of 2,275,000 options in August 2004 and 365,000 options in April 2005. Of the options issued in August 2004, 2,050,000 were issued as payment of share issue costs, and therefore, have no impact on net loss or total equity as the fair value was accounted for as a reduction of the proceeds of the share issuance.



**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

- The Company issued 500,000 share options to an outside consultant during the year ended 30 June 2004 as an incentive for future performance.
- The Company issued 2,000,000 share options to GEM during the year ended 30 June 2003, pursuant to an agreement for a fully underwritten \$7.5 million equity line of credit.

The following weighted-average assumptions were used in calculating the estimated fair value:

- risk-free interest rate of 5.36% for fiscal 2005, 5.55% for fiscal 2004 and 5.31% for fiscal 2003;
- no dividends;
- expected volatility of 57% for fiscal 2005 and 70% for fiscal 2004 and 2003;
- expected life of 2 years for 2005, 2.5 years for 2004 and 1.6 years for 2003.

The resulting compensation cost is charged to earnings ratably over the estimated vesting period.

The following table summarizes the activity of share options issued to consultants during the years ended 30 June 2005, 2004 and 2003:

	Years Ended 30 June					
	2005		2004		2003	
	Number of Options	Weighted Average Exercise Price \$	Number of Options	Weighted Average Exercise Price \$	Number of Options	Weighted Average Exercise Price \$
Outstanding at beginning of year	500,000	0.61	2,000,000	0.20	—	—
Granted	2,640,000	1.07	500,000	0.61	2,000,000	0.20
Exercised	—		(2,000,000)	0.20	—	
Forfeited	(10,000)	1.18	—		—	
Expired	—		—		—	
Outstanding at end of year	3,130,000	1.00	500,000	0.61	2,000,000	0.20
Exercisable at end of year	3,055,000	1.00	250,000	0.61	2,000,000	0.20
	<u>2005</u>		<u>2004</u>		<u>2003</u>	
Weighted average grant date fair value						
Exercise price exceeds market price	\$0.38		\$0.50		\$0.03	
Exercise price equals market price	\$0.40		—		—	

***Options issued to directors, executives and employees***

Under US GAAP, the Company has elected to account for the issuance of share options to the directors, executives and employees in accordance with Accounting Principles Board (“APB”) Opinion No. 25, “Accounting for Stock Issued to Employees” and related interpretations (collectively, “APB 25”). Under APB 25, compensation cost is recognized to the extent that the fair value of the stock exceeds the

**PSIVIDA LIMITED AND SUBSIDIARIES  
(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)  
In Australian Dollars (except as otherwise stated)**

exercise price of the options at the measurement date, and is charged to earnings ratably over the vesting period. Following is a summary of the share options accounted for under APB 25:

pSivida

- pSivida issued 12,041,537 share options under the ESOP to directors, executives and employees during the year ended 30 June 2005, consisting of 8,889,537 options in August 2004 and 3,152,000 options in April 2005.
  - Of the options issued in August 2004, 638,537 options were issued to directors, executives and employees in consideration for the waiver of their rights under outstanding options previously issued by pSiMedica, and were accounted for as part consideration for the acquisition of pSiMedica.
  - No compensation cost was recognized for the remaining 8,251,000 options issued in August 2004 because the exercise price exceeded the quoted market price on the measurement date, corresponding to the date of grant.
  - The vesting of 2,032,000 of the options issued in April 2005 is conditional upon the achievement of performance conditions. Under US GAAP, these options are considered variable plan options as the number of shares the individuals are entitled to receive is not known at the date of grant. Compensation cost is computed on the date of grant based on management's estimate of the number of shares that will eventually be issued upon the achievement of the specific performance criteria and adjusted at each statement of financial position date (up to the vesting date) for changes in the estimate of the number of the shares and the quoted market price of the shares. No compensation cost was recognized for these options during the year because the exercise price exceeded the quoted market price as of 30 June 2005.
  - No compensation cost was recognized for the remaining 1,120,000 options issued in April 2005 because the exercise price exceeded the quoted market price on the measurement date, corresponding to the date of grant
- pSivida issued 3,895,000 share options under the ESOP to directors, executives and employees during the year ended 30 June 2004. No compensation cost was recognized for such options because the exercise price exceeded the quoted market price on the measurement date, corresponding to the date of grant.
- pSivida issued 520,000 share options under the ESOP to employees during the year ended 30 June 2003. The share options vested one year from the date of grant subject to the option holders having satisfied defined performance criteria. Under US GAAP, these options are considered variable plan options as the number of shares the individuals are entitled to receive is not known at the date of grant. Compensation cost is computed on the date of grant based on management's estimate of the number of shares that will eventually be issued upon the achievement of the specific performance criteria and adjusted at each statement of financial position date (up to the vesting date) for changes in the estimate of the number of the shares and the quoted market price of the shares. 500,000 of the share options vested during the year ended 30 June 2004.
- pSivida issued 2,200,000 share options under the ESOP to directors, executives and employees during the year ended 30 June 2002. The vesting of these share options is conditional upon a share performance measure. Under US GAAP, these options are considered variable plan options as the number of shares the individuals are entitled to receive are not known at the date of grant. As the share performance measure is beyond the control of the Company, any resulting compensation

**PSIVIDA LIMITED AND SUBSIDIARIES**  
(A Development Stage Enterprise)

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
In Australian Dollars (except as otherwise stated)

expense is recognized under APB 25 when the target is achieved. During the year ended 30 June 2004, all options vested as the share performance target was met, and accordingly, the Company recognized compensation expense under APB 25 based on the excess of the quoted market price on the vesting date over the exercise price of the share options.

The following table summarizes the activity of share options issued to directors, executives and employees of pSivida during the years ended 30 June 2005, 2004 and 2003:

	Years Ended 30 June					
	2005		2004		2003	
	Number of Options	Weighted Average Exercise Price \$	Number of Options	Weighted Average Exercise Price \$	Number of Options	Weighted Average Exercise Price \$
Outstanding at beginning of year	6,595,000	0.52	2,700,000	0.36	2,200,000	0.40
Granted	12,041,537	1.08	3,895,000	0.61	520,000	0.20
Exercised	(1,050,000)	0.30	—	—	—	—
Transferred	(1,650,000)	0.40	—	—	—	—
Forfeited	(104,824)	0.98	—	—	(20,000)	0.20
Expired	—	—	—	—	—	—
Outstanding at end of year	15,831,713	0.97	6,595,000	0.52	2,700,000	0.36
Exercisable at end of year	12,754,713	1.01	5,795,000	0.49	—	—
					2005	2004
Weighted average grant date fair value						
Exercise price exceeds market price					\$ 0.42	\$ 0.37
Exercise price less than market price					—	\$ 0.45

**pSiMedica**

- pSiMedica issued 30,300 and 12,000 share options to directors, executives and employees during the years ended 30 June 2004 and 2003, respectively. The Company recognized compensation expense for 3,375 options issued during the year ended 30 June 2004 based on the excess of the estimated fair value of stock over the exercise price on the date of grant. No compensation cost was recognized for the remaining 26,925 options issued during the year ended 30 June 2004 and all 12,000 options issued during the year ended 30 June 2003 because the exercise price exceeded the estimated fair value on the date of grant for these options.
- pSiMedica issued 29,900 and 26,600 share options to directors, executives and employees during the years ended 30 June 2004 and 2003, respectively. The share options vest three years from the date of grant subject to the option holders having satisfied defined performance criteria. Under US GAAP, these options are considered variable plan options as the number of shares the individuals are entitled to receive are not known at the date of grant. Compensation cost is computed on the date of grant based on management's estimate of the number of shares that will eventually be

**PSIVIDA LIMITED AND SUBSIDIARIES**  
(A Development Stage Enterprise)

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
In Australian Dollars (except as otherwise stated)

issued upon the achievement of the specific performance criteria and adjusted at each statement of financial position date (up to the vesting date) for changes in the estimate of the number of the shares and the estimated fair value of the shares.

The following table summarizes the activity of share options issued to directors, executives and employees of pSiMedica during the years ended 30 June 2005, 2004 and 2003:

	Years Ended 30 June					
	2005		2004		2003	
	Number of Options	Weighted Average Exercise Price £	Number of Options	Weighted Average Exercise Price £	Number of Options	Weighted Average Exercise Price £
Outstanding at beginning of year	98,800	9.66	38,600	6.25	—	—
Granted	—	—	60,200	11.84	38,600	6.25
Exchanged for pSivida options	(98,800)	9.66	—	—	—	—
Outstanding at end of year	—	—	98,800	9.66	38,600	6.25
Exercisable at end of year	—	—	—	—	—	—
				2005	2004	2003
Weighted average grant date fair value						
Exercise price exceeds market price				N/A	\$ 9.79	—
Exercise price equals market price				N/A	—	\$ 10.32
Exercise price less than market price				N/A	\$ 13.20	—

**AION Diagnostics**

- AION Diagnostics issued 1,200,000 share options to directors, executives and employees during the year ended 30 June 2005. The options vest subject to various milestone-based vesting conditions. Under US GAAP, these options are considered variable plan options as the number of shares the individuals are entitled to receive are not known at the date of grant. Compensation cost is computed on the date of grant based on management's estimate of the number of shares that will eventually be issued upon the achievement of the specific performance criteria and adjusted at each statement of financial position date (up to the vesting date) for changes in the estimate of the number of the shares and the estimated fair value of the shares. For those options with performance conditions beyond the control of AION Diagnostics, any resulting compensation expense is recognized under APB 25 when the target is achieved.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
(A Development Stage Enterprise)

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
In Australian Dollars (except as otherwise stated)

The following table summarizes the activity of share options issued to directors, executives and employees of AION during the year ended 30 June 2005:

	Year Ended 30 June 2005	
	Number of Options	Weighted Average Exercise Price \$
Outstanding at beginning of year	—	—
Granted	1,200,000	0.00
Outstanding at end of year	1,200,000	0.00
Exercisable at end of year	—	—
		<b>2005</b>
Weighted average grant date fair value		
Exercise price less than market price		\$ 0.29

**Fair value**

Had compensation cost related to the issuance of options to directors and employees been recorded at fair value on the date of grant in accordance with SFAS 123, the Company's net loss and loss per share amounts (calculated in accordance with US GAAP) would have been increased to the pro forma amounts indicated below:

	Year Ended 30 June		
	2005 \$	2004 \$ (As restated)	2003 \$ (As restated)
US GAAP net loss, as reported	(16,561,512)	(5,019,974)	(2,268,603)
Add: Stock-based employee compensation expense included in US GAAP reported net loss, net of related tax effects	125,018	448,920	10,000
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effect	(4,537,993)	(975,468)	(190,003)
US GAAP pro forma net loss	(20,974,487)	(5,546,522)	(2,448,606)
US GAAP loss per share			
Basic and diluted — as reported	\$ (0.08)	\$ (0.04)	\$ (0.02)
Basic and diluted — pro forma	\$ (0.10)	\$ (0.04)	\$ (0.02)

The following weighted-average assumptions were made in calculating the estimated fair value:

- risk-free interest rate of 5.36% for fiscal 2005, 5.55% for fiscal 2004, and 5.31% for fiscal 2003 ;
- no dividends;
- expected volatility of 57% for fiscal 2005 and 70% for fiscal 2004 and 2003;

**PSIVIDA LIMITED AND SUBSIDIARIES  
(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)  
In Australian Dollars (except as otherwise stated)**

- expected life of 2.5 years for 2005, 2.5 years for 2004 and 1.6 years for 2003.

**(b) Fair value of shares issued as consideration**

On 10 May 2001, the Company acquired the controlling economic interest in pSiMedica and issued shares for a portion of the consideration. Under A-GAAP, the fair value of the share consideration was calculated based on the price in the shareholder's agreement (which was derived from an independent valuation report). Under US GAAP, the fair value of the shares issued to affect the acquisition is the average quoted market price for a period of two days period before and two days after the date the terms of the acquisition is agreed to and announced. Accordingly, for US GAAP purposes, the Company has recorded an increase to the value of identifiable intangible assets equal to the difference. Such difference is amortized over the estimated useful life of 12 years.

**(c) Direct acquisition costs**

Under A-GAAP until 30 June 2004 the Company's accounting policy was to expense direct acquisition costs as incurred. Since 1 July 2004 the Company's accounting policy has been to capitalize direct acquisition costs as part of the purchase price. Under US GAAP, the direct acquisition costs are also capitalized as part of the purchase price. Accordingly, for all acquisitions prior to 1 July 2004, the Company has recorded an increase to the value of identifiable intangible assets equal to the amount of the direct acquisition costs for US GAAP purposes. The difference is amortized from the date of acquisition over the estimated useful life of 12 years under US GAAP.

**(d) Amortization of intangible assets**

In connection with the acquisition of pSiMedica (acquired in steps from 18 December 2000 to 4 August 2004), the Company acquired identifiable intangible assets classified as core intellectual property under A-GAAP. Under A-GAAP, the core intellectual property is currently not amortized. Rather, amortization will commence on commercial production of related products over the remaining estimated useful life. Under US GAAP, the intangible assets are classified as licenses and patents and amortized from the date of acquisition on a straight-line basis over the estimated useful life of 12 years. The aggregate US GAAP amortization expense for the next five succeeding years is estimated to be \$6,274,253 per year.

**(e) Goodwill**

Under A-GAAP, the Company amortizes goodwill attributable to the 4 August 2004 acquisition of the remaining 55.28% interest in pSiMedica on a straight line basis over the estimated period of benefit of nine years. Under US GAAP, goodwill is not amortized but instead is tested for impairment at least annually as further discussed below. Accordingly, goodwill amortization under A-GAAP has been added back in the US GAAP reconciliation.

For US GAAP purposes, SFAS No. 142, "Goodwill and Intangible Assets" requires goodwill to be tested for impairment at least annually at the reporting unit level. Goodwill attributable to the August 2004 acquisition of the minority interest in pSiMedica was tested for impairment at the reporting unit level in May 2005 and no impairment of goodwill was identified.

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

**(f) Sales of stock by subsidiaries**

During the years ended 30 June 2004 and 2002, pSiMedica and pSiOncology issued additional shares which resulted in a change in pSivida's proportionate interest in the respective subsidiaries. Details are as follows:

- On 7 March 2002, pSiMedica issued a total of 400,000 ordinary shares (as adjusted for a 100 to 1 share split) to pSivida and another shareholder at £5 (\$13.61) per share, resulting in a total of £2,000,000 (\$5,443,658) cash consideration. This issuance increased pSivida's direct ownership interest in pSiMedica from 40.05% to 42.85%.
- On 13 October 2003, pSiMedica issued a total of 237,342 preference shares to pSivida and another shareholder at £12.64 (\$30.47) per share, resulting in a total of £3,000,000 (\$7,232,401) cash consideration. This issuance increased pSivida's direct ownership interest in pSiMedica from 42.85% to 46.25%.
- On 1 March 2004, pSiOncology issued a total of 2,769 shares to pSiMedica and other minority shareholders at SGD\$1,000 (\$761.61) per share, resulting in a total of SGD\$2,769,000 (\$2,108,911). This issuance increased pSivida's direct ownership interest in pSiOncology from 38.56% to 42.26%.
- On 24 May 2004, pSiMedica issued 56,954 ordinary shares to the minority shareholders of pSiOncology at £12.64 (\$32.29) per share in consideration for the minority interest in pSiOncology, resulting in a total of £719,899 (\$1,838,822) non-cash consideration. This issuance decreased pSivida's direct ownership interest in pSiMedica from 46.25% to 44.72%.

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

Deferred taxes have not been provided on the SAB 51 gains given that pSiMedica is a foreign subsidiary and pSivida intends to permanently reinvest the undistributed earnings and thereby take advantage of the exemption allowed under APB Opinion No. 23, "Accounting for Income Taxes — Special Areas."

**(g) In-process research and development**

In connection with the acquisition of the remaining minority interest in pSiOncology during the year ended 30 June 2004, the Company acquired intangible assets classified as core intellectual property under A-GAAP. Under A-GAAP, the core intellectual property is currently not amortized. Rather, amortization will commence on commercial production of related products. For US GAAP purposes, the directors considered the guidance contained in the AICPA Practice Aid "Assets Acquired in a Business Combination to be Used in Research and Development Activities: A Focus on Software, Electronic

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

Devices, and Pharmaceutical Industries” and determined that the acquired intangible assets were in-process research and development (“IPR&D”) in nature and did not have an alternative future use. Therefore, under US GAAP, the IPR&D is written off to earnings at the date of acquisition.

**(h) Deferred income taxes**

A-GAAP does not require the recognition of deferred taxes arising from fair value adjustments attributable to a purchase business combination. US GAAP requires deferred taxes to be provided for the tax effects of differences between the fair values and the tax bases of identifiable assets acquired and liabilities assumed. Deferred taxes are only provided on goodwill when the amortization of goodwill is deductible for tax purposes in the respective tax jurisdiction. Accordingly, for US GAAP purposes, the Company recorded a deferred tax liability for the difference in the fair value and tax basis of the acquired intangibles attributable to the step acquisition of pSiMedica. Where the recognition of the deferred tax liability resulted in additional basis of the related intangible asset, such additional basis is being amortized over the remaining estimated useful life of the related intangible asset for US GAAP purposes.

Under US GAAP, the existence of sufficient taxable temporary differences will enable utilization of the tax benefit of operating loss carryforwards. Accordingly, for US GAAP purposes, the Company recorded a deferred tax benefit attributable to the pSiMedica operating loss carryforwards expected to be utilized by the reversal of the deferred tax liabilities recognized in connection with the step acquisition of pSiMedica as per the above. Such deferred tax benefit was not recognized under A-GAAP as sufficient taxable temporary differences are not available under A-GAAP.

**(i) Outside equity interest**

Certain of the A-GAAP to US GAAP adjustments relate to subsidiaries in which there exists an outside equity interest. Such adjustments are attributed to the outside equity interest accordingly.

Under A-GAAP, the outside equity interest in controlled entities is classified as a component of total equity. Under US GAAP, the outside equity interest (also referred to as “minority interest”) is classified between liabilities and stockholders’ equity in the consolidated statements of financial position. The effect of this adjustment has been disclosed in the reconciliation of total equity to US GAAP.

**(j) Loss per share**

Under A-GAAP, loss per share is calculated by dividing operating profit (loss) after tax and minority shareholders interest by the weighted average number of shares on issue for the year. Methods of computing loss per share in accordance with US GAAP are documented in SFAS No. 128, “Earnings per Share”.

For each of the years ended in the period ended 30 June 2005, there were no differences in the calculation methodology of loss per share under A-GAAP and US GAAP.

**(k) Consolidated statement of financial performance classification differences**

Under A-GAAP, interest income is reported as a component of revenue from ordinary activities. Under US GAAP, interest income is reported as a component of non-operating income/(loss).



**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

Under A-GAAP, proceeds from the disposal of property, plant and equipment is reported as a component of revenue from ordinary activities. Under US GAAP, only the net gain/(loss) is reported in operating income/(loss).

Under A-GAAP, interest expense is reported as a component of loss from ordinary activities. Under US GAAP, interest expense is reported as a component of non-operating income/(loss).

**(l) Consolidated statement of comprehensive loss**

Set out below is an analysis of comprehensive income/(loss) under A-GAAP for the years ended 30 June 2005, 2004 and 2003:

	Years Ended 30 June		
	2005 \$	2004 \$	2003 \$
Net loss in accordance with A-GAAP	(14,726,523)	(3,683,205)	(2,765,153)
Other comprehensive (loss)/income:	—	—	—
Foreign currency translation adjustment, net of tax of \$0	(350,287)	77,985	(31,765)
Comprehensive loss in accordance with A-GAAP	<u>(15,076,810)</u>	<u>(3,605,220)</u>	<u>(2,796,918)</u>

**(m) Income tax**

The Company has adopted SFAS No. 109 “Accounting for Income Taxes” (“SFAS 109”) for US GAAP purposes. SFAS 109 requires a “liability approach” to accounting for income taxes, which as it applies to the Company, is very similar to that adopted under A-GAAP. Under A-GAAP, the deferred tax asset in respect of income tax losses carried forward disclosed in Note 5 is not recognized unless the benefit is virtually certain of realization. Under US GAAP, the benefit is not recognized unless realization is more likely than not.

The components of A-GAAP loss from ordinary activities before income tax expense consisted of the following for the years ended 30 June 2005, 2004 and 2003:

	Years Ended 30 June		
	2005 \$	2004 \$	2003 \$
Australia	(7,590,833)	(637,675)	(855,756)
United Kingdom	(6,076,779)	(5,736,347)	(4,054,871)
Singapore	(1,458,107)	(1,144,954)	(445,701)
	<u>(15,125,719)</u>	<u>(7,518,976)</u>	<u>(5,356,328)</u>

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

The components of deferred tax assets and liabilities in accordance with A-GAAP as of 30 June 2005 and 2004 are as follows:

	Years Ended 30 June	
	2005 \$	2004 \$
Deferred tax assets		
Net operating loss carryforwards	9,291,377	5,049,704
Provision accruals	8,964	—
Other	4,147	2,189
Total gross deferred tax assets	9,304,488	5,051,893
Deferred tax liabilities		
Prepayments	96,880	8,687
Net deferred tax asset	9,207,608	5,043,206
Valuation allowance	(9,207,608)	(5,043,206)
Net recorded deferred taxes	—	—

As at 30 June 2005, the Company has operating loss carry forwards of \$31,945,180. Carryforwards of net operating losses do not expire on a time basis in any of the jurisdictions in which the Company incurs such losses. Expiration will depend on the legislation of the countries in which losses are incurred, and will generally be triggered by a change in control or business activity.

## 28. Recently issued but not yet adopted US Pronouncements

In December 2004, the Financial Accounting Standards Board (“FASB”) issued SFAS No. 123 (revised 2004): “Share-Based Payments” (“SFAS 123R”). This statement eliminates the option to apply the intrinsic value measurement provisions of APB 25 to stock compensation awards issued to directors and employees. Rather, SFAS 123R requires companies to measure the cost of director, executive and employee services received in exchange for an award of equity instruments based on the grant date fair value of the award. That cost will be recognized over the period during which the director, executive or employee is required to provide services in exchange for the award — the requisite service period (usually the vesting period). SFAS 123R applies to all awards granted after the required effective date (July 1, 2005 for pSivida) and to awards modified, repurchased, or cancelled after that date. As permitted by SFAS 123, the Company currently accounts for share-based payments to directors, executives and employees using APB 25, the intrinsic value method. Accordingly, the adoption of the SFAS 123R fair value method may have a significant impact on the Company’s results of operations, although it will have no impact on its overall financial position. The full impact of the adoption of SFAS 123R cannot be predicted at this time, as it depends on levels of share-based payments for future grants. However, had the Company adopted SFAS 123R for director, executive and employee options in prior periods, the impact of that standard would have approximated the pro forma impact of SFAS 123, as disclosed in Note 27(a), Share-based compensation — *Options issued to directors, executives and employees*.

In December 2004, the FASB issued SFAS No. 153: “Exchanges of Nonmonetary Assets — an amendment of APB Opinion No. 29” (“SFAS 153”), which amends APB Opinion No. 29: “Accounting for Nonmonetary Transactions” to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not

**PSIVIDA LIMITED AND SUBSIDIARIES**  
**(A Development Stage Enterprise)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**In Australian Dollars (except as otherwise stated)**

have commercial substance. SFAS 153 is effective for nonmonetary assets exchanges occurring in fiscal periods beginning after June 15, 2005 (fiscal 2006 for pSivida). At this time, management reasonably believes that the adoption of SFAS 153 will not have a material effect on the consolidated entity's financial position or results of operations.

In May 2005, the FASB issued SFAS No. 154: "Accounting Changes and Error Corrections — a replacement of APB Opinion No. 20 and FASB Statement No. 3 ("SFAS 154"), effective for fiscal years beginning after December 15, 2005 (fiscal 2007 for pSivida). SFAS 154 changes the requirements for the accounting for and reporting of a voluntary change in accounting principle as well as the changes required by an accounting pronouncement which does not include specific transition provisions. At this time management reasonably believes that the adoption of SFAS 154 will not have a material effect on the Company's financial position or results of operations.

**CONTROL DELIVERY SYSTEMS, INC.**  
**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

	<u>Page</u>
<a href="#">Report of Independent Auditors</a>	G-2
<a href="#">Consolidated Balance Sheets as of December 31, 2003 and 2004 and as of September 30, 2005 (unaudited)</a>	G-3
<a href="#">Consolidated Statements of Operations for the years ended December 31, 2002, 2003 and 2004 and for the nine months ended September 30, 2004 and 2005 (unaudited)</a>	G-4
<a href="#">Consolidated Statements of Stockholders' Deficit and Comprehensive Earnings (Loss) for the years ended December 31, 2002, 2003 and 2004 and for the nine months ended September 30, 2005 (unaudited)</a>	G-5
<a href="#">Consolidated Statements of Cash Flows for the years ended December 31, 2002, 2003 and 2004 and for the nine months ended September 30, 2004 and 2005 (unaudited)</a>	G-6
<a href="#">Notes to Consolidated Financial Statements</a>	G-7

## Report of Independent Auditors

To the Board of Directors and Stockholders of  
Control Delivery Systems, Inc.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of stockholders' deficit and comprehensive loss and of cash flows present fairly, in all material respects, the financial position of Control Delivery Systems, Inc. and its subsidiary, or CDS, at December 31, 2003 and 2004, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of CDS' management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Note 2, CDS changed its method for accounting for stock options in 2003.

The accompanying financial statements have been prepared assuming that CDS will continue as a going concern. As discussed in Note 1 in the financial statements, CDS has incurred losses from operations and expects to continue to incur losses from operations raising substantial doubt about its ability to continue as a going concern. Management's plan in regard to this matter is also described in Note 1. The financial statements do not include any adjustments that might result from this uncertainty.

PricewaterhouseCoopers LLP

December 2, 2005

G-2

---

## Control Delivery Systems, Inc.

## Consolidated Balance Sheets

	<u>December 31,</u>		<u>September 30,</u>
	<u>2003</u>	<u>2004</u>	<u>2005</u>
	(In thousands, except share data)		
<b>ASSETS</b>			
<b>Current assets</b>			
Cash and cash equivalents	\$ 4,733	\$ 1,015	\$ 1,817
Short-term investments	1,540	—	—
Accounts receivable — related party	25	31	59
Prepaid expenses and other current assets	248	76	190
Total current assets	6,546	1,122	2,066
Property and equipment, net	5,461	4,312	559
Total assets	<u>\$ 12,007</u>	<u>\$ 5,434</u>	<u>\$ 2,625</u>
<b>LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT</b>			
<b>Current liabilities</b>			
Accounts payable	\$ 223	\$ 585	\$ 737
Accrued expenses and other liabilities	987	897	1,792
Deferred revenue	—	750	1,351
Current portion of long-term debt	200	200	—
Advance from related party	3,000	2,795	—
Total current liabilities	4,410	5,227	3,880
Advance from related party, net of current portion	2,795	—	—
Long-term debt, net of current portion	3,529	3,329	—
Total liabilities	10,734	8,556	3,880
Commitments and contingencies (Notes 11, 12 and 14)			
Series A redeemable convertible preferred stock, \$0.01 par value; 2,000,000 shares authorized; 641,642 shares issued and outstanding at December 31, 2003, December 31, 2004 and September 30, 2005, respectively (liquidation value at December 31, 2004 and at September 30, 2005 of \$34,482)			
	<u>27,767</u>	<u>28,027</u>	<u>29,677</u>
Stockholders' deficit			
Common stock, \$0.01 par value; 5,000,000 shares authorized, 2,298,990, 2,373,847 and 2,393,847 shares issued and outstanding at December 31, 2003, December 31, 2004 and September 30, 2005, respectively			
	23	24	24
Additional paid-in capital	13,755	13,056	11,805
Deferred stock-based compensation	(2,469)	(692)	(820)
Accumulated other comprehensive loss	(311)	(169)	—
Accumulated deficit	(37,492)	(43,368)	(41,941)
Total stockholders' deficit	(26,494)	(31,149)	(30,932)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	<u>\$ 12,007</u>	<u>\$ 5,434</u>	<u>\$ 2,625</u>

**Control Delivery Systems, Inc.**  
**Consolidated Statements of Operations**

	Year Ended December 31,			Nine Months Ended September 30,	
	2002	2003	2004	2004	2005
	(In thousands)			(Unaudited)	
<b>Revenues</b>					
Collaborative research and development — related party	\$ 20,875	\$ 10,945	\$ 3,000	\$ —	\$ 3,500
Collaborative research and development — other					176
Royalties — related party	168	132	120	89	3,074
<b>Total revenues</b>	<u>21,043</u>	<u>11,077</u>	<u>3,120</u>	<u>89</u>	<u>6,750</u>
<b>Operating expenses</b>					
Research and development	17,983	12,187	3,083	2,336	1,507
Royalties	82	66	60	44	37
General and administrative	11,022	7,571	5,646	4,539	3,741
Charge for asset impairment	—	6,575	—	—	—
<b>Total operating expenses</b>	<u>29,087</u>	<u>26,399</u>	<u>8,789</u>	<u>6,919</u>	<u>5,285</u>
Earnings (loss) from operations	(8,044)	(15,322)	(5,669)	(6,830)	1,465
Interest expense	(84)	(199)	(239)	(179)	(59)
Interest income	515	243	38	34	3
Other income(expense)	64	24	(6)	(6)	18
<b>Net earnings (loss)</b>	<u>(7,549)</u>	<u>(15,254)</u>	<u>(5,876)</u>	<u>(6,981)</u>	<u>1,427</u>
Accretion of redeemable convertible preferred stock	(472)	(942)	(2,124)	(1,501)	(1,926)
<b>Net loss attributable to common stockholders</b>	<u>\$ (8,021)</u>	<u>\$ (16,196)</u>	<u>\$ (8,000)</u>	<u>\$ (8,482)</u>	<u>\$ (499)</u>

See accompanying Notes to Consolidated Financial Statements

Control Delivery Systems, Inc.

Consolidated Statements of Stockholders' Deficit and Comprehensive Loss  
(Information for the nine months ended September 30, 2005 is Condensed and Unaudited)

	Common Stock		Additional Paid-In Capital	Deferred Stock Compensation	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit	Comprehensive Loss
	Shares	Amount						
	(In thousands, except share data)							
<b>Balance at January 1, 2002</b>	1,925,583	\$ 19	\$ 6,282	\$ (236)	\$ 32	\$ (14,689)	\$ (8,592)	
Accretion of redeemable convertible preferred stock to redemption value			(472)				(472)	
Exercise of employee stock options	27,435	1	206				207	
Exercise of warrants	18,314		—				—	
Amortization of deferred stock compensation			(84)	135			51	
Gift of stock from shareholder to employee			595				595	
Change in unrealized loss on short-term investments					(30)		(30)	\$ (30)
Change in unrealized loss on interest rate swap					(407)		(407)	(407)
Net loss						(7,549)	(7,549)	(7,549)
Comprehensive loss								\$ (7,986)
<b>Balance at December 31, 2002</b>	<u>1,971,332</u>	<u>\$ 20</u>	<u>\$ 6,527</u>	<u>\$ (101)</u>	<u>\$ (405)</u>	<u>\$ (22,238)</u>	<u>\$ (16,197)</u>	
Accretion of redeemable convertible preferred stock to redemption value			(942)				(942)	
Beneficial conversion feature adjustment			5,496				5,496	
Issuance of restricted stock	327,658	3	2,674	(2,677)			—	
Amortization of deferred stock compensation				309			309	
Change in unrealized loss on short-term investments					(1)		(1)	\$ (1)
Change in unrealized loss on interest rate swap					95		95	95
Net loss						(15,254)	(15,254)	(15,254)
Comprehensive loss								\$ (15,160)
<b>Balance at December 31, 2003</b>	<u>2,298,990</u>	<u>\$ 23</u>	<u>\$ 13,755</u>	<u>\$ (2,469)</u>	<u>\$ (311)</u>	<u>\$ (37,492)</u>	<u>\$ (26,494)</u>	
Accretion of redeemable convertible preferred stock to redemption value			(2,124)				(2,124)	
Beneficial conversion feature adjustment			1,864				1,864	
Issuance of restricted stock	129,610	1	43	(44)			—	
Cancellation of restricted stock	(54,753)		(482)	482			—	
Amortization of deferred stock compensation				1,339			1,339	
Change in unrealized loss on interest rate swap					142		142	142
Net loss						(5,876)	(5,876)	(5,876)
Comprehensive loss								\$ (5,734)
<b>Balance at December 31, 2004</b>	<u>2,373,847</u>	<u>\$ 24</u>	<u>\$ 13,056</u>	<u>\$ (692)</u>	<u>\$ (169)</u>	<u>\$ (43,368)</u>	<u>\$ (31,149)</u>	
Accretion of redeemable convertible preferred stock to redemption value			(1,926)				(1,926)	
Beneficial conversion feature adjustment			276				276	
Issuance of restricted stock	20,000		399	(399)			—	
Amortization of deferred stock compensation				271			271	
Change in unrealized loss on interest rate swap					169		169	169
Net earnings						1,427	1,427	1,427
Comprehensive earnings loss								\$ 1,596
<b>Balance at September 30, 2005 (unaudited)</b>	<u>2,393,847</u>	<u>\$ 24</u>	<u>\$ 11,805</u>	<u>\$ (820)</u>	<u>\$ —</u>	<u>\$ (41,941)</u>	<u>\$ (30,932)</u>	

See accompanying Notes to Consolidated Financial Statements



**Control Delivery Systems, Inc.**  
**Consolidated Statements of Cash flows**

	Year Ended December 31,			Nine Months Ended September 30,	
	2002	2003	2004	2004	2005
	(In thousands)			(Unaudited)	
<b>Cash flows from operating activities</b>					
Net earnings (loss)	\$ (7,549)	\$ (15,254)	\$ (5,876)	\$ (6,981)	\$ 1,427
Adjustments to reconcile net (loss) to net cash provided by (used in) operating activities					
(Gain)/loss on sale of assets	—	62	147	—	(62)
Non-cash charges for asset impairment	—	6,575	—	—	—
Depreciation	1,448	1,954	1,032	783	437
Noncash charges for stock-based compensation	647	309	1,339	1,322	271
Changes in operating assets and liabilities					
Accounts receivable — related party	3	17	(6)	(6)	(28)
Income tax receivable	454	297	—	—	—
Prepaid expenses and other current assets	672	1,530	172	29	(114)
Accounts payable	(660)	(1,174)	362	(55)	152
Accrued expenses	2,091	(4,244)	52	(8)	690
Deferred revenue	(7,322)	(5,140)	750	—	601
Advance from related party	—	5,795	(3,000)	—	(2,795)
Net cash provided by (used in) operating activities	<u>(10,216)</u>	<u>(9,273)</u>	<u>(5,028)</u>	<u>(4,916)</u>	<u>579</u>
<b>Cash flows from investing activities</b>					
Purchases of short-term investments	(43,343)	(10,928)	(5,610)	(5,510)	—
Sales and maturities of short-term investments	50,477	18,425	7,150	7,050	—
Proceeds from sale of assets	—	8	11	10	3,762
Purchases of property and equipment	(6,266)	(1,474)	(41)	(41)	(10)
Net cash provided by investing activities	<u>868</u>	<u>6,031</u>	<u>1,510</u>	<u>1,509</u>	<u>3,752</u>
<b>Cash flows from financing activities</b>					
Proceeds from the issuance of long-term debt	4,000	—	—	—	—
Repayments of long-term debt	(66)	(205)	(200)	(150)	(3,529)
Proceeds from the sale of common stock	207	—	—	—	—
Net cash provided by (used in) financing activities	<u>4,141</u>	<u>(205)</u>	<u>(200)</u>	<u>(150)</u>	<u>(3,529)</u>
Net increase (decrease) in cash and cash equivalents	(5,207)	(3,447)	(3,718)	(3,557)	802
Cash and cash equivalents at beginning of period	13,387	8,180	4,733	4,733	1,015
Cash and cash equivalents at end of period	<u>\$ 8,180</u>	<u>\$ 4,733</u>	<u>\$ 1,015</u>	<u>\$ 1,176</u>	<u>\$ 1,817</u>
<b>Supplemental disclosure of cash flow information</b>					
Cash paid for interest	\$ 80	\$ 251	\$ 239	\$ 181	\$ 80
Cash paid for (refunds of) taxes	(443)	(338)	(3)	—	1

See accompanying Notes to Consolidated Financial Statements

**CONTROL DELIVERY SYSTEMS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**(Information as of September 30, 2005 and for the nine months ended**  
**September 30, 2004 and 2005 is Condensed and Unaudited)**

**1. Description of CDS' Business**

CDS designs and develops innovative sustained-release drug delivery products. CDS' 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 CDS' target diseases such as the adverse side effects characteristic of high dosing levels and reduced treatment benefits due to variations in drug levels at the target site.

CDS has two commercial products utilizing the AEON system approved by the FDA 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, or Bausch & Lomb, and sold since 1996, Vitrasert is a treatment 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. Medidur, an injectable AEON product, is also designed to treat diabetic macular edema, or DME, and is currently in Phase III clinical trials conducted by Alimera Sciences Inc.

The accompanying financial statements have been prepared on a basis which assumes that CDS will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. However, CDS' recurring losses from operations and expected future losses from operations raise substantial doubt about CDS' ability to continue as a going concern. Management's plans with regard to these matters include continued research and development in an effort to develop commercial products and completing a merger of the Company as described in Note 19. If this merger proves unsuccessful, CDS will seek additional financing. Management estimates that these efforts together with potential royalties will provide adequate resources to fund CDS' operations. There can be no assurance that CDS will be able to complete this merger or obtain additional financing to provide the liquidity necessary for CDS to continue its operations. The financial statements do not include any adjustment that might result from the outcome of this uncertainty.

To date, CDS has focused its efforts primarily on research and development of products based on its AEON system. In Phase I studies, CDS has explored the use of its CODRUG system for the treatment of post-surgical pain and two skin diseases.

CDS is subject to risks common to companies in the biopharmaceutical industry including, but not limited to, the need for additional funding, uncertainties relating to the successful development and commercialization of products, clinical trial uncertainty, fluctuations in operating losses results and financial risks, protection of proprietary technology and patent risks, dependence on key personnel and collaborative partners, competition, technological and medical risks, customer demand, uncertain reimbursement from third-party payers, compliance with the U.S. Food and Drug Administration and other government regulations and potential exposure to product liability claims.

As discussed in Note 15, Bausch & Lomb informed CDS in June 2003 that all future research and development related to the ophthalmic technology, licensed by CDS to Bausch & Lomb under a license and development agreement, would be undertaken directly by Bausch & Lomb and, as a result, in June 2003, CDS terminated 74 employees most of whose costs were funded directly or indirectly by Bausch & Lomb.

On October 3, 2005, CDS entered into an Agreement and Plan of Merger with pSivida Limited, an Australian corporation, and pSivida Inc., its wholly owned subsidiary (Note 19). The accompanying

**CONTROL DELIVERY SYSTEMS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**(Information as of September 30, 2005 and for the nine months ended**  
**September 30, 2004 and 2005 is Condensed and Unaudited)**

Consolidated Financial Statements have been prepared on the assumption that CDS continues on a stand-alone basis and do not reflect any adjustments or disclosures that may be required upon consummation of the merger.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

The accompanying consolidated financial statements reflect the financial position and results of operations of CDS and CDS Securities Corporation, its wholly owned subsidiary. All significant inter-company balances and transactions have been eliminated. CDS Securities Corporation was dissolved in May 2005.

***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the dates of the financial statements, and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates.

***Cash and Cash Equivalents***

CDS considers all highly liquid investment instruments with an original maturity of three months or less to be cash equivalents. Cash equivalents, which consist of money market funds, municipal notes and bonds, and commercial paper, are recorded at cost plus accrued interest.

***Investments***

Investments consist of marketable securities, which are classified as available for sale. Investments are stated at fair value with unrealized gains and losses included as a component of accumulated other comprehensive income (loss), which is a separate component of stockholders' deficit, until realized. The fair value of these securities is based on quoted market prices. Realized gains and losses are determined on the specific identification method and are included in investment income.

***Concentration of Credit Risk***

Financial instruments that potentially subject CDS to concentrations of credit risk primarily consist of money market funds, marketable securities and an interest rate swap. CDS places these investments with financial institutions, which management believes are of high credit quality.

At December 31, 2003 and 2004 and September 30, 2005, all of CDS' accounts receivable-related party were due from Bausch & Lomb. Revenue from Bausch & Lomb represented 100% of total revenues during each of the years ended December 31, 2002, 2003 and 2004, respectively and 100% and 97% of total revenues for the nine months ended September 30, 2004 and 2005, respectively. (Note 14)

***Fair Value of Financial Instruments***

The carrying value of CDS' financial instruments, including cash and cash equivalents, accounts receivable, accounts payable and accrued expenses, at December 31, 2003 and 2004 and September 30, 2005 approximated their fair value due to the short-term nature of these items. The carrying value of

CONTROL DELIVERY SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)  
(Information as of September 30, 2005 and for the nine months ended  
September 30, 2004 and 2005 is Condensed and Unaudited)

CDS' variable rate long-term debt and related interest rate swap approximated its fair value. The carrying value of CDS' payable to related party as of December 31, 2004 approximated its fair value due to the short-term nature of this item.

***Derivative Instruments***

CDS recognizes all derivatives as either assets or liabilities, with the instruments measured at fair value. The accounting for changes in fair value, gains or losses, depends on the intended use of the derivative and its resulting designation. Changes in the fair value of CDS' interest rate swap are included in Other Comprehensive Income because the terms of the swap were matched to the corresponding debt instruments at the inception of the swap.

***Property and Equipment***

Property and equipment are recorded at cost and depreciated using the straight-line method over their estimated useful lives. Leasehold improvements are amortized over the shorter of the asset life or the lease term. Property and equipment held under capital leases are initially recorded at the lower of the fair market value of the related asset or the present value of the minimum lease payments at the inception of the lease. Repairs and maintenance that do not improve or extend the life of the respective assets are charged to operations. On disposal, the related accumulated depreciation or amortization is removed from the accounts and any resulting gain or loss is included in the results of operations.

***Impairment or Disposal of Long-Lived Assets***

CDS evaluates the recoverability of its property and equipment and other long-lived assets when circumstances indicate that an event of impairment may have occurred in accordance with the provisions of Statement of Financial Accounting Standards, or SFAS No. 144, *Accounting for the Impairment of Long-Lived Assets or Disposal of Long-Lived Assets*. If an indicator of impairment has occurred, SFAS 144 requires recognition of impairment of long-lived assets if the net book value of such assets exceeds the future undiscounted cash flows attributable to such assets or the business to which such assets relate. Impairment is measured based on the difference between the carrying value of the related assets or businesses and the discounted future cash flows of such assets or businesses.

***Revenue Recognition***

CDS' business strategy includes entering into collaborative license and development agreements with biotechnology and pharmaceutical companies for the development and commercialization of CDS' product candidates. The terms of the agreements typically include non-refundable license fees, funding or co-funding of research and development, payments based upon achievement of clinical development milestones and either royalties on product sales or a share of profits on product sales. CDS follows the provisions of the Securities and Exchange Commission's Staff Accounting Bulletin 104, or SAB No. 104, *Revenue Recognition*, Emerging Issues Task Force, or EITF, Issue No. 00-21, or EITF 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*, EITF Issue No. 99-19, or EITF 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent*, and EITF Issue No. 01-9, or EITF 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*.

Non-refundable license fees are recognized as revenue when CDS has a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and CDS has no further performance obligations under the license agreement. Multiple

**CONTROL DELIVERY SYSTEMS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**(Information as of September 30, 2005 and for the nine months ended**  
**September 30, 2004 and 2005 is Condensed and Unaudited)**

element arrangements, such as license and development arrangements are analyzed to determine whether the license and the performance obligations can be separated or whether they must be accounted for as a single unit of accounting in accordance with EITF 00-21. CDS recognizes up-front license payments as revenue upon delivery of the license only if the license has standalone value and the fair value of the undelivered performance obligations, typically including research or steering committee services, can be determined. If the fair value of the undelivered performance obligations can be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not have stand-alone value or (ii) have stand-alone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted for as a single unit of accounting and the license payments and payments for performance obligations are recognized as revenue over the estimated period of when the performance obligations are performed.

Whenever CDS determines that an arrangement should be accounted for as a single unit of accounting, it must determine the period over which the performance obligations will be performed and revenue will be recognized. Revenue will be recognized using either a relative performance or straight-line method. CDS recognizes revenue using the relative performance method provided that CDS can reasonably estimate the level of effort required to complete its performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Direct labor hours or full-time equivalents are typically used as the measure of performance.

Application of this policy requires that CDS make the following calculations at the end of each reporting period to determine CDS' revenue from these agreements during that period. First, CDS determines the actual costs it has incurred through the end of the reporting period related to the agreement, and adds to that amount the costs it expects to incur in the future to complete the agreement, to arrive at the total cost CDS expects to incur from inception to completion of the agreement. CDS then divides the actual costs it has incurred through the end of the reporting period by the total costs it expects to incur from inception to completion to arrive at the percentage of the agreement CDS has completed at the end of the reporting period. CDS multiplies this percentage by the sum of total license fees received, nonsubstantive milestone payments earned and research and development payments received and expected to be received under the agreement, and subtracts from that product the revenue it has recognized under the agreement during previous reporting periods, to arrive at the amount of revenue related to the agreement it will recognize for the current reporting period. CDS considers contingent payments, such as milestone payments, to be earned only if CDS has satisfied all the contingencies related to the payment and CDS' collaboration partner is obligated to make the payment to CDS. Revisions in cost estimates and contractual payments, as contracts progress, have the effect of increasing or decreasing revenue recognized in the current and future periods. Revenue is limited to the cumulative amount of payments received or the cumulative amount of revenues earned, as determined using the relative performance method, as of each reporting period.

If CDS cannot reasonably estimate the level of effort required to complete its performance obligations under an arrangement and the performance obligations are provided on a best-efforts basis, then the total payments under the arrangement, excluding royalties and payments contingent upon achievement of substantive milestones, would be recognized as revenue on a straight-line basis over the period CDS expects to complete its performance obligations. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the straight-line basis, as of the period ending date.

**CONTROL DELIVERY SYSTEMS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**(Information as of September 30, 2005 and for the nine months ended**  
**September 30, 2004 and 2005 is Condensed and Unaudited)**

Significant management judgment is required in determining the level of effort required under an arrangement and the period over which CDS is expected to complete its performance obligations under an arrangement.

Collaboration agreements may also contain substantive milestones. Substantive milestone payments are considered to be performance bonuses that are recognized upon achievement of the milestone only if all of the following conditions are met:

- the milestone payments are non-refundable;
- achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement;
- substantive effort is involved in achieving the milestone;
- the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone; and
- a reasonable amount of time passes between the up-front license payment and the first milestone payment as well as between each subsequent milestone payment.

Determination as to whether a milestone meets the aforementioned conditions involves management's judgment. If any of these conditions are not met, the milestone payment would not be considered a substantive milestone, and the resulting payment would be recognized as revenue as such performance obligations are performed under either the relative performance or straight-line methods, as applicable, and in accordance with these policies as described above.

Reimbursement of costs is recognized as revenue provided the provisions of EITF 99-19 are met, the amounts are determinable, and collection of the related receivable is reasonably assured.

Royalty revenue is recognized upon the sale of the related products, provided that the royalty amounts are fixed or determinable, collection of the related receivable is reasonably assured and CDS has no remaining performance obligations under the arrangement. If royalties are received when CDS has remaining performance obligations, the royalty payments would be attributed to the services being provided under the arrangement and therefore would be recognized as such performance obligations are performed under either the relative performance or straight line methods, as applicable, and in accordance with these policies as described above.

For revenue generating arrangements where CDS, as a vendor, provides consideration to a licensor or collaborator, as a customer, CDS applies the provisions of EITF 01-9. EITF 01-9 addresses the accounting for revenue arrangements where the vendor gives consideration to the customer. Cash consideration paid to a customer is presumed to be a reduction of the selling price unless CDS receives an identifiable benefit for the payment and CDS can reasonably estimate the fair value of the benefit received. Payments to a customer that are deemed a reduction of selling price are recorded first as a reduction of revenue, to the extent of both cumulative revenue recorded to date and of probable future revenues, which include any unamortized deferred revenue balances, under all arrangements with such customer and then as an expense. Payments that are not deemed to be a reduction of selling price would be recorded as an expense.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets.

## CONTROL DELIVERY SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)  
(Information as of September 30, 2005 and for the nine months ended  
September 30, 2004 and 2005 is Condensed and Unaudited)**Research and Development**

All costs associated with internal research and development, research and development conducted for others and research and development services for which CDS has externally contracted are expensed as incurred. Costs allocated to research and development expense include, but are not limited to, salaries and benefits, clinical trial costs, outside consultants, cost to manufacture clinical trial materials and facility related expenses.

**Patents**

All costs to obtain and maintain patents are expensed as incurred.

**Stock-Based Compensation**

In December 2004, the FASB issued Statement of Financial Accounting Standards, or SFAS, No. 123 (revised 2004), "Share-Based Payments" or SFAS 123R. This statement eliminates the option to apply the intrinsic value measurement provisions of Accounting Principles Board, or APB, Opinion No. 25, "Accounting for Stock Issued to Employees" to stock compensation awards issued to employees. Rather, SFAS 123R requires companies to measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost will be recognized over the period during which an employee is required to provide services in exchange for the award — the requisite service period (usually the vesting period). SFAS 123R applies to all awards granted after the required effective date and to awards modified, repurchased, or cancelled after that date.

CDS applied APB No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, in accounting for its stock-based compensation plans for fiscal year 2002. CDS had adopted the disclosure-only provisions of SFAS No. 148, *Accounting for Stock-Based Compensation — Transition and Disclosure, an amendment of FASB Statement No. 123*; therefore, no compensation expense was included in the statement of operations for fiscal year 2002 related to employee options, for which the exercise price was equal to or greater than the fair market value of CDS' common stock on the date of grant.

Effective January 1, 2003, CDS adopted SFAS 148, on a prospective basis. Accordingly, for fiscal years 2003 and 2004 and for the nine months ended September 30, 2005, compensation expense related to all stock options granted on and after January 1, 2003 is included in the statement of operations, as calculated under the fair value method.

CDS has used the following assumptions in determining compensation expense for the years ended December 31, 2002, 2003 and 2004 related to stock options granted.

	Year Ended December 31,		
	2002	2003	2004
Expected option term (in years)	5.00	5.00	5.00
Risk-free interest rate	4.39%	4.00%	4.07%
Expected dividend yield	none	none	none

## CONTROL DELIVERY SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)  
(Information as of September 30, 2005 and for the nine months ended  
September 30, 2004 and 2005 is Condensed and Unaudited)

Had compensation cost for stock options in fiscal year 2002 been determined based on the fair value at the grant date for all options and awards under this plan, consistent with the methodology prescribed in SFAS No. 148, CDS' pro forma net loss would have been as follows:

	Year Ended December 31,	
	2002	2003
	(In thousands)	
Net loss attributable to common stockholders		
As reported	\$ (8,021)	\$ (16,196)
Add: Employee stock-based compensation expense recorded	51	309
Deduct: Pro forma stock-based compensation expense determined under fair-value method	(632)	(579)
Pro forma net loss attributable to common stockholders	<u>\$ (8,602)</u>	<u>\$ (16,466)</u>

The proforma net loss attributable to common stockholders in the preceding chart includes compensation cost, as calculated under the fair value method, for all options, including those granted prior to January 1, 2003.

Since options vest over several years and additional option grants may be made in future years, the pro forma results are not representative of the pro forma results for future years. For purposes of the preceding analysis, the fair value of each option grant is estimated on the date of grant using the minimum value method.

**Income Taxes**

CDS recognizes deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax liabilities and assets are determined based on the difference between the financial statement and tax bases of assets and liabilities, as well as net operating loss carry forwards, or NOLs, and are measured using enacted tax rates in effect for the year in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance unless their ultimate realization is considered more likely than not.

**Comprehensive Income (Loss)**

CDS accounts for comprehensive income (loss) under SFAS No. 130, *Reporting Comprehensive Income*. SFAS 130 establishes standards for reporting comprehensive income and its components in the financial statements. Comprehensive income, as defined, includes all changes in equity during a period from non-owner sources. Accumulated other comprehensive loss is comprised of accumulated unrealized losses on the interest rate swap.



## CONTROL DELIVERY SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)  
(Information as of September 30, 2005 and for the nine months ended  
September 30, 2004 and 2005 is Condensed and Unaudited)**3. Investments and Cash and Cash Equivalents**

Cash and cash equivalents consist of the following:

	December 31,		September 30, 2005
	2003	2004 (In thousands)	
Cash and money market funds	\$ 1,030	\$ 815	\$ 1,817
Municipal notes and bonds	3,703	200	—
	<u>\$ 4,733</u>	<u>\$ 1,015</u>	<u>\$ 1,817</u>

There were no gross unrealized gains or losses on municipal notes and bonds classified as cash equivalents at December 31, 2003 and 2004.

Short-term investments at amortized cost, including accrued interest, and fair value at December 31, 2003 were as follows:

	Amortized Cost	Gross Unrealized Gains (In thousands)	Gross Unrealized Losses	Fair Value
Government agencies	1,541	—	(1)	1,540
	<u>\$ 1,541</u>	<u>\$ —</u>	<u>\$ (1)</u>	<u>\$ 1,540</u>

There were no gross realized gains or losses for the year ended December 31, 2003 and 2004 and for the nine months ended September 30, 2004 and 2005, respectively. All short-term investments held at December 31, 2003 mature within one year.

**4. Impairment of Long-Lived Assets**

In June 2003, Bausch & Lomb informed CDS that all future research and development related to the licensed ophthalmic technology would be undertaken by Bausch & Lomb (Note 15). In June 2003, CDS reduced its workforce by terminating 74 employees most of whose costs were funded directly or indirectly by Bausch & Lomb. Due to these events, there was a significant adverse change in the extent or manner in which CDS' long-lived assets, including CDS' equipment, land, building and building improvements were to be used. As a result, CDS performed a test for recoverability and CDS concluded that the book values of certain assets of CDS were significantly higher than their expected future cash flows and that an impairment had occurred. In 2003, CDS wrote down the cost basis of these assets to their estimated fair values, considering quotations received from third parties and recorded impairment charges of \$335,000 for CDS' computer equipment, manufacturing equipment and furniture and fixtures and \$6,240,000 for CDS' land, building and building improvements, resulting in a total impairment charge of \$6,575,000.

## CONTROL DELIVERY SYSTEMS, INC.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**(Information as of September 30, 2005 and for the nine months ended**  
**September 30, 2004 and 2005 is Condensed and Unaudited)**

**5. Property and Equipment**

Property and equipment consist of the following:

	Estimated Useful Life (Years)	December 31,		September 30, 2005
		2003	2004 (In thousands)	
Computer equipment and software	3	\$ 724	\$ 584	\$ 571
Equipment	5	809	472	379
Research and development equipment	5	2,177	2,048	1,980
Leasehold improvement	1.5	—	—	10
Land	N/A	1,055	1,055	—
Building	25	533	533	—
Building improvements	10	2,035	2,042	—
		7,333	6,734	2,940
Less: accumulated depreciation		1,871	2,422	2,381
Property and equipment, net		\$ 5,461	\$ 4,312	\$ 559

Depreciation expense was \$1,448,000, \$1,954,000 and \$1,032,000 for the years ended December 31, 2002, 2003 and 2004, respectively. Depreciation expense was \$783,000 and \$437,000 for the nine months ended September 30, 2004 and 2005 respectively.

**6. Accrued Expenses and Other Liabilities**

Accrued expenses and other liabilities consist of the following:

	December 31,		September 30, 2005
	2003	2004 (In thousands)	
Obligation under government grants	\$ 99	\$ 99	\$ 99
Accrued payroll and benefits	142	277	817
Fair value of interest rate swap classified as a hedge	311	169	—
Accrued professional fees	226	243	115
Deferred gain on sale of building	—	—	374
Accrued financing cost	—	—	335
Accrued clinical trial costs	169	55	—
Accrued other	40	54	52
	\$ 987	\$ 897	\$ 1,792

**7. Preferred Stock**

In August 2000, CDS' board of directors designated 641,642 shares of preferred stock as Series A convertible preferred stock, \$0.01 par value, and CDS sold 641,642 shares of Series A preferred stock to third-party investors at \$53.74 per share for total gross proceeds of \$34.5 million. CDS recorded the Series A preferred stock at \$31.2 million, which is net of \$2.2 million of cash issuance costs and the \$1.1 million fair value of warrants issued in conjunction with the preferred stock offering. The carrying

**CONTROL DELIVERY SYSTEMS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**(Information as of September 30, 2005 and for the nine months ended**  
**September 30, 2004 and 2005 is Condensed and Unaudited)**

value of the Series A preferred stock is being accreted to the redemption value on straight-line basis through the first redemption date of August 7, 2007.

After August 7, 2007, holders of a majority of the Series A Preferred Stock may require that CDS redeem all then outstanding shares of Series A Preferred Stock at a price per share of \$53.74 plus all then accrued and unpaid dividends.

Series A preferred stockholders vote together with the common stockholders as a single class. Each share of Series A preferred stock is convertible at the holder's option into one share of common stock, subject to adjustments, and is entitled to non-cumulative dividends when and if declared, at the annual rate of \$4.30 per share. Holders of a majority of the outstanding Series A preferred stock may elect on and after August 8, 2007 to have CDS redeem all then outstanding Series A preferred stock at the issue price plus any accrued and unpaid dividends. On liquidation, the holders of the Series A preferred stock are entitled to a liquidation preference equal to the issue price plus all accrued and unpaid dividends. The Series A preferred stock outstanding will automatically be converted into shares of common stock upon the earliest of (1) the closing by CDS of a public offering raising gross proceeds of \$20 million or more at an offering price per share greater than or equal to 200% of the then-applicable conversion price, (2) following completion of a public offering not triggering conversion under (1) above, the date on which the average closing price of the common stock has exceeded 200% of the issue price of the Series A preferred stock for any 20 consecutive trading days, or (3) the receipt by CDS of a written consent of the holders of at least 66<sup>2</sup>/<sub>3</sub>% of the Series A preferred stock then outstanding or conversion of at least 66<sup>2</sup>/<sub>3</sub>% of the Series A preferred stock originally issued.

Due to the issuance of restricted stock in May and October 2003 (Note 9), the conversion price for the Series A preferred stock was adjusted in accordance with the Series A preferred stock agreement. The May 2003 issuance of restricted stock resulted in a reduction of the conversion price to \$51.63 per share with a resulting increase of 26,215 shares of common stock that would be received by the holders of the Series A preferred stock upon conversion. The October 2003 issuance of restricted stock adjusted the conversion price to \$46.13 per share with a resulting increase of 79,628 shares of common stock that would be received by the Series A preferred stock holders. During fiscal 2004, CDS issued restricted stock subject to vesting requirements. These 2004 issuances adjusted the conversion price of the Series A preferred stock to \$43.68 with a resulting increase of 41,838 shares of common stock that would be received by the holders of the Series A preferred stock upon conversion. These adjustments represent contingent conversion options as defined by EITF 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments*. Accordingly, CDS recorded a beneficial conversion feature of \$5,496,000 in 2003 and \$1,864,000 in 2004 as an increase to additional paid-in capital and a reduction in the carrying value of the Series A preferred stock in the years ended December 31, 2003 and 2004, respectively. The carrying value of the Series A preferred stock will be accreted to its redemption value of \$34.5 million plus accrued and unpaid dividends by August 2007 through charges to additional paid-in capital or, if none, to accumulated deficit.

**8. Warrants**

In connection with the issuance of the Series A preferred stock, CDS issued warrants to a third party to purchase up to 37,402 shares of CDS' common stock at an exercise price of \$53.73 per share. The fair value of the warrants was determined using the Black-Scholes pricing model, and \$1.1 million was recorded in equity as additional paid-in capital and as a discount on the preferred stock. In April 2002, CDS issued 18,314 shares of its common stock upon the cashless exercise of all of the warrants.

**CONTROL DELIVERY SYSTEMS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**(Information as of September 30, 2005 and for the nine months ended**  
**September 30, 2004 and 2005 is Condensed and Unaudited)**

**9. Common Stock**

In 2003 and 2004, CDS issued 327,658 and 129,610 shares of its common stock to certain employees that vest over periods ranging from two to five years. These shares of common stock are restricted based on the continuing employment of the employees over the respective vesting periods. For the May 2003 issuance of 59,613 shares of restricted stock, CDS estimated the fair value of CDS' restricted stock at \$16.42 per share and recorded deferred compensation of \$979,000. CDS estimated the fair value of the restricted common stock to be \$5.00 per share for the October 2003 issuance of 268,045 shares of restricted common stock. CDS recorded deferred compensation equal to the fair value of the October 2003 restricted shares and that portion of compensation related to the options which were simultaneously canceled that had not been previously expensed, resulting in total deferred compensation of \$1,698,000, which is being amortized over the remaining vesting period of the restricted stock. Due to negative trends in CDS' business, the fair value of CDS' common stock declined from \$5.00 to \$0.01 per share during 2004. For the 2004 issuance of 129,610 shares of restricted stock, CDS recorded deferred compensation of \$39,000 based on the estimated fair value of the shares.

In May 2005, CDS granted 20,000 shares of restricted stock. CDS estimated the fair value of CDS' restricted stock at \$20.00 per share and recorded deferred compensation of \$400,000.

The reductions in the estimated fair value of CDS' restricted stock during 2003 and 2004 reflect the significant reductions in CDS' workforce during that period as a result of Bausch and Lomb's decision in June 2003 to cease funding research and development undertaken by CDS under the 1999 license agreement (Note 14). During 2003 and 2004, CDS did not consummate a financing, a strategic collaboration or a business combination and CDS' cash resources continued to diminish.

During the first quarter of 2005, CDS consummated a strategic collaboration with Alimera Sciences. During the second quarter of 2005, CDS earned all of the milestones under the Alimera agreement, sold its real estate and repaid the outstanding term loan agreement, the FDA approved the product for posterior uveitis, CDS received \$3,000,000 from Bausch & Lomb as an advance payment in lieu of future royalties and CDS began discussions with pSivida about a potential acquisition of CDS by pSivida. The merger agreement with pSivida was approved by the CDS Board in the third quarter of 2005. The increase in CDS' estimate of the fair market of its restricted stock from 2004 to 2005 reflects the significant improvement in its business during 2005 and the prospective acquisition by pSivida (Note 19).

After terminating approximately 70% of its workforce in June 2003, CDS further reduced its workforce in August 2004. In connection with the 2004 layoff, CDS modified a majority of the terminated employees' restricted stock agreements. As a result, the unvested restricted stock held by such employees was not forfeited upon termination of employment, but instead will be forfeited on August 16, 2007 unless a sale or an initial public offering of CDS or similar liquidity event occurs before that date. If a liquidity event occurs before August 16, 2007, all unvested shares held by affected terminated employees will then vest. CDS has not amortized any of the deferred compensation related to these shares of restricted stock since the employees' termination date. Also, in August 2004 CDS vested certain shares of restricted stock held by two remaining employees as part of the restructuring of their employment arrangement. CDS expensed unamortized deferred compensation related to these vested shares in 2004.

The deferred compensation is being amortized to compensation expense over the vesting periods of the restricted stock. CDS recorded compensation charges of \$303,000 and \$1,339,000 related to the grants of restricted stock to employees for the year ended December 31, 2003 and December 31, 2004,

## CONTROL DELIVERY SYSTEMS, INC.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**(Information as of September 30, 2005 and for the nine months ended**  
**September 30, 2004 and 2005 is Condensed and Unaudited)**

respectively. CDS recorded compensation charges of \$1,322,000 and \$271,000 related to the grants of restricted stock to employees for the nine months ended September 30, 2004 and 2005, respectively.

**10. Incentive Plans**

CDS adopted the 1997 Stock Option Plan under which up to 300,000 shares of common stock may be issued, and the 2001 Incentive Plan, under which up to 300,000 shares of common stock may be issued. At December 31, 2003 and December 31, 2004, CDS has reserved a total of 600,000 shares of common stock for issuance under these plans. CDS had 66,167 shares available for future grant as of December 31, 2004. Both plans provide for the grant of incentive stock options, or ISOs, to employees as well as restricted stock and nonqualified stock options to employees, directors and other individuals providing services to CDS. The 2001 Incentive Plan also provides for the issuance of other incentives. The Board of Directors determines for each award, the term, exercise price, if any, number of shares, whether options are ISOs or nonqualified stock options, whether restrictions will be imposed on the shares subject to awards and the vesting period for each award. The exercise price for ISOs cannot be less than the fair value per share of the underlying common stock on the date granted and the term cannot exceed ten years. The existing awards outstanding as of December 31, 2004 primarily vest over the next one to three years.

A summary of the status of options granted under CDS' incentive plans as of December 31, 2002, 2003 and 2004 and changes during the years then ended is presented below:

	2002		2003		2004	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year	245,400	\$ 49.03	309,467	\$ 77.03	50,975	\$ 26.08
Granted	151,592	105.30	4,900	105.30	1,650	0.01
Exercised	(27,435)	7.54	—	—	—	—
Canceled	(60,090)	65.75	(263,392)	87.41	(3,125)	48.92
Outstanding at end of year	<u>309,467</u>	\$ 77.03	<u>50,975</u>	\$ 26.08	<u>49,500</u>	\$ 23.77
Outstanding and exercisable at end of year	121,833	\$ 46.90	46,912	\$ 19.96	47,184	\$ 23.45
Weighted average grant date fair value						
Options granted at above fair value		\$ —		\$ —		\$ —
Options granted at fair value		\$ 105.30		\$ 105.30		\$ 0.01
Options granted at less than fair value		\$ —		\$ —		\$ —

## CONTROL DELIVERY SYSTEMS, INC.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**(Information as of September 30, 2005 and for the nine months ended**  
**September 30, 2004 and 2005 is Condensed and Unaudited)**

The following table summarizes information about stock options granted to employees and directors, which were outstanding at December 31, 2004:

Exercise Price per Share	Options Outstanding			Options Exercisable		
	Number Outstanding	Weighted Average Remaining Contractual Life (In Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price	
\$ .01	1,650	4.37	\$ 0.01	—	\$ 0.01	
6.25	20,000	2.72	6.25	20,000	6.25	
8.00	10,000	4.65	8.00	10,000	8.00	
12.00	10,000	4.87	12.00	10,000	12.00	
105.30	4,750	2.87	105.30	4,084	105.30	
113.40	3,100	1.47	113.40	3,100	113.40	
<u>\$ .01-\$113.40</u>	<u>49,500</u>	<u>3.53</u>	<u>\$ 23.77</u>	<u>47,184</u>	<u>\$ 23.45</u>	

CDS granted 52,100 options in 1999 and 13,500 options in 2000 to employees of CDS at a price it subsequently deemed to be less than fair market value and recorded stock-based compensation expense associated with employee stock option grants of \$6,000 and \$6,000 for the years ended December 31, 2002 and 2003, respectively.

During 2002, a principal shareholder of CDS gave 30,000 shares of common stock to a former employee of CDS. In accordance with APB No. 25, CDS has accounted for the transaction as a contribution of capital by the stockholder and as a transfer of shares to the former employee. For the year ended December 31, 2002, CDS recorded a non-cash expense related to this transaction of \$595,000.

#### 11. Commitments

CDS leased some of its facilities under non-cancelable operating lease agreements that expired in November 2003. Rental expense associated with operating leases was \$638,000, \$573,000 and \$0 for the years ended December 31, 2002, 2003 and 2004, respectively, and \$0 and \$266,000 for the nine months ended September 30, 2004 and 2005, respectively. As of December 31, 2004, CDS had no future minimum lease payments.

In April 2005, CDS sold its land, building and building improvements for \$4,000,000, and used the net proceeds from this sale to repay CDS' term loan agreement, which had been collateralized by the land, building and building improvements. In connection with this agreement, CDS signed a lease agreement with the purchaser of the building to lease a portion of the facilities for a period of 18 months for \$25,294 a month. CDS has the right, and the owner has a separate right to require CDS, to extend the lease for an additional 18 months for \$26,444 per month. Since CDS is leasing back more than a minor part of the building, CDS has deferred the gain on the sale of the building of \$449,000. The gain is being amortized over the 36 month lease term in accordance with SFAS No. 28, *Accounting for Sales with Leasebacks*.

## CONTROL DELIVERY SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)  
(Information as of September 30, 2005 and for the nine months ended  
September 30, 2004 and 2005 is Condensed and Unaudited)

Assuming the lease renewal option is exercised, the future minimum lease payments (net of security payment) under non-cancelable operating leases as of September 30, 2005 are as follows:

Period	
Fourth quarter ending December 31, 2005	\$ 136,000
Fiscal year 2006	143,000
Fiscal year 2007	317,000
Fiscal year 2008	79,000
Total minimum lease payments	<u>\$ 675,000</u>

**12. Long-Term Debt**

Long-term debt at December 31, 2003 and 2004 consists of the following:

	2003	2004
	(In thousands)	
Term loan agreement	\$ 3,729	\$ 3,529
Less current portion	(200)	(200)
Long-term debt, net of current portion	<u>\$ 3,529</u>	<u>\$ 3,329</u>

During July 2002, CDS entered into a term loan agreement with a bank under which CDS borrowed \$4.0 million for finance general corporate purposes, which is collateralized by CDS' land, building and building improvements. Interest on the borrowings is measured at the bank's 30-day "Libor" rate plus 100 basis points (3.28% at December 31, 2004). CDS utilizes an interest rate swap to fix the interest rate on its variable rate term loan in order to minimize the impact of changes in interest rates on earnings and cash flow. In 2002, CDS entered into a five-year interest rate swap agreement on a declining notional amount, which matches with the scheduled principal amounts outstanding of CDS' long-term debt. At December 31, 2004, the notional amount of the interest rate swap, and the remaining principal amount of the bank term loan, was \$3,529,000. Under the swap agreement, CDS pays a fixed rate of 6.45% on the notional amount and receives LIBOR plus one hundred basis points. The interest differential payable or accruable on the swap agreement is recognized on an accrual basis as an adjustment to interest expense. The criteria used to apply hedge accounting for this interest rate swap include management's designating the swap as a hedge against the variable rate debt, combined with the terms of the swap matching the terms of the underlying debt, including the notional amount, the timing of the interest reset dates, the indices used and the payment dates. At December 31, 2004, CDS had recorded a total unrealized loss of \$169,000 as a component of other comprehensive loss based on the fair value of the interest rate swap. The fair value of this interest rate swap represents the amount CDS would pay to terminate the agreement, and is based on dealer quotes. The variable interest rate received on the swap at December 31, 2004 was 3.28%. Credit risk exposure from the swap is minimized as the agreement is with a major financial institution. CDS monitors the credit worthiness of this financial institution and full performance is anticipated.

The loan was payable in 60 monthly principal installments of \$16,667 through June 2007, with remaining principal of \$3,000,000 payable in July 2007.

## CONTROL DELIVERY SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)  
(Information as of September 30, 2005 and for the nine months ended  
September 30, 2004 and 2005 is Condensed and Unaudited)

At December 31, 2004, payments of principal on existing debt were due as follows:

	(In thousands)
2005	200
2006	200
2007	3,129
Total debt	3,529
Less current portion	(200)
Long-term debt, net of current portion	\$ 3,329

In April 2005, CDS sold its land, building and building improvements for \$4,000,000, and used the net proceeds from this sale to repay CDS' term loan agreement, which had been collateralized by the land, building and building improvements, and to settle the interest rate swap. Since CDS is leasing back more than a minor part of the building, CDS has deferred the gain on the sale of the building of \$449,000. The gain is being amortized over the 36 month lease term in accordance with SFAS No. 28, *Accounting for Sales with Leasebacks*.

### 13. Income Taxes

At December 31, 2004, CDS had federal and state net operating loss carry forwards, or NOLs, of approximately \$28.0 million and \$31.0 million, respectively. The federal and state NOLs begin to expire in 2023 and 2005, respectively. In addition, CDS had federal and state research and development credits of \$248,000 and \$158,000, respectively, at December 31, 2004. These federal and state credits begin to expire in 2023 and 2018, respectively. NOLs and research and development credits may be used to reduce future tax payments.

CDS has provided a valuation allowance for the full amount of its net deferred tax assets since realization of any future benefit from temporary differences and NOL and tax credit carry forwards, since it is more likely than not that some or all of the deferred tax assets will not be realized.

Under the provisions of the Internal Revenue Code, certain substantial changes in CDS' ownership may result in a limitation on the amount of NOLs and research and development credit carry forwards that can be used in future years.



## CONTROL DELIVERY SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)  
 (Information as of September 30, 2005 and for the nine months ended  
 September 30, 2004 and 2005 is Condensed and Unaudited)

The components of CDS' net deferred tax asset are as follows:

	2003	2004
	(In thousands)	
Depreciation, amortization and impairment charge	\$ 2,759	\$ 2,671
Federal net operating loss	7,957	9,536
State net operating loss	1,664	1,945
Research and development credit	505	353
Stock compensation	227	792
Accrued expenses	90	59
Other	180	298
Total deferred tax asset	13,382	15,654
Valuation allowance	(13,382)	(15,654)
Net deferred tax asset	\$ —	\$ —

The following is reconciliation between the United States federal statutory rate and the effective tax rate, computed by dividing each item by that year's pre-tax loss:

	2002	2003	2004
Federal statutory rate	34.0%	34.0%	34.0%
State taxes	8.0	6.2	6.2
Research and development credit	3.1	1.0	(2.4)
Valuation allowance	(42.0)	(41.3)	(38.0)
Gift of stock from shareholder to employee	(2.7)	—	—
Other	(.4)	.1	.2
Effective tax rate	—%	—%	—%

#### 14. Agreements

##### *University of Kentucky Research Foundation*

University of Kentucky Research Foundation, or UKRF, has granted CDS exclusive, worldwide rights to make, use, sell and sublicense products using certain United States and related foreign patents. CDS is required to pay royalties at various percentages of net sales or net royalties it receives on sales of products utilizing technology covered by patents licensed from UKRF. Under these agreements, CDS recorded royalty expenses totaling \$82,000, \$66,000 and \$60,000 for the fiscal years ended December 31, 2002, 2003 and 2004, respectively, and \$44,000 and \$37,000 for the nine months ended September 30, 2004 and 2005, respectively.

An officer previously conducted research at the University of Kentucky, and pursuant to agreements between him and UKRF, a portion of the royalties paid to UKRF by CDS were paid to the officer as subroyalties as follows: \$7,000, \$7,000 and \$8,000 for the years ended December 31, 2002, 2003 and 2004, respectively, and \$5,000 and \$2,000 for the nine months ended September 30, 2004 and 2005, respectively.

##### *Strategic Collaborations-related party*

In 1992, CDS entered into a license and development agreement with Chiron Vision Corporation with respect to CDS' first commercialized product, *Vitrasert*. Bausch & Lomb acquired Chiron Vision in 1997.

**CONTROL DELIVERY SYSTEMS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**(Information as of September 30, 2005 and for the nine months ended**  
**September 30, 2004 and 2005 is Condensed and Unaudited)**

Under the terms of the agreement, Bausch & Lomb acquired exclusive worldwide rights to make, use and sell *Vitrasert* and other products utilizing certain licensed patents for the treatment of conditions of the eye, for which CDS receives royalty payments on worldwide net sales. Royalty payments earned from Bausch & Lomb were \$168,000, \$132,000 and \$120,000 for the years ended December 31, 2002, 2003 and 2004, respectively, and \$89,000 and \$74,000 for the nine months ended September 30, 2004 and 2005, respectively.

In 1999, CDS and Bausch & Lomb entered into a license and development agreement with respect to treatment of conditions of the eye. CDS granted Bausch & Lomb an exclusive, worldwide license to make, use and sell products for treatment of the eye based on CDS' patents and other technology. Bausch & Lomb agreed to fund the joint development costs of CDS and Bausch & Lomb related to products for the treatment of DME, posterior uveitis and wet age-related macular degeneration based on agreed-upon research and development plans and budgets, and pay CDS license and license maintenance fees and milestone payments and royalties based on net sales of licensed products.

The amounts of license fees and collaborative research and development payments received and milestone payments earned from Bausch & Lomb under the agreement that have been recognized as revenue, were \$20.9 million, \$10.9 million and \$3.0 million for the years ended December 31, 2002, 2003 and 2004, respectively, and were \$0 million and \$6.5 million for the nine months ended September 30, 2004 and 2005, respectively. Revenues reflected through December 31, 2003 reflect the completion of the contract. The costs incurred under the agreement with Bausch & Lomb were \$15.6 million and \$9.1 million for the years ended December 31, 2002 and 2003, respectively.

In June 2003, Bausch & Lomb informed CDS that all future research and development related to the licensed ophthalmic technology would be undertaken directly by Bausch & Lomb. Bausch & Lomb and CDS amended the 1992 and 1999 agreements effective December 9, 2003. Under the amended agreement, CDS granted Bausch & Lomb a worldwide, exclusive license to certain of CDS technologies to make and sell *Vitrasert* and CDS first generation products, including the *Retisert* device, for the treatment, prevention and diagnosis of any disease, disorder or condition of the human eye. CDS also granted Bausch & Lomb a non-exclusive license to these technologies to make and sell certain other products for the delivery of specified active ingredients, using specified delivery systems, methods of delivery and anchoring methods, to be used in specified locations for specified indications. Bausch & Lomb agreed to pay CDS royalties based on net sales for licensed products and to make milestone payments for certain events for certain licensed products. Bausch & Lomb may terminate this agreement without cause, in its entirety or with respect to *Vitrasert* or any non-exclusively licensed product, on 90 days' written notice. In the event Bausch & Lomb terminates the agreement in its entirety, Bausch & Lomb's license to the CDS technologies will terminate. In the event Bausch & Lomb terminates the agreement with respect to *Vitrasert* or a non-exclusively licensed product Bausch & Lomb will lose the right to rely upon CDS' intellectual property to make and sell the relevant product. During the period from January to June 2003, Bausch & Lomb advanced CDS \$9.8 million of research and development funding, which became subject to repayment pursuant to the amended agreement. CDS' obligation to Bausch & Lomb was settled as follows: \$4.0 million was repaid in cash in 2003; \$3.0 million in 2004 and \$2.8 million in the nine months ended June 30, 2005 were settled in lieu of Bausch & Lomb making milestone and royalty payments due to CDS. The total milestones earned in the nine months ended September 30, 2005 were \$3.5 million, of which \$2.8 million was used to settle remaining balance of the advance and the remaining \$700,000 was paid to CDS in cash. Bausch & Lomb also granted CDS an option on or before September 30, 2004 to acquire all of the 600,000 shares of CDS stock owned by Bausch & Lomb, which was not exercised.

The sum of total license fees received, milestone payments earned and research and development payments received and expected to be received under the 1999 agreement at December 31, 2003 was

**CONTROL DELIVERY SYSTEMS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**  
**(Information as of September 30, 2005 and for the nine months ended**  
**September 30, 2004 and 2005 is Condensed and Unaudited)**

\$53.3 million which CDS recognized through December 31, 2003, reflecting its estimate that through that date CDS had incurred 100% of the total costs it expected to incur under the 1999 agreement.

In June 2005, CDS received \$3,000,000 from Bausch & Lomb as an advance payment in lieu of \$6,250,000 of royalties that otherwise would be payable to CDS. Under the terms of the related agreement the royalty advance will be reduced as follows: Bausch & Lomb will retain 50% of the first \$3,000,000 of royalties or \$1,500,000 and 100% of the next \$4,750,000 of royalties. Since this advance is non refundable, other than as an offset to future royalties receivable by CDS and there are no future performance obligations by CDS, the \$3.0 million has been reflected as Royalty Revenue in the nine months ended September 30, 2005.

***Strategic Collaborations-other***

In February 2005, CDS granted Alimera Sciences a world-wide exclusive right to use certain CDS technologies to make and sell, for the treatment and prevention of eye diseases (except uveitis) in humans, products that have a drug core within a polymer layer and are approved or designed to be approved to deliver only specified compounds by a direct delivery method to the posterior portion of the eye. In addition, CDS granted to Alimera Sciences a worldwide exclusive right to use certain CDS technologies to treat DME by delivering a compound or formulation by a direct delivery method other than through specified incisions and which are not exclusively licensed to Bausch & Lomb. CDS and Alimera Sciences each pays co-development costs, and will share in profits. Alimera Sciences paid a licensing fee upon the signing of the agreement and a milestone payment, which aggregate \$1,500,000, \$750,000 of which was received in 2004 and the balance of which was received in the nine months ended September 30, 2005.

Under the terms of the agreement, CDS is responsible for the pre clinical work, the manufacturing of clinical trial material and the technology transfer to the commercial scale manufacturer. The license fee and milestones are being accounted for as a single unit of accounting and are being recognized as revenues over the period of CDS' required performance under the agreement. During the period ended September 30, 2005, CDS recognized \$176,000 of revenue in connection with this agreement.

**15. Government Research Grants**

Prior to fiscal 2002, CDS received federal government research grants primarily to research and to evaluate certain ophthalmic products. No grant revenues were reported for the years ended December 31, 2002, 2003 and 2004 or for the nine months ended September 30, 2005.

Reimbursement under government grants is available only for approved costs, which must be substantiated in accordance with government record-keeping requirements and are subject to government review and audit. Government grant recipients are also required to submit various reports and certifications. As a result of an internal compliance review in fiscal year 2002, CDS determined that it had some deficiencies in grant administration including claims for expense reimbursements that did not satisfy government requirements and overdue reports. CDS disclosed these deficiencies to the government, repaid amounts owed and filed the overdue reports. Grant recipients are subject to government review and audit, which may result in refunds or penalties such as restrictions or prohibitions on eligibility for future grants. CDS does not believe that its deficiencies in grant administration will have any material adverse effect on it or its financial position.

**16. Related Party**

CDS is a party to a 2003 license and development agreement with Bausch & Lomb described in Note 14. Bausch & Lomb is a stockholder of CDS, and its Chief Financial Officer is a member of CDS's Board of Directors. CDS recognized total revenue from Bausch & Lomb of \$21.0 million, \$11.1 million

CONTROL DELIVERY SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)  
(Information as of September 30, 2005 and for the nine months ended  
September 30, 2004 and 2005 is Condensed and Unaudited)

and \$3.1 million for the years ended December 31, 2002, 2003 and 2004, respectively, and \$89,000 and \$3.6 million for the nine months ended September 30, 2004 and 2005, respectively. CDS had accounts receivable due from Bausch & Lomb of \$25,000, \$31,000 and \$59,000 at December 31, 2003 and 2004 and September 30, 2005 respectively. As of December 31, 2004, CDS had a payable to Bausch & Lomb of \$2.8 million (Note 14).

**17. Employee Benefit Plans**

Effective January 1, 2001, CDS established a savings plan for its employees, designed to be qualified under section 401(k) of the Internal Revenue Code. Eligible employees are permitted to contribute to the 401(k) plan through payroll deduction, subject to statutory and plan limits. CDS matches 100% of the employee contributions up to 5% of each employee's qualified compensation. Contributions to the plan provided by CDS were \$276,000, \$212,000 and \$86,000 for the years ended December 31, 2002, 2003 and 2004, respectively, and \$77,000, and \$41,000 for the nine months ended September 30, 2004 and 2005, respectively.

**18. Restructuring**

In June 2003 Bausch & Lomb informed CDS that all future research and development related to the licensed ophthalmic technology would be undertaken directly by Bausch and Lomb. As a result of this decision CDS significantly reduced its workforce. The reduction in the CDS workforce is considered an exit activity and the costs of terminating these employees including severance pay and payment of terminated employees' medical insurance premiums are considered one-time termination costs under SFAS No. 146 *Accounting for Costs Associated with Exit or Disposal Activities*. These one-time termination costs related to the 2003 restructuring aggregated \$407,000 and were all incurred in, and paid in 2003. \$249,000 is included in research and development expenses and \$158,000 is included in general and administrative expenses.

In August 2004 CDS further reduced its workforce as a result of decreased cash resources. The costs of terminating these employees including severance pay and payment of terminated employees' medical insurance premiums are considered one-time termination premiums. These costs related to the 2004 restructuring aggregated \$46,000 and were all incurred and paid in 2004. \$22,000 is included in research and development expenses and \$24,000 is included in general and administrative expenses.

**19. Subsequent Event**

CDS entered into an Agreement and Plan of Merger as of October 3, 2005 with pSivida Limited, an Australian corporation, and its wholly owned subsidiary, pursuant to which pSivida will acquire CDS through a merger of its subsidiary into CDS. Upon consummation of the merger, each share of CDS preferred and common stock will be converted into the right to receive an aggregate of approximately 16 million pSivida American Depositary Receipts, or ADSs. Based on the CDS capitalization as of October 31, 2005, each share of CDS Series A preferred stock will be converted into the right to receive 11.79 ADSs and each share of CDS common stock will be converted into the right to receive approximately 3.52 ADSs. Consummation of the merger is subject to various closing conditions. Until the proposed merger is closed or the merger agreement is terminated, CDS has agreed to operate its business generally in the ordinary course and to comply with various covenants.